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DEPARTMENT OF ENERGY

2 CFR Part 910

[DOE–HQ–2024–0029]

RIN 1991–AC18

Financial Assistance Regulations—Conflict of Interest and Conflict of Commitment Policy Requirements

AGENCY: Office of Acquisition Management, U.S. Department of Energy.

ACTION: Final rule.

SUMMARY: The Department of Energy (DOE or Department) is amending its Financial Assistance Regulations to establish conflict of interest and conflict of commitment policies and requirements for non-Federal entities applying for or receiving financial assistance awards from the Department, and to implement and standardize certain disclosure requirements applicable to financial assistance applications and awards, including responsibilities, general rules, and procedures for non-Federal entities to identify, evaluate, resolve, and report conflicts of interest, conflicts of commitment, and organizational conflicts of interest, in financial assistance applications and awards.

DATES: This rule is effective on August 17, 2026.

ADDRESSES: The docket for this rulemaking, which includes **Federal Register** notices and comments, can be found at *Regulations.gov* (*www.regulations.gov/document/DOE-HQ-2024-0029-0001*). The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT: Ms. Bari Brooks, U.S. Department of Energy, Office of Acquisition Management, 1000 Independence Avenue SW, Washington, DC 20585; (202) 586–1027 or mail to: *bari.brooks@hq.doe.gov*.

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K. Review Under the Treasury and General Government Appropriations Act, 2001
L. Congressional Notification
IV. Approval by the Office of the Secretary of Energy

I. Background

The purpose of this rulemaking is to amend the Department's Financial Assistance Regulations at 2 CFR part 910. Specifically, DOE is amending part 910 to prescribe responsibilities, requirements, and procedures for non-Federal entities to identify, evaluate, resolve, and report conflicts of interest, conflicts of commitment, and organizational conflicts of interest in Federal financial assistance applications and awards, as those terms are defined in this final rule.

This final rule implements Office of Management and Budget (OMB) guidance to Federal agencies regarding the establishment of conflict of interest (COI) policies for Federal awards by codifying existing DOE policy, consistent with National Security Presidential Memorandum 33 (NSPM–33) [1] and the CHIPS and Science Act of 2022 (Pub. L. 117–167; August 9, 2022).

DOE is required to establish COI policies for Federal awards pursuant to 2 CFR 200.112, which specifies a non-Federal entity recipient or sub-recipient of a Federal financial assistance award must disclose in writing any potential COI to the Federal awarding agency or pass-through entity in accordance with applicable Federal awarding agency policy.

On December 20, 2021, DOE issued an interim COI policy [2] addressing COI and organizational conflicts of interest. The interim COI policy has been incorporated in and made enforceable through the Special Terms and Conditions for DOE financial assistance awards. The standards established in the interim COI policy provide a reasonable expectation that the design, conduct, and reporting of projects funded wholly or in part under DOE financial assistance awards (*e.g.,* a grant, cooperative agreement, or technology investment agreement) will be free from bias resulting from COI or conflict of commitment (COC).[3] To minimize the implementation burden on non-Federal entities, the interim COI policy largely aligned with the long-standing COI regulations established by the Public Health Service (PHS) at 42 CFR part 50, subpart F, which are applicable to research and development entities that include R&D funded by Public Health Service grants or cooperative agreements.

On June 18, 2024, DOE published in the **Federal Register** a notice of proposed rulemaking proposing to codify in regulation the interim COI policy, COC requirements, and organizational conflict of interest requirements. *See* 89 FR 51460 (June 2024 NOPR). Comments were received from the following:

[1] NSPM–33 established national security policy for U.S. Government-supported research and development (R&D). The purpose of NSPM–33 is to strengthen protections of U.S. Government-supported R&D against foreign government interference and misappropriation, while maintaining an open environment to foster research discoveries and innovation that benefit the United States and the world. NPSM–33 is available at *https://trumpwhitehouse.archives.gov/presidential-actions/presidential-memorandum-united-states-government-supported-research-development-national-security-policy/*.

[2] Financial Assistance Letter No. 2022–02, *Department of Energy Interim Conflict of Interest Policy Requirements for Financial Assistance.* (FAL No. 2022–02) Available at *https://www.energy.gov/management/financial-assistance-letters.*

[3] In general, COC means a situation in which an individual accepts or incurs conflicting obligations, whether foreign or domestic, between or among multiple employers or other entities and may include conflicting commitments of time and effort, including obligations to dedicate time in excess of institutional or DOE policies or commitments.

TABLE I–1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS TO THE JUNE 2024 NOPR

Commenter(s)	Comment No. in the Docket	Reference in this final rule
Arizona State University	9	ASU.
Association of American Universities, Council on Government Relations, Association of Public & Land-Grant Universities.	3	AAU *et al.*
Clean Future	7	Clean Future.
Harvard Medical School	18	Harvard Medical School.
Harvard University	4	Harvard.
Ohio State University	21	OSU.
Pennsylvania State University Office for Research Protections	22	Penn State.
Princeton University	19	Princeton.
Purdue University	20	Purdue.
Kacey Strickland	2	Strickland.
UCLA Research & Creative Activities	12	UCLA.
University of California	6	UC.
University of Idaho	17	University of ID.
University of Illinois Urbana-Champaign	13	University of Illinois.
University of Maryland Division of Research	15	University of MD.
University of Mississippi	5	University of MS.
University of New Mexico	8	University of NM
University of Pennsylvania	16	University of PA.
University of Rochester	14	University of Rochester.
University of Wisconsin—Madison	10	UW-Madison.
Washington University in St. Louis	11	Washington University.

A parenthetical reference at the end of a comment quotation or paraphrase in this final rule provides the location of the item in the public record.[4]

The requirements adopted in this final rule are codified in subpart C to 2 CFR part 910 (Subpart C). The requirements regarding COI, COC, and organizational conflicts of interest (OCI) [5] generally apply to non-Federal entities applying and receiving financial assistance awards from DOE as described in 2 CFR 910.122. Subpart C will not be applicable to applicants to or recipients of financial assistance under the programs of the DOE Office of Indian Energy, given that office's statutory mission to maximize the development and deployment of energy solutions for the benefit of American Indians and Alaska Natives; the unique sovereign status of Tribes; the practical limitations such regulations would present Tribes serving their communities, which in certain instances are small and remote; and consideration of traditional Tribal practices.

DOE program offices may tailor as appropriate the COI, COC, and OCI provisions for individuals applying for or receiving a DOE financial assistance award in their individual capacity. Upon the effective date of this final rule, the regulations at 2 CFR part 910, subpart C will supersede the interim COI policy, FAL No. 2022–02.

II. Section-by-Section Analysis

DOE is amending chapter IX of title 2 of the Code of Federal Regulations to add subpart C. Subpart C provides the general requirement for applicants for and recipients of Federal financial assistance from DOE to maintain a COI and COC policy; definitions relevant to the COI and COC policy requirements; and for the disclosure of certain COI, COC, and OCI, by applicants and recipients. Beginning October 1, 2024, updates to several parts of the OMB Guidance for Grants and Agreements (now called the OMB Guidance for Federal Financial Assistance) located in title 2 of the Code of Federal Regulations went into effect. *See* 89 FR 30046; April 22, 2024. In the June 2024 NOPR, DOE stated that it would consider conforming changes to the regulations proposed in the June 2024 NOPR based on the finalized OMB guidance once effective, as appropriate. *See* 89 FR 51460, 51461. This final rule uses terminology and citations consistent with the OMB Guidance for Federal Financial Assistance.

Generally, commenters supported the codification of COI requirements in regulation to ensure the integrity of projects funded by DOE financial assistance, and stated that precise definitions, clear reporting, investigation, and transparency rules serve only to improve the financial assistance process. (UC, No. 6 at 1; Clean Future, No. 1 at 1; Purdue, No. 20 at 1)

Certain commenters expressed concern that parts of the proposed rule were duplicative and redundant in the face of existing, similar Federal requirements. (UC No. 6 at 1–3; AAU *et al.,* No. 3 [6] at 1, 4–5; Purdue, No. 20 at 2; UW-Madison, No. 10 at 1) Commenters requested DOE adopt the interim COI policy with modifications to align it with the PHS standards established by the U.S. Department of Health and Human Services (HHS) already adopted by some organizations. (*Id.*) Commenters claimed that complying with DOE's proposed rule would be unreasonably burdensome, and asserted DOE's proposal was inconsistent with other Agency rules contrary to broader goals of Federal alignment of COI policy. (*Id.*)

UC and AAU *et al.* requested a one-year lead time to allow institutions sufficient time to update their policies, stated insufficient lead time would make compliance impractical, and the one-year lead time provided by PHS

[4] The parenthetical reference provides a reference for information located in the docket for this rulemaking. (Docket No. DOE–HQ–2024–0029–0001, which is maintained at *www.regulations.gov*) The references are arranged as follows: (commenter name, comment docket ID number, page(s) of that document).

[5] An OCI means that because of relationships with a parent company, affiliate, or subsidiary organization, a non- Federal entity is unable or appears to be unable to be impartial in conducting a procurement action involving a related organization. 2 CFR 200.318(c)(2).

[6] A number of commenters expressed support for the AAU *et al.* comments, stating that their institutional positions aligned with the AAU letter (UC, No. 6 at 2; Washington University, No.1 at 1; UCLA, No. 12 at 1; Penn State, No. 22 at 1; University of MD, No. 15 at 1; University of NM, No. 8 at 1; University of MS, No. 5 at 1; Princeton, No. 19 at 1; Harvard Medical School, No. 18 at 1; Harvard, No. 4 at 1; University of PA, No. 16 at 1; University of Rochester, No. 14 at 1; University of ID, No. 17 at 1; ASU, No. 9 at 1; OSU, No. 21 at 1; UW-Madison, No. 10 at 1; University of Illinois, No. 13 at 1).

when establishing its COI regulations. (UC, No. 6 at 8; AAU *et al.,* No. 3 at 8)

The regulations adopted in this final rule generally codify DOE's existing requirements applicable to DOE's financial assistance awards since 2022. *See* FAL No. 2022–02. Additionally, the final rule establishes requirements substantively similar to PHS. Given that this final rule largely reflects existing requirements, the regulations adopted in this final rule are effective 30 days following publication in the **Federal Register**.

As discussed in the following sections, DOE is adopting the COI, COC, and OCI requirements generally as proposed. The final rule codifies and replaces the interim COI policy, which avoids duplication of requirements. The final rule aligns with the COI, COC, and OCI requirements currently applicable to recipients of DOE financial assistance awards, and provides additional details related to the mitigation and reporting of conflicts. Additionally, the adopted COI, COC, and OCI regulations are based on and do not conflict with the PHS requirements. This final rule aligns with the objectives of Executive Order 14303, ''Restoring Gold Standard Science,'' specifically for science to be conducted without conflicts of interest. (*See* 90 FR 22601; May 23, 2025).

New 2 CFR part 910, subpart C as adopted in this final rule consists of §§ 910.200 through 910.270 and appendix A as set forth below:

§ 910.200 Definitions

In the June 2024 NOPR, DOE proposed definitions applicable to the new subpart C. Specifically, DOE proposed to define *conflict of commitment (COC), conflict of interest (COI), covered individual, financial interest, other support, principal investigator (PI), project,* and *significant financial interest. See* 89 FR 51460, 51464–51466. For the reasons provided in the June 2024 NOPR and provided in the following paragraphs, DOE is adopting the definitions as proposed in the June 2024 NOPR with certain changes as discussed in this section.

AAU *et al.* requested DOE remove examples from the regulatory definition of *conflict of commitment,* recommending that examples be reserved for guidance to allow more practical implementation. (AAU *et al.,* No. 3, at 5–6) AAU *et al.* also requested DOE delete reference to certain examples (*i.e.,* obligations to improperly share information with, or to withhold information from, an employer or DOE). (*Id.* at 6) AAU *et al.* further requested DOE remove references to pending employment from the definition of *conflict of commitment,* asserting it is practically impossible for institutions to identify or mitigate COCs in this area, as researchers do not typically share plans to seek other employment with their current employers. (*Id.*)

DOE is maintaining the examples in the *conflict of commitment* definition as proposed. Inclusion of examples in the regulatory text facilitates compliance and avoids the need to consult multiple sources. Obligations to improperly share or withhold information present significant risks to the integrity of DOE funded projects and therefore merit inclusion as an example. The regulations adopted in this final rule specify the criteria required of COC policies adopted by a non-Federal entity. Included in the criteria is a requirement for each covered individual who is participating in a DOE Federal financial assistance award update disclosures on an annual basis and as soon as any new actual, apparent, or potential COI or COC arises. To the extent pending employment results in an actual, apparent, or potential COI or COC, a covered individual would be obligated to report the COI or COC to the non-Federal entity. Accordingly, DOE is including a reference to pending employment in definition of *conflict or commitment* and is adopting the definition of that term as proposed.

DOE proposed *conflict of interest* to mean a situation in which a covered individual or the spouse or a child of the covered individual has a significant financial interest or financial relationship, whether with a domestic or foreign entity, that could directly and significantly affect the design, conduct, reporting or funding of a project or other Federal financial assistance award-related activities. *See* 89 FR 51460, 51465. Examples of situations that may give rise to a COI include, but are not limited to, holding an Executive position, director position, or equity over a certain dollar amount in a company that stands to benefit from Federal financial assistance award-related activities, receiving financial compensation in the form of consulting payments or payment for services from a company that stands to benefit from Federal financial assistance award-related activities, or intellectual property rights or royalties from such rights whose value may be affected by the outcome of Federal financial assistance award-related activities. *Id.*

Commenters objected to the proposed definition of COI, asserting that it does not align with the PHS definition. (UC, No. 6 at 3, 7; AAU *et al.,* No. 3 at 6) UC and AAU *et al.* stated that such inconsistency would require costly realignment of institutional policies. Commenters also recommended removing examples from the regulatory text and placing them in guidance to allow flexibility for real-world circumstances. (*Id.*)

The definition of COI as proposed in the June 2024 NOPR is substantively the same as the PHS term, which is defined as a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research. See 42 CFR 50.603. Both the DOE proposed definitions and the PHS definitions specify which individuals' interests must be considered (*e.g.,* the spouse or a child of the covered individual in addition to the covered individual)—DOE in the proposed definition of *conflict of interest* and PHS in the definition of *significant financial interest* definition.

DOE is maintaining the examples in the definition of *conflict of interest.* Including examples in the regulations avoids the need for applicants and recipients to consult additional documents when determining the applicability of the requirements.

For the reasons provided in the preceding paragraphs, DOE is adopting the definition of *conflict of interest* as proposed in the June 2024 NOPR.

In the June 2024 NOPR, DOE proposed *covered individual* to mean any individual, regardless of title or position, who: (1) Contributes in a substantive, meaningful way to the development or execution (*e.g.,* purpose, design, conduct, or reporting) of a project funded by DOE or proposed for funding by DOE; and, (2) Is designated as a covered individual by DOE. *See* 89 FR 51460, 51465. DOE proposed specifically designating any principal investigator (PI), project director (PD), co-principal investigator (Co-PI), co-project director (Co-PD), or project manager; and any individual (including an individual at the masters or baccalaureate level) that contributes in a substantive, meaningful way to the development or execution of a subject project that is listed by the non-Federal entity in the application for Federal financial assistance, approved budget, progress report, or any other report submitted to DOE by the non-Federal entity regarding the subject project. *Id.*

Several commenters urged narrowing the definition of *covered individual* to focus on individuals with significant influence over project design or execution. (UC, No. 6 at 4, 7–8; Washington University, No. 11, 1–2; AAU *et al.,* No. 3, at 7–8; UW-Madison, No. 10 at 1). Commenters asserted that including all participants, regardless of

role, creates unnecessary administrative burden. (*Id.*)

Under the proposed definition, a *covered individual* would be an individual with significant influence over project design or execution. To clarify further that the *covered individual* definition requires project level control, DOE is defining *covered individual* as an individual who contributes in a substantive, meaningful way to the development or execution of the *scope of work* of a project. The adopted definition also specifies DOE designation applies to individuals for whom a current and pending support disclosure and/or biosketch/resume is submitted with an application for financial assistance. Submission of these forms indicates an individual has sufficient involvement to warrant inclusion as a *covered individual.*

As adopted in this final rule, *covered individual* means any individual, regardless of title or position, who: (1) Contributes in a substantive, meaningful way to the development or execution of the scope of work of a project funded by DOE or proposed for funding by DOE; and, (2) is designated as a covered individual by DOE. Additionally, the final rule designates as covered individuals any principal investigator (PI), project director (PD), co-principal investigator (Co-PI), co-project director (Co-PD), project manager, and any individual regardless of title that is functionally performing as a PI, PD, Co-PI, Co-PD, or project manager; and persons designated in the applicable Notice of Funding Opportunity (NOFO) or terms and conditions of the Federal financial assistance award. Submission of a current and pending support disclosure and/or biosketch/resume for a particular person serves as an acknowledgement that DOE designates that person as a covered individual.

The adopted definition remains consistent with consideration of an individual's responsibilities in the PHS definition of *investigator,* which covers individuals responsible for the design, conduct, or reporting of research funded by PHS. See, 42 CFR 50.603. Additionally, the definition adopted in this final rule is consistent with the use of *covered individual* under the implementation of NPSM–33 and reflects applicants and recipients of DOE funding may use different titles and terminology than those under PHS funding. The adopted definition also provides DOE flexibility to designate additional individuals depending on the sensitivity of a project and potential research security concerns.

The prime applicant is responsible for assessing the applicability of the *covered individual* definition against each person listed on an application for financial assistance from DOE. Further, the prime applicant is responsible for identifying any such individual to DOE for designation as a covered individual, if not already designated by DOE as described above.

Regarding the definition of *significant financial interest,* commenters recommended a *de minimis* disclosure threshold of $5,000 for certain categories (*e.g.,* intellectual property interests, reimbursed travel), noting that requiring disclosure of smaller amounts diverts resources from higher risk oversight. (UC, No. 6 at 4–5, 7; Washington University, No. 11 at 2; AAU *et al.,* No. 3 at 10)

As explained by HHS when establishing a comparable definition of *significant financial interest,* requiring the disclosure of the value of travel reimbursements could be difficult, particularly in the case of sponsored travel, which is paid on behalf of the covered individual and not reimbursed by the covered individual, so that the exact monetary value may not be readily available. *See* 76 FR 53256, 53265 (September 26, 2011). HHS identified similar difficulties in determining the precise value of intellectual property interests. *Id.*

Because of the difficulty in determining the monetary value of sponsored travel and intellectual property interests, a *de minimis* threshold would risk creating uncertainty when determining compliance. Moreover, applying a *de minimis* threshold could potentially lead to additional burden in determining whether the threshold is exceeded (*e.g.,* covered individuals would need to obtain estimates or appraisals to determine whether a significant financial interest existed).

For the reasons discussed in the preceding paragraphs, DOE adopts the definition of *significant financial interest* as proposed and consistent with the definition established by HHS.

The proposed definition of *significant financial interest* includes consideration of *other support,* for which DOE separately proposed a definition. DOE proposed *other support* to mean all resources made available to a covered individual in support of and/or related to all of their professional research (including basic and fundamental research), development, demonstration, and/or deployment efforts, including resources provided directly to the covered individual rather than through the research organization, and regardless of whether or not they have monetary value (*e.g.,* even if the support received is only in-kind, such as office/laboratory space, equipment, supplies, or employees). *See* 89 FR 51460, 51465. The proposed definition further provided the term includes resource and/or financial support from all foreign and domestic entities, including but not limited to, gifts provided with terms or conditions, financial support for laboratory personnel, and participation of student and visiting researchers and visiting scholars supported by other sources of funding. *Id.*

AAU *et al.* opposed inclusion of a definition for *other support,* describing it as redundant and a source of compliance uncertainty. (AAU *et al.,* No. 3 at 8) DOE proposed a definition of *other support* recognizing certain resources made available to a covered individual may not readily be characterized as current or pending support, and that such support has the potential to create a conflict. There may be instances in which support could be characterized as either *other support* or as current and pending support. This potential overlap does not impact the reporting required by a covered individual as reporting does not require further categorization of a significant financial interest.

DOE is adopting language to clarify *other support* includes gifts provided without terms or conditions. This clarification is consistent with what is required to be reported under the Current and Pending Financial Assistance Letter 2022–04. Accordingly, DOE is establishing a definition for *other support* as proposed.

§ 910.210 Applicability

Section 910.210 establishes the applicability of the COI and COC policy and reporting requirements in new subpart C as proposed. In general, the requirements are applicable to non-Federal entities that are applicants to or recipients of a DOE Federal financial assistance award.

Washington University recommended removing the proposed provision allowing the requirements to be tailored for individuals receiving financial assistance. Washington University, No. 11 at 3. Washington University stated that permitting such tailoring would defeat the purpose of a unifying set of requirements and significantly increase the administrative burden on institutions to comply with varying application of the same regulation. (*Id.*)

DOE clarifies that the tailoring provision at § 910.210(a)(2) applies to individuals applying for or receiving financial assistance in their individual capacity. DOE would not tailor the requirements of this subpart when the

non-Federal entity is a university or research facility.

§ 910.220

Reserved.

§ 910.230 Required Conflict of Interest (COI) and Conflict of Commitment (COC) Policies

As proposed in the June 2024 NOPR, § 910.230 would require non-Federal entities that are applicants to or recipients of DOE Federal financial assistance to establish and maintain written and enforced policies addressing actual, apparent, and potential COI and COC. *See* 89 FR 51460, 51466–51467. Proposed § 910.230 would also establish requirements COI and COC policy requirements for subrecipients. Under the proposed regulations, COI and COC policies would be required to mandate certain reporting by covered individuals to the non-Federal entity, as well as required training.

Per the June 2024 NOPR, any non-Federal entity that is an applicant to or recipient of a DOE Federal financial assistance award must maintain a written and enforced policy addressing actual, apparent, and potential COI and COC, both foreign and domestic.

Washington University commented inclusion of ''actual, apparent, or potential'' does not align with, nor is included in, the definition of a COI, and that inclusion of the terms creates ambiguity in what institutions should identify as a COI or COC. (Washington University, No. 11 at 4.) AAU *et al.* recommended deletion of the term ''apparent'' from the phrase ''actual, apparent, or potential'' COI in proposed § 910.230(a), stating that absent a precise regulatory definition use of the term risks uncertainty and redundancy. (AAU *et al.,* No. 3 at 9)

''Actual, apparent, or potential'' describe the relevant types of COIs and COCs. An actual COI occurs when a significant financial interest or financial relationship exists that could directly and significantly affect the design, conduct, reporting or funding of a project or other Federal financial assistance award-related activities. A potential COI occurs when there is the possibility such a significant or financial relationship will arise in the future (*e.g.,* when an individual applies for employment). Under FAL 2022–02, apparent conflicts are included in the definition of *potential conflicts.* However, an apparent conflict may be distinct from a potential conflict. An apparent conflict occurs when a conflict may appear to exist to a reasonable outside observer even if there is no actual or potential conflict. To clarify the distinction between an apparent conflict and a potential conflict, DOE proposed to separately specify the terms. Use of *apparent* and *potential* are consistent with the common understanding of those terms and regulatory definitions are not necessary. DOE is adopting the use of ''actual, potential, and apparent'' as proposed.

Commenters recommended removing the COC policy requirements, asserting that institutions cannot reasonably monitor individual commitments. (AAU *et al.,* No. 3 at 10; Washington University, No. 11 at 4) Washington University stated that requirements extending a recipient's COC policy to a subrecipient are impractical as they would require the recipient institution to have knowledge of both external commitments and the institutional obligations of each covered individual for a subrecipient. (Washington University, No. 11 at 4) AAU *et al.* commented COC concerns are already addressed though FAL 2022–02 and the common disclosure forms contain an individual certification statement that each senior/key person must complete regarding current and pending support. (AAU *et al.,* No. 3)

The proposed regulations would require a subrecipient to certify it has COI and COC policies that comply with the DOE regulations, or if a subrecipient cannot provide such certification, the subrecipient's covered individuals would be subject to the COI and COC policy of the recipient. Under either option, a covered individual would be required to report an actual, apparent, and potential COC to the subrecipient or recipient comparable to the requirement to reporting required for a COI. An implemented COC policy and COI policy both rely on the reporting of the covered individuals. As proposed, applicability of the COI and COC policies to a subrecipient must be established in a written agreement between the recipient and subrecipient. Such a written agreement would establish the reporting, timing, and compliance obligations of the subrecipient to the recipient.

Common forms and use of tools such as digital persistent identifiers provide means for tracking and demonstrating compliance, but in and of themselves, do not establish a transparent requirement and process for ensuring any such conflicts are identified and appropriately mitigated. As noted, adoption of this final rule will supersede FAL 2022–02.

Codifying the requirements for COI and COC upholds NSPM–33 through clearly articulated requirements and processes for appropriate disclosure of information related to both COIs and COCs. Effective implementation across recipients and subrecipients of DOE financial assistance will make it more difficult for individuals to conceal materially important support, obligations, conflicts of interest, and/or relationships that, when concealed, could lead to DOE making inadequately informed funding decisions. Effective implementation will also make it easier for recipients to identify and address noncompliance in a timely and fair manner. For these reasons, DOE is adopting the COC provisions in 2 CFR 200.201 as proposed.

DOE proposed covered individuals update required disclosures to the non-Federal entity on an annual basis and as soon as any new actual, apparent, or potential COI or COC arises. *See* 89 FR 51460, 51466. AAU *et al.* and UC requested aligning the timing of ongoing reporting requirements with existing PHS rules and inclusion of a clear compliance timeline, noting that the proposed rule would increase administrative burden. (AAU *et al.,* No. 3 at 9; UC No. 6 at 8–9) Strikland requested DOE define ''as soon as.'' (Strikland, No. 2 at 1) AAU *et al.* and UC requested specifying a 30-day period to report new conflicts, stating that a defined time would provide more regulatory certainty and be better understood by researchers. (AAU *et al.,* No. 3 at 9; UC No. 6 at 8–9)

DOE is generally adopting the reporting criteria as proposed. The reporting criteria reflects DOE's general requirement that applicants for financial assistance as well as recipients comply with the COI and COC policies and generally align with the requirements applicable under FAL 2022–02. DOE acknowledges that requiring reporting ''as soon as possible'' is less certain than specifying a timeframe. To reduce this uncertainty, the final rule specifies that a new COI or COC must be reported as soon as practicable, but not later than 15 days, after it arises.

DOE proposed requiring COI and COC policies to mandate each covered individual to complete COI and COC training prior to engaging in projects funded under a DOE Federal financial assistance award and complete refresher training least every two years. *See* 89 FR 51460, 51466. Commenters recommended increasing required training intervals to four years to align with PHS regulations and minimize administrative impact. (AAU *et al.,* No. 3 at 10; Purdue, No. 20 at 2–3; Washington University, No. 11 at 3)

DOE is adopting the training frequency as proposed. Covered

individuals are required to update their disclosures annually and periodically as COIs and COCs arise. Training more frequently than every four years helps ensure the annual and periodic updates are completed correctly and completely. The two-year training cycle reflects the focus on increased training under the CHIPS and Science Act of 2022 and NPSM–33. Further, the final rule does not prohibit non-federal entities from aligning the two-year cycle with longer training cycles as may be adopted by other agencies. Additionally, the research security training developed for compliance with CHIPs and Science Act of 2022 [7] addresses COIs and COCs and therefore could be relied upon to meet this requirement.

§ 910.240 Reporting Conflicts of Interest (COIs) and Conflicts of Commitment (COCs)

As proposed, § 910.240 would establish requirements for non-Federal entities to report to DOE certain identified COIs and COCs and mitigation measures. *See* 89 FR 51460, 51467. In general, proposed § 910.240(a) would require applicants and recipients of DOE financial assistance to disclose to DOE any actual, apparent, or potential COI or COC if such conflict cannot be eliminated or appropriately managed or reduced in accordance with the non-Federal entity's policy. In addition, the proposed subsection would require disclosure of any actual, apparent, or potential COI or COC involving any foreign governments, their instrumentalities, or any other entities owned, funded, or otherwise controlled by a foreign government, as well as any measures the entity has taken to eliminate or, where appropriate, manage or reduce the COI or COC.

UC requested removal of the reference to 2 CFR 200.112, stating that the referenced CFR section is limited to conflicts that might arise when a non-federal entity expends funds under a Federal award, such as decisions about subrecipient selection or procurement, and the reference may lead to confusion. (UC, No. 6 at 9).

The language of 2 CFR 200.112 is not as narrow as suggested by UC. That section requires Federal agencies to establish COI policies for Federal awards and a recipient or subrecipient to disclose in writing any potential COI to the Federal agency in accordance with the established Federal agency policies. 2 CFR 200.112. Reference to section 2 CFR 200.112 explicitly identifies the requirements in proposed 2 CFR 910.240 as DOE's implementation of the regulatory direction in the OMB Guidance for Federal Financial Assistance at 2 CFR part 200. DOE is including the reference to 2 CFR 200.112 in the adopted § 910.240.

Commenters opposed requiring COI and COC reporting as part of an application for DOE financial assistance stating the costs of such reviews would be unreasonable, absent assurance of award. (AAU *et al.,* No. 3 at 10; UC, No. 6 at 6–7; Washington University, No. 11 at 5) Commenters further stated that it would be overly burdensome to require reviews prior to submission as such reporting would require institutions to complete reviews, identify potential conflicts, and design and implement management plans for projects that may not be funded, and that there is not sufficient time between receipt of completed proposals from investigators, and submission deadlines. (*Id.*)

Under the proposed reporting requirements, individuals that would qualify as covered individuals under a funding opportunity would be required to identify any actual, apparent, or potential COI or COC were the non-Federal entity awarded financial assistance under that opportunity. *See* 89 FR 51460, 51467. As a result of annual COI and COC reporting and periodic training, it is expected that individuals participating in an application for financial assistance will be able to readily ascertain whether an award would create an actual, apparent, or potential COI or COC. DOE recognizes that changes may occur after application. However, in evaluating potential selections for award, it is crucial for DOE to be aware of possible COIs and COCs that would arise under the award and that could not be mitigated. For example, identifying a COI or COC that cannot be mitigated for the primary investigator listed on an application weighs into DOE's evaluation of the personnel on a proposed project. Identifying such COIs and COCs as part of the application process will facilitate submission of applications that are more representative of a project were it awarded. Additionally, as part of DOE's on-going research security responsibilities it is crucial to be aware of possible COIs and COCs involving any foreign governments, their instrumentalities, or any other entities owned, funded, or otherwise controlled by a foreign government, were DOE to award the applicant project. Identification of COIs and COCs that cannot be mitigated and COIs and COCs related to foreign governments at the application process reduces the likelihood of selected projects not proceeding to award because of such conflicts. DOE is adopting the reporting requirements applicable to applicants and recipients as proposed.

UC recommended limiting the reporting of COIs and COCs related to foreign governments ''if known'' and ''where appropriate,'' and stated it can be complicated to determine if an entity is connected to a foreign government as the information may not be publicly available or accessible. (UC, No. 6 at 9)

DOE is not adopting language as suggested by UC. If a covered individual is listed on an application for or participating in a project receiving DOE financial assistance, it is incumbent on the individual have a reasonable understanding of whom that individual is conducting business and exercise due diligence to determine whether such interest presents an actual, apparent, or potential COI or COC.

Washington University asserted that the proposed rule required four different reporting scenarios, (unmanageable COI/COC, all foreign COI/COC, all COI/COC as required by the funding opportunity, and all COI/COC per the terms and conditions of an award) and that the multiple reporting matrices overcomplicates reporting by requiring award specific reporting requirements and increases the risk for failure to report. (Washington University, No. 11 at 4; *see also* AAU *et al.,* No. 3 at 10) AAU *et al.* recommended removal of the ''case-specific'' reporting requirements and instead adoption of a uniform reporting requirement that aligns with the PHS standards. (AAU *et al.,* No. 3 at 12)

As explained, the proposed rule would require reporting of all COIs and COCs that are unmanageable and all COIs and COCs related to foreign governments. Based on the sensitivity of the funded subject area or an awarded project, DOE proposed that reporting of additional conflicts could be required. It is not uncommon for DOE to specify tailored application and award requirements in order to address concerns and/or circumstances specific to a funding opportunity or an award. Any such tailored reporting requirements would be explicitly delineated in the relevant notice of funding opportunity or award, as may be applicable. DOE strives for consistency across Federal agencies to the extent such consistency is consistent with DOE's mission and responsibilities. DOE is adopting the provisions which provide DOE flexibility that make application/award specific modifications to the COI and COC reporting requirements

[7] *See www.nsf.gov/research-security/training.*

commensurate with sensitives and risks particular to a funding opportunity or award, as proposed.

Proposed § 910.240(d) provided that in addition to the annual COI/COC report, DOE may require a non-Federal entity to routinely, or upon request, submit all or some covered individuals' disclosures. *See* 89 FR 51460, 51467. AAU *et al.* objected to routine reporting requirements in addition to the annual reporting, stating mandating disclosures ''routinely'' would make it extremely difficult for institutions to establish and maintain efficient processes for collecting and reviewing disclosures and making required reports. (AAU *et al.,* No. 3 at 12)

Proposed § 910.240(d) addresses instances in which reporting more than on an annual basis may be necessary. Such instances, as specified in the proposed regulation: as part of monitoring the non-Federal entity's compliance with this subpart; bankruptcy of the non-Federal entity; other legal winding down of the non-Federal entity; acquisition of the non-Federal entity by a foreign entity, where ''acquisition'' includes a foreign entity obtaining a controlling interest in the non-Federal entity; or as otherwise set forth in 2 CFR part 200 and this part. As illustrated by the specified circumstances, routine submission of covered individuals' disclosures would be required in circumstances that may warrant a heightened degree of oversight. DOE does not anticipate such routine reporting to be typical. DOE is establishing § 910.240(d) as proposed.

Proposed § 200.240(e) provided if a non-Federal entity becomes aware that a covered individual failed to comply with the non-Federal entity's COI and COC policy or a management plan, the non-Federal entity must promptly notify DOE in writing of the failure to comply and of the corrective action taken or to be taken. *See* 89 FR 51460, 51467.

AAU *et al.* requested a non-Federal entity be provided 60 days to report such failures, stating 60 days would provide time to take any necessary corrective action and would align with the NASA and PHS requirements, and FAL 2022–02. (AAU *et al.,* No. 3 at 12)

DOE is not adopting a 60-day period for reporting non-compliance as suggested by AAU *et al.* DOE notes that FAL 2022–02 establishes a requirement to ''promptly'' report noncompliance. *See* FAL 2022–02, *Remedies.* Receiving prompt notification allows DOE to take corrective action in a timely manner. DOE also notes that the proposal would not require the non-Federal entity to have taken corrective action prior to reporting, explicitly stating that report may include corrective action the non-Federal entity will take.

For the reasons discussed in the preceding paragraphs, DOE is adopting § 910.240, *Reporting conflicts of interest (COIs) and conflicts of commitment (COCs),* as proposed.

§ 910.250 Organizational Conflicts

Consistent with 2 CFR 200.318, DOE proposed requirements regarding non-Federal entities with a parent, affiliate, or subsidiary organization that is not a state government, local government, or Indian tribe, the non-Federal entity must maintain written standards of conduct covering organizational conflicts of interest (OCIs) as that term is defined in 2 CFR 200.318(c)(2). *See* 89 FR 51460, 51467. DOE notes that in the context of the Federal Acquisition Regulations, the head of an agency or their designee may waive the organizational conflicts of interest requirement by determining that its application in a particular situation would not be in the Government's interest. 48 CFR 9.503.

DOE is adopting § 910.250 as proposed.

§ 910.260 Reporting Organizational Conflicts of Interest (OCIs)

DOE proposed reporting requirements relevant to any potential or actual OCI to DOE. *See* 89 FR 51460, 51467. Proposed section 910.260 would establish the timing and content required of such reports. As proposed, non-Federal entities would be required to report any potential or actual OCI within five business days of learning of the conflict. Washington University recommended extending reporting timelines from five days to 60 days to align with PHS standards and reduce administrative burden. (Washington University, No. 11 at 5–6).

Identifying and mitigating OCIs is necessary to ensure the integrity of procurement activities under a Federally funded award. A failure or delay in identifying an OCI can make mitigation more difficult and risks costs associated with the subject procurement being unallowable, which can increase the administrative burden and costs to recipients when addressing identified OCIs. As proposed, the non-Federal entity would not be required to have implemented mitigation measures prior to reporting. The recipient would be required to report plans to avoid, eliminate, or mitigate the OCI. Timely reporting of an OCI allows DOE to coordinate and undertake necessary measures. DOE recognizes that five business days may not be sufficient time for a non-Federal entity to report an OCI. DOE is adopting a 15-day period for reporting consistent with historical practice for the terms and conditions of DOE awards.

DOE is adopting § 910.260 as proposed, but with a 15-day period required for reporting.

§ 910.270 Remedies, Penalties, and Enforcement

Proposed § 910.270 would specify actions DOE may take if a non-Federal entity fails to disclose a COI or COC or fails to sufficiently manage or mitigate such a conflict. *See* 89 FR 51460, 51467–51468. Proposed section 910.270 would also specify the remedies for failure to disclose an OCI. *See* 89 FR 51460, 51468.

AAU *et al.* expressed concern with language requiring a disclosure or mitigation to ''ensure the integrity of the DOE-supported project'' and ''protect the government's interests,'' asserting that the meaning of these terms is not defined and not readily ascertainable by non-Federal entities. (AAU *et al.,* No. 3 at 13–14) Similarly, AAU *et al.* expressed concern with DOE's evaluation of whether a COI or COC would ''adversely impact the project.'' (AAU *et al.,* No. 3 at 14)

In exercising appropriate stewardship over Federal funding, DOE has the responsibility of ensuring funding is spent in a manner consistent with the Department's programmatic objectives, that safeguards the security of federally funded projects, and that maintains the integrity of science produced using Federal funds. Recipients of Federal funds accept such funding subject to Federal oversight. As proposed, § 910.270(a) specifies the actions DOE may take in response to a failure to disclose or adequately manage, or mitigate a COI or COC, including providing the non-Federal entity an opportunity to take additional action.

AAU *et al.* further requested limiting § 910.270 to procurement activities as opposed to ''procurement or transaction'' activities as proposed. (AAU *et al.,* No. 3 at 14)

Non-Federal entities may undertake transactions to acquire goods and services similar to procurement transactions, but that rely on different mechanisms and/or authorities. These other transactions have the potential to raise OCI concerns in the same manner as procurement transactions. DOE is clarifying the applicability of § 910.270 extends to such other transactions.

To provide for the appropriate exercise of Federal stewardship over federally funded projects, DOE is adopting § 910.270 as proposed, but clarifying its applicability to other

transactions similar to procurement transactions.

Appendix A

AAU *et al.* and Washington University requested replacing appendix certification statements with institution-specific attestation statements to reduce administrative burden. (AAU *et al.,* No. 3 at 10; Washington University, No. 11 at 3)

DOE is adopting the specific certification statement as proposed. Appendix A provides uniform language that avoids the need for non-Federal entities to separately develop statements and ensures the legal enforceability of such statements.

III. Regulatory Review and Procedural Requirements

A. Review under Executive Orders 12866 and 14192

Executive Order (E.O.) 12866, ''Regulatory Planning and Review,'' requires agencies, to the extent permitted by law to: (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fee or profit or marketable permits, or providing information upon which choices can be made by the public. DOE has determined that this final rule is consistent with these principles, including the requirement that, to the extent permitted by law, agencies adopt a regulation only upon a reasoned determination that its benefits justify its costs and, in choosing among alternative regulatory approaches, those approaches maximize net benefits.

Section 6(a) of E.O. 12866 also requires agencies to submit ''significant regulatory actions'' to the Office of Information and Regulatory Affairs (OIRA) for review. OIRA has determined that this regulatory action does not constitute a ''significant regulatory action'' under section 3(f) of E.O. 12866. Accordingly, this action was not submitted to OIRA for review under E.O. 12866.

DOE has examined this rulemaking and has determined that it is consistent with the policies and directives outlined in E.O. 14192, ''Unleashing Prosperity Through Deregulation.'' This final rule is considered an E.O. 14192 deregulatory action. The final rule will not impose additional costs to applicants and recipients of financial assistance. The regulations codify and streamline the Department's policies and requirements currently addressed through financial assistance letters, notice of funding opportunity announcements, and award terms and conditions. Moreover, the rule streamlines the financial assistance process by facilitating the use of common forms and improve consistency in the disclosure requirements across Federal agencies, consistent with NSPM–33. DOE did not estimate the cost savings of this final rule.

B. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' (61 FR 4729, February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction.

With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the United States Attorney General.

Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or if it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this rule meets the relevant standards of Executive Order 12988.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.)* requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' (67 FR 53461, August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process (68 FR 7990). DOE has made its procedures and policies available on the Office of General Counsel's website at *www.energy.gov/gc/office-general-counsel.*

DOE has reviewed this rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003. DOE certifies that this rule will not have significant economic impact on a substantial number of small entities. The factual basis for this certification is set forth below.

The final rule is applicable to non-Federal entities that are applicants to or recipients of financial assistance awards from the Department. Non-Federal entities, including small entities, are currently subject to the Department's interim policies implementing the conflicts provisions at 2 CFR 200.112 and the requirements regarding OCI at 2 CFR 200.318(c). This final rule codifies the existing policies applicable to financial assistance awards from the Department. Additionally, the applicable DOE program office may tailor as appropriate the COI, COC, and OCI provisions for individuals that are applicants to or recipients of a DOE financial assistance award.

Accordingly, DOE certifies that this rule will not have a significant economic impact on a substantial number of small entities, and, therefore, no regulatory flexibility analysis is required. DOE will transmit a certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

D. Review Under the Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Ch. 3506; 5 CFR part 1320, appendix A.1) (PRA), DOE reviewed this rule and determined that there are no new collections of information contained therein. DOE's financial assistance reporting and recordkeeping burdens have been approved under OMB Control No. 1910–0400.

E. Review Under the National Environmental Policy Act.

DOE has determined that promulgation of this rule falls into a class of actions that would not individually or cumulatively have a significant impact on the human environment, as determined by DOE's regulations implementing the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) (NEPA). Specifically, DOE determined that this rule is covered under the categorical exclusion found in DOE's NEPA regulations at paragraph A6 of appendix A to subpart D, 10 CFR part 1021.

Categorical exclusion A6 applies to rulemakings that are strictly procedural. Additionally, DOE has preliminarily determined that this rule is covered under the Categorical Exclusion found in DOE's NEPA regulations at paragraph A5 of appendix A to subpart D, 10 CFR part 1021, which applies to a rulemaking that amends an existing rule or regulation and that does not change the environmental effect of the rule or regulation being amended. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

F. Review Under Executive Order 13132

Executive Order 13132, ''Federalism'' (64 FR 43255, August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. The Executive order requires agencies to have an accountability process to ensure meaningful and timely input by state and local officials in the development of regulatory policies that have federalism implications.

On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations (65 FR 13735). DOE has examined the rule and has determined that it does not preempt State law and does not have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

G. Review Under Executive Order 13175

Under Executive Order 13175 (65 FR 67249, November 6, 2000) on ''Consultation and Coordination with Indian Tribal Governments,'' DOE may not issue a discretionary rule that has ''Tribal'' implications and imposes substantial direct compliance costs on Indian Tribal governments. DOE has determined that the final rule would not have such effects and concludes that Executive Order 13175 does not apply to this rulemaking.

H. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect them. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *https://energy.gov/sites/prod/files/gcprod/documents/umra_97.pdf*. This rule does not contain a Federal intergovernmental mandate, nor is it expected to require expenditures of $100 million or more in any one year by the private sector. As a result, the analytical requirements of UMRA do not apply.

I. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277), requires Federal agencies to issue a Family Policymaking Assessment for any rulemaking or policy that may affect family well-being. This rulemaking will have no impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

J. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use,'' (66 FR 28355, May 22, 2001), requires Federal agencies to prepare and submit to OIRA, of the Office of Management and Budget (OMB), a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) is a significant regulatory action under Executive Order 12866, or any successor order, (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution and use. This rule is not a significant energy action. Moreover, it will not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects.

K. Review Under the Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and

DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed this rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

L. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule before its effective date. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

IV. Approval by the Office of the Secretary of Energy

The Secretary of Energy has approved publication of this final rule.

List of Subjects in 2 CFR Part 910

Accounting, Administrative practice and procedure, Grant programs, Reporting and recordkeeping requirements.

Signing Authority

This document of the Department of Energy was signed on July 10, 2026, by Derek Passarelli, Director of the Golden Field Office and Senior Procurement Executive, and William J. Quigley, Deputy Associate Administrator for Office of Partnership and Acquisition Services and Senior Procurement Executive, National Nuclear Security Administration, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE/NNSA. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register.**

Signed in Washington, DC on July 14, 2026.

Treena V. Garrett,

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

For reasons set out in the preamble, DOE amends chapter IX of title 2 of the Code of Federal Regulations as set forth below:

PART 910—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS

■ 1. The authority citation for part 910 continues to read as follows:

Authority: 42 U.S.C. 7101, *et seq.;* 31 U.S.C. 6301–6308; 50 U.S.C. 2401 *et seq.;* 2 CFR part 200.

■ 2. Add subpart C to read as follows:

Subpart C—Conflicts of Interest, Conflicts of Commitment, Organizational Conflicts of Interest, and Other Matters of Concern

Sec.

910.200 Definitions.
910.210 Applicability.
910.220 [Reserved]
910.230 Required conflict of interest (COI) and conflict of commitment (COC) policies.
910.240 Reporting conflicts of interest (COIs) and conflicts of commitment (COCs).
910.250 Organizational conflicts.
910.260 Reporting organizational conflicts of interest (OCIs).
910.270 Remedies, penalties, and enforcement.
Appendix A to Subpart C of Part 910—Disclosure Certification Statement

§ 910.200 Definitions.

For the purposes of this subpart, the following definitions are applicable:

Conflict of commitment (COC) means a situation in which an individual accepts or incurs conflicting obligations, whether foreign or domestic, between or among multiple employers or other entities. This may include conflicting commitments of time and effort, including obligations to dedicate time in excess of institutional or DOE policies or commitments. Other types of conflicting obligations, including but not limited to, obligations to improperly share information with, or to withhold information from, an employer or DOE, can also threaten research, technology or economic security and integrity. Examples of situations that may give rise to conflicts of commitment include, but are not limited to, current or pending employment; positions, appointments, or affiliations such as titled academic, professional, or institutional appointments, whether remuneration is received and whether full-time, part-time, or voluntary (including adjunct, visiting, or honorary positions); and participation in or applications to foreign government-sponsored talent recruitment or similar programs.

Conflict of interest (COI) means a situation in which a covered individual or the spouse or a child of the covered individual has a significant financial interest or financial relationship, whether with a domestic or foreign entity, that could directly and significantly affect the design, conduct, reporting or funding of a project or other Federal financial assistance award-related activities. Examples of situations that may give rise to a COI include, but are not limited to, holding an Executive position, director position, or equity over a certain dollar amount in a company that stands to benefit from Federal financial assistance award-related activities, receiving financial compensation in the form of consulting payments or payment for services from a company that stands to benefit from Federal financial assistance award-related activities, or intellectual property rights or royalties from such rights whose value may be affected by the outcome of Federal financial assistance award-related activities.

Covered individual means any individual, regardless of title or position, who:

(1) Contributes in a substantive, meaningful way to the development or execution of the scope of work of a project funded by DOE or proposed for funding by DOE; and,

(2) Is designated as a covered individual by DOE.

(3) DOE designates as covered individuals any principal investigator (PI), project director (PD), co-principal investigator (Co-PI), co-project director (Co-PD), project manager, and any individual regardless of title that is functionally performing as a PI, PD, Co-PI, Co-PD, or project manager; and persons designated in the applicable Notice of Funding Opportunity (NOFO) or terms and conditions of the Federal financial assistance award. Submission of a current and pending support disclosure and/or biosketch/resume for a particular person serves as an acknowledgement that DOE designates that person as a covered individual.

DOE means the U.S. Department of Energy and the National Nuclear Security Administration (NNSA).

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

Other support means all resources made available to a covered individual in support of and/or related to all of their professional research (including basic and fundamental research), development, demonstration, and/or deployment efforts, including resources provided directly to the covered individual rather than through the research organization, and regardless of whether or not they have monetary

value (*e.g.,* even if the support received is only in-kind, such as office/laboratory space, equipment, supplies, or employees). This includes resource and/or financial support from all foreign and domestic entities, including, but not limited to, gifts provided with terms or conditions, gifts provided without terms or conditions, financial support for laboratory personnel, and participation of student and visiting researchers and visiting scholars supported by other sources of funding.

Principal investigator (PI) means an individual identified to direct a project by an applicant to or recipient of a DOE Federal financial assistance award.

Project means the interdependent activities funded wholly or in part under the DOE Federal financial assistance award. A project has a defined start and end point with objectives described in an application or in an approved scope that, when attained, signify completion and achievement of a specific goal, and creation of a unique product, service, or result. For Federal financial assistance awards that include recipient cost share as part of the approved budget, activities funded with that recipient cost share are included.

Significant financial interest means:

(1) A financial interest consisting of one or more of the following interests of the covered individual (and those of the covered individual's spouse and dependent children) that reasonably appears to be related to the covered individual's non-Federal entity responsibilities:

(i) With regard to any foreign or domestic publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. For purposes of this definition, remuneration includes salary and any payment for services not otherwise identified as salary (*e.g.,* consulting fees, honoraria, paid authorship); equity interest includes any stock, stock option, or other ownership interest, as determined through reference to public prices or other reasonable measures of fair market value;

(ii) With regard to any foreign or domestic non-publicly traded entity, a significant financial interest exists if the value of any remuneration, not otherwise disclosed as current, pending, or other support, received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the covered individual (or the covered individual's spouse or dependent children) holds any equity interest (*e.g.,* stock, stock option, or other ownership interest); and

(iii) Intellectual property rights and interests (*e.g.,* patents, copyrights), upon receipt of income related to such rights and interests.

(2) Any reimbursed or sponsored travel (*i.e.,* that which is paid on behalf of the covered individual and not reimbursed to the covered individual so that the exact monetary value may not be readily available) related to their institutional responsibilities that is not otherwise disclosed in current and pending or other support disclosures, but does not include travel that is reimbursed or sponsored by a Federal, State, or local government agency of the United States; a domestic Institution of Higher Education; or a domestic research institute that is affiliated with a domestic Institution of Higher Education.

(3) The term *significant financial interest* does not include the following types of financial interests: salary, royalties, or other remuneration paid by the non-Federal entity to the covered individual if the covered individual is currently employed or otherwise appointed by the non-Federal entity, including intellectual property rights assigned to the non-Federal entity and agreements to share in royalties related to such rights; any ownership interest in the non-Federal entity held by the covered individual, if the non-Federal entity is a commercial or for-profit organization; income from investment vehicles, such as mutual funds and retirement accounts, as long as the covered individual does not directly control the investment decisions made in these vehicles; income from seminars, lectures, or teaching engagements sponsored by a Federal, State, or local government agency of the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic Institution of Higher Education; or income from service on advisory committees or review panels for a Federal, State, or local government agency of the United States, a domestic Institution of Higher Education, or a domestic research institute that is affiliated with a domestic Institution of Higher Education.

§ 910.210 Applicability.

(a) This subpart applies to any non-Federal entity that is an applicant to or recipient of a DOE Federal financial assistance award on or after August 17, 2026, including any covered individual who plans to participate in or is participating in the project funded wholly or in part under the DOE Federal financial assistance award, and each non-Federal entity subrecipient under the Federal financial assistance award, subject to the following exceptions:

(1) This subpart does not apply to DOE Office of Indian Energy applications and Federal financial assistance awards.

(2) For an individual that is an applicant to or recipient of a DOE Federal financial assistance award the requirements of this subpart may be tailored to the extent determined appropriate by the applicable DOE program office.

(b) [Reserved]

§ 910.220 [Reserved]

§ 910.230 Required conflict of interest (COI) and conflict of commitment (COC) policies.

(a) Any non-Federal entity that is an applicant to or recipient of a DOE Federal financial assistance award must maintain a written and enforced policy addressing actual, apparent, and potential COI and COC, both foreign and domestic. The non-Federal entity must make its written policy available within five business days following any request for the policy.

(b) The policy required under paragraph (a) of this section must:

(1) Designate a non-Federal entity official(s) to solicit and review COI and COC disclosures from each covered individual who is planning to participate in, or is participating in, the project funded under a DOE Federal financial assistance award;

(2) Require review by the designated official(s) of all covered individuals' disclosures to determine whether an actual, apparent, or potential COI or COC exists; and, if so, require the designated official(s) determine the actions that have been and shall be taken to eliminate or, where appropriate, manage or reduce the conflict. Examples of conditions or restrictions that a recipient or subrecipient might impose to manage, reduce, or eliminate a conflict include, but are not limited to:

(i) Public disclosure of the conflict (*e.g.,* when presenting or publishing the project);

(ii) For projects involving human subjects, disclosure of the conflict directly to participants;

(iii) Appointment of an independent monitor or oversight committee capable of taking measures to protect the purpose, design, conduct, and reporting of the project against bias resulting from the conflict;

(iv) Modification of the project plan;

(v) Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the project;

(vi) Reduction or elimination of the financial interest (*e.g.,* sale of an equity interest) or commitment; or

(vii) Severance of relationship(s) that create the conflict;

(3) Ensure that covered individuals have provided all required disclosures to the non-Federal entity no later than the time an application is submitted to DOE. In the event a non-Federal entity seeks to add a covered individual after the time of application, the non-Federal entity must require the covered individual make such disclosures prior to participating in a project funded under a DOE Federal financial assistance award;

(4) Require each covered individual who is participating in the DOE Federal financial assistance award update those disclosures on an annual basis and as soon as practicable, but in no event later than 15 days after any new actual, apparent, or potential COI or COC arises;

(5) Require each disclosure be signed and dated by the covered individual and include the certification statement in appendix A to this subpart;

(6) Require each covered individual to complete COI and COC training prior to engaging in projects funded under a DOE Federal financial assistance award and complete refresher training least every two years. The training must cover the non-Federal entity's COI and COC policy and the covered individual's responsibilities regarding disclosures. The non-Federal entity must require covered individual to complete COI and COC training within 30 days of any of the following circumstances:

(i) The non-Federal entity revises its COI and COC policies or procedures in any manner that affects the responsibilities of a covered individual;

(ii) A covered individual is new to a non-Federal entity; or

(iii) A non-Federal entity finds that a covered individual is not in compliance with the non-Federal entity's COI and COC policy or applicable management plan;

(7) With regard to reimbursed or sponsored travel, the non-Federal entity's COI and COC policy must require, at a minimum, reporting the purpose of the trip, the identity of the sponsor/organizer, the destination, and the duration. In accordance with the non-Federal entity's policy, the non-Federal entity official(s) will determine if further information is needed, including a determination or disclosure of monetary value, in order to determine whether the travel constitutes a COI or COC with the project funded under the DOE Federal financial assistance award; and

(8) Include adequate enforcement mechanisms and provide for sanctions where appropriate.

(c) Any non-Federal entity that receives a DOE Federal financial assistance award must ensure that subrecipients, if any, follow the requirements of this subpart by:

(1) Incorporating as part of a written agreement with the subrecipient terms that establish either the COI and COC policy of the recipient or that of the subrecipient will apply to the subrecipient's covered individuals.

(2) If the subrecipient's covered individuals must comply with the subrecipient's COI and COC policy, the subrecipient shall certify as part of the agreement referenced in paragraph (c)(1) of this section that its policy complies with this subpart. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient's covered individuals are subject to the COI and COC policy of the recipient.

(3) Additionally, if the subrecipient's covered individuals must comply with the subrecipient's COI and COC policy, the agreement referenced in paragraph (c)(1) of this section shall specify time period(s) for the subrecipient to report all identified financial COI and COC to the recipient. Such time period(s) shall be sufficient to enable the recipient to provide timely COI/COC reports, as necessary, to DOE, as required by this subpart.

(4) Alternatively, if the subrecipient's covered individuals must comply with the recipient's COI and COC policy, the agreement referenced in paragraph (c)(1) of this section shall specify time period(s) for the subrecipient to submit all covered individual's disclosures to the recipient. Such time period(s) shall be sufficient to enable the recipient to comply timely with its review, management, and reporting obligations under this subpart.

§ 910.240 Reporting conflicts of interest (COIs) and conflicts of commitment (COCs).

(a) Consistent with 2 CFR 200.112, a non-Federal entity that is an applicant to or recipient of DOE financial assistance must disclose to DOE in writing any actual, apparent, or potential COI or COC, including any actual, apparent, or potential COI or COC reported to the recipient by a subrecipient, if such conflict cannot be eliminated or appropriately managed or reduced in accordance with the entity's policy. In addition, such entity must disclose to DOE in writing any actual, apparent, or potential COI or COC, including any actual, apparent, or potential COI or COC reported to the recipient by a subrecipient, involving any foreign governments, their instrumentalities, or any other entities owned, funded, or otherwise controlled by a foreign government, as well as any measures the entity has taken to eliminate or, where appropriate, manage or reduce the COI or COC.

(1) For all conflicts that require disclosure to DOE:

(i) A non-Federal entity applying for DOE funding must clearly and explicitly disclose such conflict(s) in the application.

(ii) In the event a non-Federal entity seeks to add a covered individual after the time of application, the non-Federal entity must clearly and explicitly disclose such conflict(s) in writing to DOE prior to the individual participating in the project.

(2) If specified in the applicable funding opportunity announcement and/or terms and conditions of the Federal financial assistance award, a DOE program office may require the non-Federal entity disclose to DOE in writing all covered individuals' COIs and COCs, including those COIs and COCs determined by the non-Federal entity to be appropriately managed or reduced.

(b) DOE may require the non-Federal entity to provide associated disclosures, supporting documentation to demonstrate how the COI or COC was managed or reduced; and sufficient information to enable DOE to understand the nature and extent of the COI or COC, and to assess whether the actions are sufficient to ensure the integrity of the DOE-supported project and to protect the Government's interests.

(c) For any COI or COC previously reported by the non-Federal entity regarding an ongoing project funded under a DOE Federal financial assistance award, the non-Federal entity must provide DOE with an annual COI/COC report that addresses the status of the COI or COC and, if applicable, any changes to the management plan for the duration of the DOE Federal financial assistance award. The annual COI/COC report must specify whether the conflict is still being managed or if it remains unmanaged/unmanageable. Alternatively, the annual COI/COC report must explain why the conflict no longer exists. The non-Federal entity must provide annual COI/COC reports to DOE for the duration of the project period (including extensions with or

without funds) in the time and manner required by term and condition of the Federal financial assistance award.

(d) In addition to the annual COI/COC report, DOE may require a non-Federal entity to routinely, or upon request, submit all or some covered individuals' disclosures. Circumstances when DOE may require a non-Federal entity to submit all or some of such covered individual disclosures include but are not limited to:

(1) As part of monitoring the non-Federal entity's compliance with this subpart;

(2) Bankruptcy of the non-Federal entity;

(3) Other legal winding down of the non-Federal entity;

(4) Acquisition of the non-Federal entity by a foreign entity, where ''acquisition'' includes a foreign entity obtaining a controlling interest in the non-Federal entity; or

(5) As otherwise set forth in 2 CFR part 200 and this part.

(e) If a non-Federal entity becomes aware that a covered individual failed to comply with the non-Federal entity's COI and COC policy or a management plan, the non-Federal entity must promptly notify DOE in writing of the failure to comply and of the corrective action taken or to be taken. DOE will evaluate the situation and, as necessary, take appropriate action, which may include referring the matter to the non-Federal entity for further corrective action consistent with non-Federal entity's established COI and COC policies, DOE directing the non-Federal entity to take specific mitigation measures, or termination of the Federal financial assistance award.

§ 910.250 Organizational conflicts.

(a) Consistent with 2 CFR 200.318, if a non-Federal entity has a parent, affiliate, or subsidiary organization that is not a State government, local government, or Indian Tribe, the non-Federal entity must maintain written standards of conduct covering organizational conflicts of interest (OCI) as that term is defined in 2 CFR 200.318(c)(2).

(b) If the effects of a potential or actual OCI cannot be avoided, eliminated, or mitigated, the procurement or other transaction anticipated by the non-Federal entity must not be made using DOE or cost share funds.

§ 910.260 Reporting organizational conflicts of interest (OCIs).

The non-Federal entity must disclose in writing any potential or actual OCI to DOE within 15 business days of learning of the conflict.

(a) The non-Federal entity must provide the disclosure to DOE in an application for financial assistance and prior to engaging in a procurement or other transaction to acquire services or property, using DOE funds with a parent, affiliate, or subsidiary organization that is not a State government, local government, or Indian Tribe.

(b) The disclosure must include, at a minimum, the following:

(1) The name, address, and website (as applicable) of the entity that presents a potential or actual OCI;

(2) The relationship between the non-Federal entity and the entity at issue;

(3) The nature of the anticipated procurement or other transaction with the parent, affiliate, or subsidiary organization; the anticipated value of the procurement or other transaction; and the basis for making the procurement or other transaction with the parent, affiliate, or subsidiary organization;

(4) The basis for the non-Federal entity's determination regarding the existence of an OCI; and

(5) How the non-Federal entity will avoid, eliminate, or mitigate the OCI.

§ 920.270 Remedies, penalties, and enforcement.

(a)(1) If a non-Federal entity fails to disclose a conflict of interest (COI) or conflict of commitment (COC) as required under this subpart, or fails to sufficiently manage or mitigate a COI or COC to ensure the integrity of the DOE-supported project or to protect the Government's interests, DOE may:

(i) Require the non-Federal entity take action to eliminate or mitigate the conflict to a risk level acceptable to DOE. In the event the non-Federal entity does not eliminate or mitigate the conflict to a risk level acceptable to DOE, DOE may determine the Federal financial assistance award no longer effectuates the program goals or agency priorities and terminate the Federal financial assistance award;

(ii) Determine the circumstances disqualify an entity or individual from participating in all or a portion of a Federal financial assistance award; or

(iii) Reject an application.

(2) DOE may inquire, at any time before, during, or after a Federal financial assistance award, into any covered individual's disclosures and the non-Federal entity's review (including any retrospective review) of and response to such disclosure, regardless of whether the disclosure resulted in the non-Federal entity's determination of a COI or COC. A non-Federal entity is required to submit or permit on-site review of all records pertinent to compliance with this subpart. To the extent permitted by law, DOE will maintain the confidentiality of all records of financial interests. Based on its review of records or other information that may be available, DOE may determine that a particular COI or COC will bias the objectivity of or adversely impact the project funded under the DOE Federal financial assistance award to such an extent that further corrective action is needed or that the non-Federal entity has not managed the COI or COC in accordance with this subpart. DOE may determine that the imposition of specific award conditions under 2 CFR 200.208 is necessary. DOE may also take one or more the actions specified under 2 CFR 200.339, as appropriate in such circumstances.

(b) If a non-Federal entity fails to disclose an OCI to DOE prior to engaging in a procurement or other transaction to acquire services or property, using DOE funds with a parent, affiliate, or subsidiary organization that is not a State, local government, or Indian Tribe, the costs of such procurement or transaction may be disallowed. If a non-Federal entity fails to disclose an OCI to DOE that is not avoided, eliminated, or mitigated or fails to avoid, eliminate, or mitigate a disclosed OCI, prior to engaging in a procurement or other transaction using DOE funds with a parent, affiliate, or subsidiary organization that is not a State, local government, or Indian Tribe, DOE may determine that imposition of specific award conditions under 2 CFR 200.208 is necessary. DOE may also take one or more actions specified under 2 CFR 200.339, as appropriate in the circumstances.

(c) Any false, fictitious, or fraudulent information, or the omission of any material fact, on a disclosure, report, or other record required under this subpart may be subject to criminal, civil, or administrative penalties for fraud, false statements, false claims or otherwise. (18 U.S.C. 287 and 1001 and 31 U.S.C. 3729–3733 and 3801–3812)

(d) If fraud, misrepresentation, or related misconduct is suspected in relation to any disclosure submitted to DOE, then the cognizant contracting officer and/or program official should coordinate with appropriate counsel and thereafter, as appropriate, refer the matter to the DOE Office of Inspector General (OIG).

(e) If a covered individual knowingly fails to disclose required information, DOE may take one or more of the following enforcement or other actions:

(1) Reject an application;

(2) Suspend or terminate a Federal financial assistance award;

(3) Temporarily or permanently discontinue or de-obligate any or all funding for the covered individual or non-Federal entity;

(4) Refer recipients for consideration of suspension or debarment proceedings;

(5) Refer the failure to disclose to the DOE OIG for further investigation or to Federal law enforcement authorities to determine whether any criminal or civil laws were violated;

(6) Report the entity in the Federal Awardee Performance and Integrity Information System (FAPIIS) to alert other Federal agencies to the noncompliance;

(7) Take one or more of the actions described in 2 CFR 200.339; or

(8) Take such other actions against the covered individual or non-Federal entity as authorized under applicable law or regulations.

Appendix A to Subpart C of Part 910—Disclosure Certification Statement

All disclosures required under this subpart must include the following certification statement:

''I understand that this Disclosure is required to obtain funding from the U.S. Government. I, [Full Name and Title], certify to the best of my knowledge and belief that the information contained in this Disclosure Statement is true, complete, and accurate. I understand that any false, fictitious, or fraudulent information, misrepresentations, half-truths, or omissions of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims, or otherwise. (18 U.S.C. 287, 1001, and 1031, and 31 U.S.C. 3729–3733 and 3801–3812). I further understand and agree that:

(1) The statements and representations made herein are material to the U.S. Government's funding decision, and

(2) I have a responsibility to update the disclosures during the period of performance of the Federal financial assistance award should circumstances change which impact the responses provided above.''

[FR Doc. 2026–14333 Filed 7–15–26; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 21 and 22

[Docket No. FAA–2026–6965]

Accepted Consensus Standards for Light-Sport Category Aircraft: Airplane, Glider, Powered Lift, and Gyroplane

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

ACTION: Notification of Availability (NOA).

SUMMARY: This document announces the availability of ASTM International (ASTM) consensus standards for use as an FAA-accepted means of compliance (MOC) to support issuance of special airworthiness certificates for the categories of light-sport category aircraft and light-sport category kit-built aircraft described herein. The FAA accepts the following ASTM standards (with changes identified in this document): F3815–26a, ''Standard Specification for Integration for Light Sport Airplane,'' F3836–26, ''Standard Specification for Integration for Light Sport Glider,'' F3840–26,[1] ''Standard Specification for Integration for Light Sport Powered-Lift and Multicopter,'' and F3841–26, ''Standard Specification for Integration for Light Sport Gyroplane''. FAA's acceptance of these ASTM integration standards as an MOC includes FAA's acceptance of the underlying ASTM functional standards as set forth Tables 1–8 herein. The FAA will maintain a listing of FAA accepted MOCs for light-sport category aircraft on the FAA's Light-Sport Category Aircraft web page at *https://www.faa.gov/aircraft/gen_av/light_sport.*

DATES: Acceptance of these MOC is effective on July 16, 2026. Comments must be received on or before August 17, 2026.

ADDRESSES: Send comments identified by docket number FAA–2026–6965 using any of the following methods:

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

☐ *Email:* Send comments to: *9-ACE-AVR-LSA-Comments@faa.gov.* Specify the standard being addressed by ASTM designation and title. Mark all comments: Consensus Standards Comments.

FOR FURTHER INFORMATION CONTACT: John Stoll, Federal Aviation Administration, Policy and Standards Division, AIR–600, Product Policy Management: Systems Standards Section, AIR–63A; email: *john.stoll@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to submit any written data, views, or arguments about this notice. Comments should identify the consensus standard number and be sent to an address listed under **ADDRESSES**. The FAA will forward all comments received on or before the closing date to the ASTM F37 Committee on Light-Sport Aircraft for consideration, who may change the standard in light of the comments received. The FAA will address all comments received during its recurring review of the consensus standards and participation in the consensus standards revision process.

Background

Under the provisions of the National Technology Transfer and Advancement Act of 1995 [2] and Office of Management and Budget (OMB) Circular A–119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities,'' effective January 27, 2016, the FAA participates in the development of consensus standards for use as a means of carrying out its policy objectives where appropriate.

Consistent with the ''Certification of Aircraft and Airmen for the Operation of Light-Sport Aircraft'' final rule (69 FR44772, July 27, 2004) and the ''Small Airplane Revitalization Act of 2013'',[3] the FAA has been working with industry and other stakeholders through the ASTM F37 Committee on Light-Sport Aircraft (hereafter F37) to develop consensus standards as an MOC in certificating airplanes, gliders, powered-parachutes, weight-shift control, and lighter-than-air under §§ 21.190 and 21.191(i)(2) since 2004.

The Modernization of Special Airworthiness Certification (MOSAIC) final rule (90 FR 35034), published on July 24, 2025, anticipated that beginning on July 24, 2026, new consensus standards would need to be developed as the MOC to the design, production, and airworthiness requirements of part 22 subpart B, including the performance

[1] The ASTM Standard F3840–26 is intended to serve as an MOC for both powered-lift and multicopters, but at this time FAA is only accepting it as an MOC for powered-lift light-sport category aircraft.

[2] *Ref* Public Law 104–113, as amended by Public Law 107–107.

[3] Public Law 113–53.

expansions and new classes of aircraft allowed by this rule. With FAA participation, F37 has worked to publish a new framework of standards that could serve as MOCs to the changes provided by the MOSAIC final rule. In addition to the previously addressed categories of aircraft, these new standards also expand the applicability to new categories of aircraft such as gyroplane and powered-lift.

As stated in the MOSAIC final rule, the FAA would publish a notice of availability (NOA) of those consensus standards in the **Federal Register** when the Administrator accepts the consensus standards as an acceptable MOC. The FAA reviewed the published ASTM consensus standards developed by F37 as the basis for an MOC to §§ 21.190, 21.191(k), 21.193(h), and each section of part 22 subpart B except § 22.175. The Administrator accepts ASTM F3815–26a, F3836–26, F3840–26, and F3841–26 as an MOC for the requirements of §§ 21.190, 21.191(k), 21.193(h), and part 22 subpart B.

Consensus standards that have been FAA-accepted prior to the July 24, 2026, effective date of part 22 will:

- Still apply to:
  - Alterations and repairs of ''light-sport aircraft'' (the terminology of such aircraft prior to MOSAIC) certificated prior to July 24, 2026; and
  - Issuance of airworthiness certificates for the experimental purpose of operating light-sport category kit-built aircraft with a light-sport category aircraft statement of compliance (FAA Form 8130–15) signed prior to July 24, 2026.
- Not apply to:
  - Light-sport category aircraft certificated on or after July 24, 2026; or
  - Issuance of airworthiness certificates for the experimental purpose of operating light-sport category kit-built aircraft with a light-sport category aircraft statement of compliance (FAA Form 8130–15) signed after July 24, 2026.

Aircraft certificated as light-sport category aircraft or kit aircraft for the experimental purpose of operating light-sport category kit-built aircraft on or after July 24, 2026, must comply with part 22 and consensus standards that have been accepted by the FAA as an MOC to part 22.

Means of Compliance Accepted

F37 has structured their light-sport category aircraft consensus standards under an integration and functional standard framework. F37 has developed integration standards for specific categories of light-sport category aircraft (*e.g.,* airplane, glider, powered lift, and gyroplane). These integration standards identify a package of functional standards that are applicable to the specific light-sport category of aircraft addressed by that integration standard and that are intended to work together as a whole. Each underlying functional standard covers a specific topic such as structures, landing gear, propellers, engines, etc. Many functional standards are applicable to more than one category of light-sport aircraft and will be identified in multiple integration standards whereas other functional standards are only applicable to a specific light-sport category of aircraft and will only be identified in the integration standard applicable to that category. For each light-sport category of aircraft, a tailored integration standard identifies which functional standards are required to be the MOC to part 22 and certain portions of part 21.

The FAA accepts ASTM integration standards F3815–26a, F3836–26, F3840–26, and F3841–26 as an MOC for the airworthiness requirements of §§ 21.190, 21.191(k), 21.193(h), and part 22 subpart B, with the footnotes identified in Tables 1, 3, 5, and 7. This acceptance includes only the version of the functional standards referenced in the MOC summary tables in those integration standards.[4] If an underlying functional standard is revised, that standard is not accepted by the FAA until it is identified in a new revision of the integration standard that is accepted by the FAA. For ease of use, Tables 2, 4, 6, and 8 provide a side-by-side view, linking the applicable §§ 21.190, 21.191(k), 21.193(h), and part 22 subpart B regulations to the respective ASTM integration standard.

Guidance

This is a guidance document. Its content is not legally binding in its own right and will not be relied upon by the Department as a separate basis for affirmative enforcement action or other administrative penalty. Conformity with the guidance document is voluntary only, and nonconformity will not affect rights and obligations under existing statutes and regulations.

[4] The FAA previously accepted ASTM F2930–16, Standard Guide for Compliance with Light Sport Aircraft Standards (*see* 82 FR 16271, April 3, 2017). F2930–16 is not referenced in the F3815–26a, F3836–26, F3840–26, or F3841–26 integration standards and is not being accepted by this NOA. While F2930–16 is not required for compliance with the regulations discussed in this NOA, that standard may continue to be used for reference purposes only.

TABLE 1—PART 22 SUBPART B ACCEPTED MOC FOR LIGHT-SPORT CATEGORY AIRPLANES BASED ON ASTM CONSENSUS STANDARDS F3815–26a

ASTM number as identified in F3815–26a	ASTM document title
F2316–12 (2022).	Standard Specification for Airframe Emergency Parachutes.
F2339–26	Standard Practice for Design and Manufacture of Reciprocating Engines for Light Sport Aircraft.
F2483–26	Standard Practice for Maintenance Program for Light Sport Category Aircraft.
F2506–26	Standard Specification for Design and Testing of Light Sport Aircraft Propellers.
F2563–16 (2025).	Standard Practice for Kit Assembly Instructions of Aircraft Intended Primarily for Recreation.
F2745–15 (2023).	Standard Specification for Required Product Information to be Provided with an Airplane.
F2746–26a	Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft.
F2839–11 (2025)[5].	Standard Practice for Compliance Audits to ASTM Standards on Light Sport Aircraft.
F2840–26a	Standard Practice for Design and Manufacture of Electric Engine for Light Sport Aircraft.
F2972–26	Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
F3035–26	Standard Practice for Production Acceptance in the Manufacture of a Light Sport Aircraft.
F3198–25	Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program.
F3331–18 (2023).	Standard Practice for Aircraft Water Loads.
F3338–24	Standard Specification for Design of Electric Engines for General Aviation Aircraft.
F3619–26	Standard Specification for Aeroelasticity Requirements for a Light Sport Category Airplane.
F3695–26	Standard Specification for Angle of Attack (AoA) Functional Requirements.
F3737–25	Standard Specification for Aircraft Design and Construction.
F3746–26	Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
F3768–26a	Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft.

TABLE 1—PART 22 SUBPART B ACCEPTED MOC FOR LIGHT-SPORT CATEGORY AIRPLANES BASED ON ASTM CONSENSUS STANDARDS F3815–26a—Continued

ASTM number as identified in F3815–26a	ASTM document title
F3792–26	Standard Specification for Light Sport Category Aircraft Flown at Night.
F3793–26a	Standard Specification for Flight Characteristics and Performance.
F3810–26b	Standard Specification for Oxygen Systems for Light Sport Aircraft.
F3813–26	Standard Specification for Light Sport Category Aircraft Occupant Safety.
F3814–26	Standard Specification for Light Sport Category Aircraft Electrical Systems.
F3824–26	Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
F3825–26	Standard Specification for Operating Limitations, Markings, Placards, and Warnings for Light Sport Aircraft.
F3826–26	Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
F3827–26	Standard Specification for Indirect Flight Controls.

TABLE 1—PART 22 SUBPART B ACCEPTED MOC FOR LIGHT-SPORT CATEGORY AIRPLANES BASED ON ASTM CONSENSUS STANDARDS F3815–26a—Continued

ASTM number as identified in F3815–26a	ASTM document title
F3828–26	Standard Specification for Structures for Light Sport Category Aircraft.
F3829–26	Standard Specification for Light Sport Category Aircraft Powerplant Systems.
F3830–26	Standard Specification for Electrical Energy Storage Systems.
F3831–26	Standard Specification for Aircraft Intended for Water Operations.
F3833–26[6]	Standard Guide for Computer Based Control Systems (CBCS).
F3834–26	Standard Specification for Systems and Equipment for Light Sport Category Aircraft.
F3835–26	Standard Specification for Light Sport Category Aircraft Landing Gear Systems.
F3845–26	Standard Practice for the Design and Manufacturing of Turbine Engines for Light Sport Category Aircraft.

TABLE 1—PART 22 SUBPART B ACCEPTED MOC FOR LIGHT-SPORT CATEGORY AIRPLANES BASED ON ASTM CONSENSUS STANDARDS F3815–26a—Continued

ASTM number as identified in F3815–26a	ASTM document title
F3851–26	Standard Specification for Light Sport Category Aircraft.

[5] ASTM references F2839–11 (2025) in the ASTM integration standards for light-sport category airplanes (F3815–26a), gliders (F3836–26), powered-lifts (F3840–26), and gyroplanes (F3841–26). ASTM intended this standard to be optional and not required for compliance under all of these integration standards. However, ASTM unintentionally referenced F2839–11 (2025) as a mandatory requirement for § 21.190(d) for the powered-lift, and gyroplane integration standards. Accordingly, with respect to FAA's acceptance of F3815–26a, F3836–26, F3840–26, and F3841–26 as MOCs, F2839 is optional and is not required for compliance.

[6] ASTM references F3833–26 for § 22.185 in the ASTM integration standards for light-sport category airplanes (F3815–26a), gliders (F3836–26), powered-lifts (F3840–26), and gyroplanes (F3841–26). FAA notes that F3833–26 is not required for compliance § 22.185 and FAA has made no determination of its suitability, but that standard may be used for reference purposes.

TABLE 2—LIGHT-SPORT CATEGORY AIRPLANE SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3815–26A SECTION(S)

Title 14 regulation(s)	ASTM F3815–26a reference standards(s)
§ 21.190	
§ 21.190(c) Application for special airworthiness certificate in the light-sport category.	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F2746–26a Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft. F2745–15 (2023) Standard Specification for Required Product Information to be Provided with an Airplane. F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft. F2483–26 Standard Practice for Maintenance Program for Light Sport Category Aircraft.
§ 21.190(d) Manufacturer's Statement of Compliance	F3198–25 Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F2745–15 (2023) Standard Specification for Required Product Information to be Provided with an Airplane. F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
§ 21.191	
§ 21.191(k) Issue of experimental airworthiness certificates.	F2563–16 (2025) Standard Practice for Kit Assembly Instructions of Aircraft Intended Primarily for Recreation.
§ 21.193	
§ 21.193(h) Application for Special Airworthiness certificates issued for experimental purposes.	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.

TABLE 2—LIGHT-SPORT CATEGORY AIRPLANE SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3815–26A SECTION(S)—Continued

Title 14 regulation(s)	ASTM F3815–26a reference standards(s)
	F2746–26a Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft.
Part 22 Subpart B	
§ 22.100 Eligibility	F3851–26 Specification for Light Sport Category Aircraft.
§ 22.105 Control and maneuverability	F3793–26a Standard Specification for Flight Characteristics and Performance. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft. F3827–26 Standard Specification for Indirect Flight Controls. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements. F3831–26 Standard Specification for Aircraft Intended for Water Operations.
§ 22.110 Structural integrity	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.115 Powered-Lift: minimum safe speed	F3619–26 Standard Specification for Aeroelasticity Requirements for a Light Sport Category Airplane. F3835–26 Standard Specification for Light Sport Category Aircraft Landing Gear System. F3828–26 Standard Specification for Structures for Light Sport Category Aircraft. F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft. F3737–25 Standard Specification for Aircraft Design and Construction. F3331–18 (2023) Standard Practice for Water Loads. F3831–26 Standard Specification for Aircraft Intended for Water Operations. F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety. F2316–12 (2022) Standard Specification for Airframe Emergency Parachutes. N/A.
§ 22.125 Environmental Conditions	F3737–25 Standard Specification for Aircraft Design and Construction. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft. F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft. F3831–26 Standard Specification for Aircraft Intended for Water Operations. F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft.
§ 22.130 Suitability and durability of materials	F3737–25 Standard Specification for Aircraft Design and Construction. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.135 Instruments and equipment	F3737–25 Standard Specification for Aircraft Design and Construction. F3810–26b Standard Specification for Oxygen Systems for Light Sport Aircraft. F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3827–26 Standard Specification for Indirect Flight Controls. F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.140 Controls and Displays	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements. F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety. F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.145 Propulsion system	F3737–25 Standard Specification for Aircraft Design and Construction. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers.

TABLE 2—LIGHT-SPORT CATEGORY AIRPLANE SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3815–26A SECTION(S)—Continued

Title 14 regulation(s)	ASTM F3815–26a reference standards(s)
	F3845–26 Standard Practice for the Design and Manufacturing of Turbine Engines for Light Sport Category Aircraft.
	F3830–26 Standard Specification for Electrical Energy Storage Systems.
	F2840–26a Standard Practice for Design and Manufacture of Electric Engine for Light Sport Aircraft.
	F2339–26 Standard Practice for Design and Manufacture of Reciprocating Engines for Light Sport Aircraft.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
	F3338–24 Standard Specification for Design of Electric Engines for General Aviation Aircraft.
	F3793–26a Standard Specification for Flight Characteristics and Performance.
	F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft.
§ 22.150 Fuel system	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
§ 22.155 Fire Protection	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3830–26 Standard Specification for Electrical Energy Storage Systems.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
§ 22.160 Visibility	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
	F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night.
§ 22.165 Emergency Evacuation	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
§ 22.170 Placards and markings	F3825–26 Standard Specification for Operating Limitations, Markings, Placards, and Warnings for Light Sport Aircraft.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night.
	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.
	F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft.
	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
§ 22.180 Special requirements for light-sport category aircraft with simplified flight controls.	ASTM has not submitted for FAA acceptance, and FAA has not otherwise accepted a consensus standard to enable this requirement. Therefore, manufacturers are not eligible to declare compliance with § 21.180 and have their airplanes be designated as light-sport category aircraft with simplified flight controls at this time.
§ 22.185 Quality Assurance System	F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
	F3737–25 Standard Specification for Aircraft Design and Construction.
	F3198–25 Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program.
	F3833–26 Standard Guide for Computer Based Control Systems (CBCS).
§ 22.190 Finding of compliance by trained staff	F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
§ 22.195 Ground and flight testing	F3035–26 Standard Practice for Production Acceptance in the Manufacture of a Light Sport Aircraft.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.

TABLE 3—PART 22 SUBPART B ACCEPTED MOC FOR LIGHT-SPORT CATEGORY GLIDER BASED ON ASTM CONSENSUS STANDARDS F3836–26

ASTM No. as identified in F3836–26	ASTM document title
F2316–12 (2022)	Standard Specification for Airframe Emergency Parachutes.
F2339–26	Standard Practice for Design and Manufacture of Reciprocating Engines for Light Sport Aircraft.
F2483–26	Standard Practice for Maintenance Program for Light Sport Category Aircraft.
F2506–26	Standard Specification for Design and Testing of Light Sport Aircraft Propellers.
F2563–16 (2025)	Standard Practice for Kit Assembly Instructions of Aircraft Intended Primarily for Recreation.
F2745–15 (2023)	Standard Specification for Required Product Information to be Provided with an Airplane.
F2746–26a	Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft.
F2839–11 (2025)[7]	Standard Practice for Compliance Audits to ASTM Standards on Light Sport Aircraft.
F2840–26a	Standard Practice for Design and Manufacture of Electric Engine for Light Sport Aircraft.
F2972–26	Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
F3035–26	Standard Practice for Production Acceptance in the Manufacture of a Light Sport Aircraft.
F3198–25	Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program.
F3338–24	Standard Specification for Design of Electric Engines for General Aviation Aircraft.
F3619–26	Standard Specification for Aeroelasticity Requirements for a Light Sport Category Airplane.
F3695–26	Standard Specification for Angle of Attack (AoA) Functional Requirements.
F3737–25	Standard Specification for Aircraft Design and Construction.
F3746–26	Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
F3768–26a	Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft.
F3792–26	Standard Specification for Light Sport Category Aircraft Flown at Night.
F3793–26a	Standard Specification for Flight Characteristics and Performance.
F3810–26b	Standard Specification for Oxygen Systems for Light Sport Aircraft.
F3813–26	Standard Specification for Light Sport Category Aircraft Occupant Safety.
F3814–26	Standard Specification for Light Sport Category Aircraft Electrical Systems.
F3824–26	Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
F3825–26	Standard Specification for Operating Limitations, Markings, Placards, and Warnings for Light Sport Aircraft.
F3826–26	Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
F3827–26	Standard Specification for Indirect Flight Controls.
F3828–26	Standard Specification for Structures for Light Sport Category Aircraft.
F3829–26	Standard Specification for Light Sport Category Aircraft Powerplant Systems.
F3830–26	Standard Specification for Electrical Energy Storage Systems.
F3831–26	Standard Specification for Aircraft Intended for Water Operations.
F3833–26[8]	Standard Guide for Computer Based Control Systems (CBCS).
F3834–26	Standard Specification for Systems and Equipment for Light Sport Category Aircraft.
F3835–26	Standard Specification for Light Sport Category Aircraft Landing Gear Systems.
F3845–26	Standard Practice for the Design and Manufacturing of Turbine Engines for Light Sport Category Aircraft.
F3851–26	Standard Specification for Light Sport Category Aircraft.

[7] See the discussion in footnote 5.
[8] See the discussion in footnote 6.

TABLE 4—LIGHT-SPORT CATEGORY GLIDER SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3836–26 SECTION(S)

Title 14 regulation(s)	ASTM F3836–26 reference standards(s)
§ 21.190	
§ 21.190(c) Application for special airworthiness certificate in the light-sport category.	F2746–26a Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft. F2483–26 Standard Practice for Maintenance Program for Light Sport Category Aircraft. F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F2745–15 (2023) Standard Specification for Required Product Information to be Provided with an Airplane.
§ 21.190(d) Manufacturer's Statement of Compliance.	F2745–15 (2023) Standard Specification for Required Product Information to be Provided with an Airplane. F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3198–25 Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program.
§ 21.191	
§ 21.191(k) Issue of experimental airworthiness certificates.	F2563–16 (2025) Standard Practice for Kit Assembly Instructions of Aircraft Intended Primarily for Recreation.

TABLE 4—LIGHT-SPORT CATEGORY GLIDER SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3836–26 SECTION(S)—Continued

Title 14 regulation(s)	ASTM F3836–26 reference standards(s)
	§ 21.193
§ 21.193(h) Application for Special Airworthiness certificates issued for experimental purposes.	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft. F2746–26a Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft.
	Part 22 Subpart B
§ 22.100 Eligibility	F3851–26 Specification for Light Sport Category Aircraft.
§ 22.105 Control and maneuverability	F3793–26a Standard Specification for Flight Characteristics and Performance. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft. F3827–26 Standard Specification for Indirect Flight Controls. F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.
§ 22.110 Structural integrity	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3619–26 Standard Specification for Aeroelasticity Requirements for a Light Sport Category Airplane. F3835–26 Standard Specification for Light Sport Category Aircraft Landing Gear System. F3828–26 Standard Specification for Structures for Light Sport Category Aircraft. F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft. F3737–25 Standard Specification for Aircraft Design and Construction. F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety. F2316–12 (2022) Standard Specification for Airframe Emergency Parachutes.
§ 22.115 Powered-Lift: minimum safe speed	N/A.
§ 22.125 Environmental Conditions	F3737–25 Standard Specification for Aircraft Design and Construction. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft. F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft. F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft.
§ 22.130 Suitability and durability of materials	F3737–25 Standard Specification for Aircraft Design and Construction. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.135 Instruments and equipment	F3737–25 Standard Specification for Aircraft Design and Construction. F3810–26b Standard Specification for Oxygen Systems for Light Sport Aircraft. F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft. F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3827–26 Standard Specification for Indirect Flight Controls. F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.140 Controls and Displays	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements. F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety. F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3851–26 Specification for Light Sport Category Aircraft. [9] F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.145 Propulsion system	F3737–25 Standard Specification for Aircraft Design and Construction. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers. F3845–26 Standard Practice for the Design and Manufacturing of Turbine Engines for Light Sport Category Aircraft.

TABLE 4—LIGHT-SPORT CATEGORY GLIDER SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3836–26 SECTION(S)—Continued

Title 14 regulation(s)	ASTM F3836–26 reference standards(s)
	F3830–26 Standard Specification for Electrical Energy Storage Systems.
	F3338–24 Standard Specification for Design of Electric Engines for General Aviation Aircraft.
	F2339–26 Standard Practice for Design and Manufacture of Reciprocating Engines for Light Sport Aircraft.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
	F2840–26a Standard Practice for Design and Manufacture of Electric Engine for Light Sport Aircraft.
	F3793–26a Standard Specification for Flight Characteristics and Performance.
	F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft.
§ 22.150 Fuel system	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
§ 22.155 Fire Protection	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3830–26 Standard Specification for Electrical Energy Storage Systems.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
§ 22.160 Visibility	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
	F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night.
§ 22.165 Emergency Evacuation	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.170 Placards and markings	F3825–26 Standard Specification for Operating Limitations, Markings, Placards, and Warnings for Light Sport Aircraft.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night.
	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.
	F3768–26a Standard Specification for IFR Operations in IMC for a Light-Sport Aircraft.
	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
§ 22.180 Special requirements for light-sport category aircraft with simplified flight controls.	ASTM has not submitted for FAA acceptance, and FAA has not otherwise accepted, a consensus standard to enable this requirement. Therefore, manufacturers are not eligible to declare compliance with § 21.180 and have their gliders be designated as light-sport category aircraft with simplified flight controls at this time.
§ 22.185 Quality Assurance System	F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
	F3737–25 Standard Specification for Aircraft Design and Construction.
	F3198–25 Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program.
	F3833–26 Standard Guide for Computer Based Control Systems (CBCS).
§ 22.190 Finding of compliance by trained staff	F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
§ 22.195 Ground and flight testing	F3035–26 Standard Practice for Production Acceptance in the Manufacture of a Light Sport Aircraft.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.

[9] The glider integration standard, ASTM F3836, unintentionally listed F3851–26, as a functional standard for § 22.140 in Table A1.1. of that integration standard. F3851–26 is not required as part of the MOC for § 22.140.

TABLE 5—PART 22 SUBPART B ACCEPTED MOC FOR LIGHT-SPORT CATEGORY POWERED-LIFT BASED ON ASTM CONSENSUS STANDARDS F3840–26

ASTM No. as identified in F3840–26	ASTM document title
F2316–12 (2022)	Standard Specification for Airframe Emergency Parachutes.
F2339–26	Standard Practice for Design and Manufacture of Reciprocating Engines for Light Sport Aircraft.
F2483–26	Standard Practice for Maintenance Program for Light Sport Category Aircraft.
F2506–26	Standard Specification for Design and Testing of Light Sport Aircraft Propellers.
F2563–16 (2025)	Standard Practice for Kit Assembly Instructions of Aircraft Intended Primarily for Recreation.
F2745–15 (2023)	Standard Specification for Required Product Information to be Provided with an Airplane.
F2746–26a	Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft.
F2839–11 (2025) [10]	Standard Practice for Compliance Audits to ASTM Standards on Light Sport Aircraft.
F2840–26a	Standard Practice for Design and Manufacture of Electric Engine for Light Sport Aircraft.
F2972–26	Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
F3035–26	Standard Practice for Production Acceptance in the Manufacture of a Light Sport Aircraft.
F3198–25	Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program.
F3331–18 (2023)	Standard Practice for Aircraft Water Loads.
F3338–24	Standard Specification for Design of Electric Engines for General Aviation Aircraft.
F3619–26	Standard Specification for Aeroelasticity Requirements for a Light Sport Category Airplane.
F3695–26	Standard Specification for Angle of Attack (AoA) Functional Requirements.
F3737–25	Standard Specification for Aircraft Design and Construction.
F3746–26	Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
F3792–26	Standard Specification for Light Sport Category Aircraft Flown at Night.
F3793–26a	Standard Specification for Flight Characteristics and Performance.
F3810–26b	Standard Specification for Oxygen Systems for Light Sport Aircraft.
F3813–26	Standard Specification for Light Sport Category Aircraft Occupant Safety.
F3814–26	Standard Specification for Light Sport Category Aircraft Electrical Systems.
F3824–26	Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
F3825–26	Standard Specification for Operating Limitations, Markings, Placards, and Warnings for Light Sport Aircraft.
F3826–26	Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
F3827–26	Standard Specification for Indirect Flight Controls.
F3828–26	Standard Specification for Structures for Light Sport Category Aircraft.
F3829–26	Standard Specification for Light Sport Category Aircraft Powerplant Systems.
F3830–26	Standard Specification for Electrical Energy Storage Systems.
F3831–26	Standard Specification for Aircraft Intended for Water Operations.
F3833–26 [11]	Standard Guide for Computer Based Control Systems (CBCS).
F3834–26	Standard Specification for Systems and Equipment for Light Sport Category Aircraft.
F3835–26	Standard Specification for Light Sport Category Aircraft Landing Gear Systems.
F3838–26	Standard Specification for Light Sport Category Thrust Borne Aircraft Landing Gear Systems.
F3845–26	Standard Practice for the Design and Manufacturing of Turbine Engines for Light Sport Category Aircraft.
F3851–26	Standard Specification for Light Sport Category Aircraft.

[10] See the discussion in footnote 5.
[11] See the discussion in footnote 6.

TABLE 6—LIGHT-SPORT CATEGORY POWERED-LIFT SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3840–26 SECTION(S)

Title 14 regulation(s)	ASTM F3840–26 reference standards(s)
§ 21.190	
§ 21.190(c) Application for special airworthiness certificate in the light-sport category.	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F2746–26a Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft. F2745–15 (2023) Standard Specification for Required Product Information to be Provided with an Airplane. F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft. F2483–26 Standard Practice for Maintenance Program for Light Sport Category Aircraft
§ 21.190(d) Manufacturer's Statement of Compliance.	F3198–25 Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F2745–15 (2023) Standard Specification for Required Product Information to be Provided with an Airplane. F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
§ 21.191	
§ 21.191(k) Issue of experimental airworthiness certificates.	F2563–16 (2025) Standard Practice for Kit Assembly Instructions of Aircraft Intended Primarily for Recreation.

TABLE 6—LIGHT-SPORT CATEGORY POWERED-LIFT SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3840–26 SECTION(S)—Continued

Title 14 regulation(s)	ASTM F3840–26 reference standards(s)
§ 21.193	
§ 21.193(h) Application for Special Airworthiness certificates issued for experimental purposes.	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft. F2746–26a Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft.
Part 22 Subpart B	
§ 22.100 Eligibility	F3851–26 Specification for Light Sport Category Aircraft.
§ 22.105 Control and maneuverability	F3793–26a Standard Specification for Flight Characteristics and Performance. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3827–26 Standard Specification for Indirect Flight Controls. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements. F3831–26 Standard Specification for Aircraft Intended for Water Operations.
§ 22.110 Structural integrity	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3619–26 Standard Specification for Aeroelasticity Requirements for a Light Sport Category Airplane. F3835–26 Standard Specification for Light Sport Category Aircraft Landing Gear System. F3838–26 Standard Specification for Light Sport Category Thrust Borne Aircraft Landing Gear System. F3828–26 Standard Specification for Structures for Light Sport Category Aircraft. F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft. F3737–25 Standard Specification for Aircraft Design and Construction. F3331–18 (2023) Standard Practice for Water Loads. F3831–26 Standard Specification for Aircraft Intended for Water Operations. F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety. F2316–12 (2022) Standard Specification for Airframe Emergency Parachutes.
§ 22.115 Powered-Lift: minimum safe speed	F3793–26a Standard Specification for Flight Characteristics and Performance. F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.
§ 22.125 Environmental Conditions	F3737–25 Standard Specification for Aircraft Design and Construction. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft. F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft. F3831–26 Standard Specification for Aircraft Intended for Water Operations.
§ 22.130 Suitability and durability of materials	F3737–25 Standard Specification for Aircraft Design and Construction. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.135 Instruments and equipment	F3737–25 Standard Specification for Aircraft Design and Construction. F3810–26b Standard Specification for Oxygen Systems for Light Sport Aircraft. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3827–26 Standard Specification for Indirect Flight Controls. F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.140 Controls and Displays	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements. F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.

TABLE 6—LIGHT-SPORT CATEGORY POWERED-LIFT SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3840–26 SECTION(S)—Continued

Title 14 regulation(s)	ASTM F3840–26 reference standards(s)
	F3737–25 Standard Specification for Aircraft Design and Construction.
§ 22.145 Propulsion system	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers.
	F3845–26 Standard Practice for the Design and Manufacturing of Turbine Engines for Light Sport Category Aircraft.
	F3830–26 Standard Specification for Electrical Energy Storage Systems.
	F2840–26a Standard Practice for Design and Manufacture of Electric Engine for Light Sport Aircraft.
	F2339–26 Standard Practice for Design and Manufacture of Reciprocating Engines for Light Sport Aircraft.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
	F3338–24 Standard Specification for Design of Electric Engines for General Aviation Aircraft.
	F3793–26a Standard Specification for Flight Characteristics and Performance.
§ 22.150 Fuel system	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
§ 22.155 Fire Protection	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3830–26 Standard Specification for Electrical Energy Storage Systems.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
§ 22.160 Visibility	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night.
§ 22.165 Emergency Evacuation	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
§ 22.170 Placards and markings	F3825–26 Standard Specification for Operating Limitations, Markings, Placards, and Warnings for Light Sport Aircraft.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night.
	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.
	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
§ 22.180 Special requirements for light-sport category aircraft with simplified flight controls.	ASTM has not submitted for FAA acceptance, and FAA has not otherwise accepted, a consensus standard to enable this requirement. Therefore, manufacturers are not eligible to declare compliance with § 21.180 and have their powered-lift be designated as light-sport category aircraft with simplified flight controls at this time.
§ 22.185 Quality Assurance System	F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
	F3737–25 Standard Specification for Aircraft Design and Construction.
	F3198–25 Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program.
	F3833–26 Standard Guide for Computer Based Control Systems (CBCS).
§ 22.190 Finding of compliance by trained staff	F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
§ 22.195 Ground and flight testing	F3035–26 Standard Practice for Production Acceptance in the Manufacture of a Light Sport Aircraft.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3695–26 Standard Specification for Angle of Attack (AoA) Functional Requirements.

TABLE 7—PART 22 SUBPART B ACCEPTED MOC FOR LIGHT-SPORT CATEGORY GYROPLANE BASED ON ASTM CONSENSUS STANDARDS F3841–26

ASTM No. as identified in F3841–26	ASTM document title
F2316–12 (2022)	Standard Specification for Airframe Emergency Parachutes.
F2339–26	Standard Practice for Design and Manufacture of Reciprocating Engines for Light Sport Aircraft.
F2483–26	Standard Practice for Maintenance Program for Light Sport Category Aircraft.
F2506–26	Standard Specification for Design and Testing of Light Sport Aircraft Propellers.
F2563–16 (2025)	Standard Practice for Kit Assembly Instructions of Aircraft Intended Primarily for Recreation.
F2745–15 (2023)	Standard Specification for Required Product Information to be Provided with an Airplane.
F2746–26a	Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft.
F2839–11 (2025) [12]	Standard Practice for Compliance Audits to ASTM Standards on Light Sport Aircraft.
F2840–26a	Standard Practice for Design and Manufacture of Electric Engine for Light Sport Aircraft.
F2972–26	Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
F3035–26	Standard Practice for Production Acceptance in the Manufacture of a Light Sport Aircraft.
F3198–25	Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program.
F3331–18 (2023)	Standard Practice for Aircraft Water Loads.
F3338–24	Standard Specification for Design of Electric Engines for General Aviation Aircraft.
F3737–25	Standard Specification for Aircraft Design and Construction.
F3746–26	Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
F3792–26	Standard Specification for Light Sport Category Aircraft Flown at Night.
F3793–26a	Standard Specification for Flight Characteristics and Performance.
F3810–26b	Standard Specification for Oxygen Systems for Light Sport Aircraft.
F3813–26	Standard Specification for Light Sport Category Aircraft Occupant Safety.
F3814–26	Standard Specification for Light Sport Category Aircraft Electrical Systems.
F3824–26	Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
F3825–26	Standard Specification for Operating Limitations, Markings, Placards, and Warnings for Light Sport Aircraft.
F3826–26	Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
F3827–26	Standard Specification for Indirect Flight Controls.
F3828–26	Standard Specification for Structures for Light Sport Category Aircraft.
F3829–26	Standard Specification for Light Sport Category Aircraft Powerplant Systems.
F3830–26	Standard Specification for Electrical Energy Storage Systems.
F3831–26	Standard Specification for Aircraft Intended for Water Operations.
F3833–26 [13]	Standard Guide for Computer Based Control Systems (CBCS).
F3834–26	Standard Specification for Systems and Equipment for Light Sport Category Aircraft.
F3835–26	Standard Specification for Light Sport Category Aircraft Landing Gear Systems.
F3838–26	Standard Specification for Light Sport Category Thrust Borne Aircraft Landing Gear Systems.
F3844–26	Standard Specification for Light Sport Gyroplane Rotor System.
F3845–26	Standard Practice for the Design and Manufacturing of Turbine Engines for Light Sport Category Aircraft.
F3851–26	Standard Specification for Light Sport Category Aircraft.

TABLE 8—LIGHT-SPORT CATEGORY GYROPLANE SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3841–26 SECTION(S)

Title 14 regulation(s)	ASTM F3841–26 reference standards(s)
§ 21.190	
§ 21.190(c) Application for special airworthiness certificate in the light-sport category.	F2746–26a Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft. F2483–26 Standard Practice for Maintenance Program for Light Sport Category Aircraft. F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F2745–15 (2023) Standard Specification for Required Product Information to be Provided with an Airplane.
§ 21.190(d) Manufacturer's Statement of Compliance.	F3198–25 Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F2745–15 (2023) Standard Specification for Required Product Information to be Provided with an Airplane. F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.

[12] See the discussion in footnote 5.

[13] See the discussion in footnote 6.

TABLE 8—LIGHT-SPORT CATEGORY GYROPLANE SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3841–26 SECTION(S)—Continued

Title 14 regulation(s)	ASTM F3841–26 reference standards(s)
	§ 21.191
§ 21.191(k) Issue of experimental airworthiness certificates.	F2563–16 (2025) Standard Practice for Kit Assembly Instructions of Aircraft Intended Primarily for Recreation.
	§ 21.193
§ 21.193(h) Application for Special Airworthiness certificates issued for experimental purposes.	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft. F2746–26a Standard Specification for Pilot's Operating Handbook (POH) for Light Sport Category Aircraft.
	Part 22 Subpart B
§ 22.100 Eligibility	F3851–26 Specification for Light Sport Category Aircraft.
§ 22.105 Control and maneuverability	F3793–26a Standard Specification for Flight Characteristics and Performance. F3827–26 Standard Specification for Indirect Flight Controls. F3844–26 Standard Specification for Light Sport Gyroplane Rotor System. F3831–26 Standard Specification for Aircraft Intended for Water Operations.
§ 22.110 Structural integrity	F3737–25 Standard Specification for Aircraft Design and Construction. F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety. F3828–26 Standard Specification for Structures for Light Sport Category Aircraft. F3838–26 Standard Specification for Light Sport Category Thrust Borne Aircraft Landing Gear Systems. F3835–26 Standard Specification for Light Sport Category Aircraft Landing Gear System.[14] F3331–18 (2023) Standard Practice for Water Loads. F2316–12 (2022) Standard Specification for Airframe Emergency Parachutes. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3844–26 Standard Specification for Light Sport Gyroplane Rotor System. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft. F3831–26 Standard Specification for Aircraft Intended for Water Operations.
§ 22.115 Powered-Lift: minimum safe speed	N/A.
§ 22.125 Environmental Conditions	F3737–25 Standard Specification for Aircraft Design and Construction. F3844–26 Standard Specification for Light Sport Gyroplane Rotor System. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft. F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F3831–26 Standard Specification for Aircraft Intended for Water Operations.
§ 22.130 Suitability and durability of materials	F3737–25 Standard Specification for Aircraft Design and Construction. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.135 Instruments and equipment	F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F3810–26b Standard Specification for Oxygen Systems for Light Sport Aircraft. F3827–26 Standard Specification for Indirect Flight Controls. F3833–26 Standard Guide for Computer Based Control Systems (CBCS). F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3830–26 Standard Specification for Electrical Energy Storage Systems. F3737–25 Standard Specification for Aircraft Design and Construction.
§ 22.140 Controls and Displays	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety. F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3834–26 Standard Specification for Systems and Equipment for Light Sport Category Aircraft. F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.145 Propulsion system	F3737–25 Standard Specification for Aircraft Design and Construction. F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems. F3793–26a Standard Specification for Flight Characteristics and Performance.

TABLE 8—LIGHT-SPORT CATEGORY GYROPLANE SIDE-BY-SIDE VIEW OF §§ 21.190, 21.191(k), 21.193(h), AND PART 22 SUBPART B AND ASTM F3841–26 SECTION(S)—Continued

Title 14 regulation(s)	ASTM F3841–26 reference standards(s)
	F2339–26 Standard Practice for Design and Manufacture of Reciprocating Engines for Light Sport Aircraft.
	F2840–26a Standard Practice for Design and Manufacture of Electric Engine for Light Sport Aircraft.
	F3338–24 Standard Specification for Design of Electric Engines for General Aviation Aircraft.
	F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
	F3830–26 Standard Specification for Electrical Energy Storage Systems.
	F3845–26 Standard Practice for the Design and Manufacturing of Turbine Engines for Light Sport Category Aircraft.
§ 22.150 Fuel system	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
§ 22.155 Fire Protection	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F3830–26 Standard Specification for Electrical Energy Storage Systems.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3826–26 Standard Specification for Liquid Energy Storage Systems for Light Sport Category Aircraft.
§ 22.160 Visibility	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
	F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
§ 22.165 Emergency Evacuation	F3813–26 Standard Specification for Light Sport Category Aircraft Occupant Safety.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
§ 22.170 Placards and markings	F3825–26 Standard Specification for Operating Limitations, Markings, Placards, and Warnings for Light Sport Aircraft.
	F3792–26 Standard Specification for Light Sport Category Aircraft Flown at Night.
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.
	F3814–26 Standard Specification for Light Sport Category Aircraft Electrical Systems.
	F3829–26 Standard Specification for Light Sport Category Aircraft Powerplant Systems.
	F2506–26 Standard Specification for Design and Testing of Light Sport Aircraft Propellers.
	F3746–26 Standard Specification for Maintenance Manuals for Light Sport Category Aircraft.
§ 22.180 Special requirements for light-sport category aircraft with simplified flight controls.	ASTM has not submitted for FAA acceptance, and FAA has not otherwise accepted, a consensus standard to enable this requirement. Therefore, manufacturers are not eligible to declare compliance with § 21.180 and have their gyroplanes be designated as light-sport category aircraft with simplified flight controls at this time.
§ 22.185 Quality Assurance System	F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
	F3833–26 Standard Guide for Computer Based Control Systems (CBCS).
	F3198–25 Standard Specification for Light Sport Aircraft Manufacturer's Continued Operational Safety (COS) Program.
	F3737–25 Standard Specification for Aircraft Design and Construction.
§ 22.190 Finding of compliance by trained staff	F2972–26 Standard Specification for Light Sport Aircraft Manufacturer's Quality Assurance System.
§ 22.195 Ground and flight testing	F3035–26 Standard Practice for Production Acceptance in the Manufacture of a Light Sport Aircraft.
	F3844–26 Standard Specification for Light Sport Gyroplane Rotor System.
	F3737–25 Standard Specification for Aircraft Design and Construction.[15]
	F3824–26 Standard Specification for Non-Fatigue Aerial Work for Light Sport Category Aircraft.

Section 21.190 requires FAA-accepted consensus standards as an MOC to requirements in §§ 21.190, 21.191(k), 21.193(h), and part 22 subpart B for issuance of special airworthiness certificates for light-sport category aircraft and light-sport category kit-built aircraft. The MOC accepted by this NOA provides one means, but not the only means, of complying with these requirements. Any consensus standards body may submit other consensus

[14] ASTM F3841–26, the integration standard for gyroplanes, unintentionally omitted F3835–25 as a functional standard for § 22.110 in Table A1.1. F3835–26 is part of the MOC for § 22.110.

[15] The gyroplane integration standard, ASTM F3841, unintentionally listed F3737–25 as a functional standard for § 22.195 in Table A1.1. of that integration standard. F3737–25 is not required as part of the MOC for § 22.195.

standards to the FAA for review and acceptance for this purpose.

Editorial, Reapproval, Revision, or Withdrawal

ASTM policy states that a consensus standard should be reviewed in its entirety by the responsible subcommittee and must be balloted for reapproval, revision, or withdrawal within five years of its last approval date. When an ASTM standard is reapproved, that reapproval is denoted by the year in parentheses (*e.g.,* F2427–05a (2013)). This date indicates the completion of a review cycle with no technical changes made to the standard. In addition, ASTM issues editorial changes denoted by a superscript epsilon in the standard designation (*e.g.,* F3235–17ε[1]). This epsilon indicates information was corrected, and it did not change the meaning or intent of a standard. Since reapprovals and editorial changes do not change the technical content of standards, any standard that the FAA has accepted pursuant to this NOA that is later reapproved or editorially changed by ASTM will, unless the FAA has announced otherwise, be considered accepted by the FAA without the need for an updated NOA.

ASTM revises a standard to make changes to its technical content. Revisions are identified by a hyphen after the document number, which is followed by the last two numbers of the year of acceptance or of last revision. If the standard is revised again during the same year, this is indicated by adding an ''a'' for the second revision, ''b'' for the third revision, and so on for each revision. Since revisions change the technical content, revisions to consensus standards that are the basis for an MOC accepted by this NOA will not be automatically accepted and will require further FAA acceptance for the revisions to be an accepted MOC.

Availability

ASTM F3815–26a, ''Standard Specification for Integration for Light-Sport Airplane,'' F3836–26, ''Standard Specification for Integration for Light-Sport Glider,'' F3840–26, ''Standard Specification for Integration for Light-Sport Powered-Lift and Multicopter,'' and F3841–26, ''Standard Specification for Integration for Light-Sport Gyroplane,'' are available online at *www.astm.org/READINGLIBRARY/.* ASTM copyrights these consensus standards and charges the public a fee for service. Individual downloads or reprints of a standard (single or multiple copies, special compilations, and other related technical information), as well as information regarding membership, ASTM offices abroad, or Committee F37 on Light-Sport Aircraft, may be obtained online or by contacting ASTM by telephone: (610) 832–9585; facsimile: (610) 832–9555; or through email: *service@astm.org.*

Issued in Washington, DC on July 13, 2026.

Mark E. Giron,

Manager, System Policy Branch, Policy and Standards Division, Aircraft Certification Service.

[FR Doc. 2026–14298 Filed 7–15–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2026–4819; Airspace Docket No. 26–ANE–2]

RIN 2120–AA66

Amendment of Class D Airspace and Class E Airspace Over New Bedford, MA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends Class D and Class E airspace over New Bedford, MA. This action adds a 0.7 mile long, 3.6-mile-wide extension to the northwest side of the existing Class D airspace to properly contain current Instrument Flight Rules (IFR) operations. This action also updates the airport name and geographic coordinates in both the New Bedford, MA Class D and Class E airspace legal descriptions. This action also replaces ''Airport/Facility Directory'' in the Class D airspace legal description with ''Chart Supplement'' to comply with current FAA guidance.

DATES: Effective 0901 UTC, October 29, 2026. The Director of the Federal Register approves this incorporation by reference action under 1 CFR part 51, subject to the annual revision of FAA Order JO 7400.11 and publication of conforming amendments.

ADDRESSES: A copy of the notice of proposed rulemaking (NPRM), all comments received, this final rule, and all background material may be viewed online at *www.regulations.gov* using the FAA Docket number. Electronic retrieval help and guidelines are available on the website. It is available 24 hours a day, 365 days a year. An electronic copy of this document may also be downloaded from *www.federalregister.gov*.

FAA Order JO 7400.11K, Airspace Designations and Reporting Points, as well as subsequent amendments, can be viewed online at *www.faa.gov/air_traffic/publications/*. For further information, you may also contact the Rules and Regulations Group, Policy Directorate, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20597; Telephone: (202) 267–8783.

FOR FURTHER INFORMATION CONTACT: Marc Ellerbee, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone: (404) 305–5589.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it amends Class D and Class E airspace in New Bedford, MA.

History

The FAA published an NPRM for Docket No. FAA–2026–4819 in the **Federal Register** (91 FR 24760; May 7, 2026), proposing to amend Class D and Class E airspace in New Bedford, MA. Interested parties were invited to participate in this rulemaking effort by submitting written comments on the proposal to the FAA. No comments were received.

Difference From the NPRM

Subsequent to the publication of the NPRM in the **Federal Register**, the FAA discovered that there was a typographical error in ''The Proposal'' section of the NPRM preamble. The bearing from the airport for the extension to the Class D airspace was listed as 318° but should have been 308° as correctly listed in the proposed airspace legal description in ''The Amendment'' section of the NPRM. This change represents only a ministerial correction of a typographical error in the preamble. As mentioned, the correct bearing was provided in the proposed legal description of the NPRM.

Accordingly, the FAA finds good cause that recirculating the NPRM for public notice and comment is unnecessary.

Incorporation by Reference

Class D and Class E airspace designations are published in paragraphs 5000 and 6005 of FAA Order JO 7400.11, Airspace Designations and Reporting Points, which is incorporated by reference in 14 CFR 71.1 on an annual basis. This document amends the latest version of that order, FAA Order JO 7400.11K, dated August 4, 2025, and effective September 15, 2025. These amendments will be published in the next update to FAA Order JO 7400.11. FAA Order JO 7400.11K, which lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points, is publicly available as listed in the **ADDRESSES** section of this document.

The Rule

This action amends 14 CFR part 71 by modifying Class D and Class E airspace over New Bedford, MA. A review of the current airspace revealed that the New Bedford, MA Class D airspace did not properly contain IFR operations on the northwest side of the airport. Specifically, arrivals on the RNAV Runway 14 approach and departures to the northwest were not properly contained. This action adds an extension to the Class D airspace within 1.8 miles each side of the 308° bearing from the New Bedford Regional Airport extending from the 4-mile radius of the airport to 4.7 miles northwest of the airport.

This action also updates the airport name in both the New Bedford Class D and Class E airspace legal descriptions from ''New Bedford Municipal Airport'' to ''New Bedford Regional Airport.'' This action also updates the geographic coordinates of the New Bedford Regional Airport in both the Class D and Class E airspace legal descriptions, specifically, from (lat. 41°40′35″ N, long. 70°57′28″ W) to (lat. 41°40′36″ N long. 70°57′28″ W), which is one second of latitude. This action also updates the verbiage in the Class D airspace legal description from ''Airport/Facility Directory'' to ''Chart Supplement'' to comply with current FAA guidance.

Regulatory Notices and Analyses

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under DOT Order 2100.6B, ''Rulemaking and Guidance Procedure'' (March 10, 2025); and (3) is expected to result in, at most, de minimis costs from compliance with applicable operating requirements or minor flight rerouting for operators choosing to navigate around the controlled airspace. Since these amendments are routine and the expected impact to operators is de minimis, the FAA certifies that this rule, when promulgated, does not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

The FAA has determined that this action qualifies for categorical exclusion under the National Environmental Policy Act in accordance with FAA Order 1050.1G, ''FAA National Environmental Policy Act Implementing Procedures'' paragraph B–2.5(a). This airspace action is not expected to cause any potentially significant environmental impacts, and no extraordinary circumstances exist that warrant the preparation of an environmental assessment.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Amendment

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

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

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

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

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of FAA Order JO 7400.11K, Airspace Designations and Reporting Points, dated August 4, 2025, and effective September 15, 2025, is amended as follows:

Paragraph 5000 Class D Airspace.

* * * * *

ANE MA D New Bedford, MA [Amended]

New Bedford Regional, MA
(Lat. 41°40′36″ N, long. 70°57′28″ W)

That airspace extending upward from the surface to and including 2,600 feet MSL within a 4-mile radius of New Bedford Regional Airport and within 1.8 miles each side of the 308° bearing from the airport extending from the 4-mile radius to 4.7 miles northwest of the airport. This Class D airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Chart Supplement.

* * * * *

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

* * * * *

ANE MA E5 New Bedford, MA [Amended]

New Bedford Regional, MA
(Lat. 41°40′36″ N, long. 70°57′28″ W)

That airspace extending upward from 700 feet above the surface within a 6.5-mile radius of New Bedford Regional Airport, and within 4.5 miles each side of the 218° bearing from the airport extending from the 6.5-mile radius to 14.1 miles southwest of the airport.

* * * * *

Issued in College Park, Georgia, on July 14, 2026.

Kristen Leake,

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

[FR Doc. 2026–14391 Filed 7–15–26; 8:45 am]

BILLING CODE 4910–13–P

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1601

RIN 3046–AB41

FEP Agency Designation Procedures: Revising Location of FEP Agency Lists

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: The Equal Employment Opportunity Commission (EEOC or Commission) is revising its procedural regulations regarding fair employment practice agencies (FEP agencies or FEPAs). The lists of FEPAs in the regulations will be removed, and the agency will instead publish the lists of current FEPAs on its public website.

DATES: This rule is effective as of July 16, 2026.

FOR FURTHER INFORMATION CONTACT: Kimberly Essary, Associate Legal Counsel, Office of Legal Counsel, U.S. Equal Employment Opportunity Commission at (202) 921–3152 or *kimberly.essary@eeoc.gov*. Requests for this document in an alternative format should be made to the EEOC's Office of Communications and Legislative Affairs at (202) 921–3191 (voice), 1–800–669–

6820 (TTY), or 1–844–234–5122 (ASL video phone).

SUPPLEMENTARY INFORMATION: Section 706 of title VII of the Civil Rights Act of 1964 recognizes a State or a political subdivision of a State that has a State or local law prohibiting unlawful employment discrimination, and that authorizes a State or local authority to grant or seek relief from such unlawful practice or to institute criminal proceedings with respect to the practice. The Commission's procedural regulations at 29 CFR part 1601, subpart G set forth the criteria for formal designation of such State or local authorities as ''FEP agencies.'' The procedural regulations at subsections 1601.74 and 1601.80 include lists of the FEP agencies recognized by the Commission.

To more efficiently and effectively provide the public with access to a listing of current FEP agencies, the EEOC is removing the lists of FEP agencies currently found in subpart G of its procedural regulations and instead will publish these lists on its public website at *https://www.eeoc.gov/fair-employment-practices-agencies-fepas-and-dual-filing*. The lists will be updated at least annually.

This final rule also includes a small clarifying change to the text of subsection 1601.70(d), which makes reference to a State FEP agency, a local FEP agency, or ''both.'' A revision is made to account for circumstances where there may be more than one local agency in a State in addition to a State agency.

Under 5 U.S.C. 553(b)(B), a rulemaking can be exempt from prior notice and comment if the agency finds good cause ''that notice and public procedure thereon are impractical, unnecessary, or contrary to the public interest.'' The absence of this rule, or significant delay in its promulgation, is unnecessary and would delay informing the public in the most accessible way of current information, thus making it contrary to the public interest. Listing the FEP agencies on the EEOC's public website, which is visited regularly by charging parties, respondents, stakeholders, and the public, is the easiest and quickest way to disseminate this information to the public. This method allows the EEOC to more easily keep the lists up to date, and to ensure that the public has the most accurate information possible regarding what State and local entities are FEP agencies. It additionally saves taxpayer money otherwise spent on publication in the **Federal Register** simply to update the lists of FEP agencies, when that information can be provided more quickly, in a more accessible format, in a location that is more likely to be consulted by the public.

Because the EEOC is merely changing the location where the lists are published—an administrative rather than substantive change—there is ''good cause'' under 5 U.S.C. 553(b)(B) for this final rule to become effective without prior notice and comment. The change to subsection 1601.70 is likewise not a substantive change, as it has no impact on FEP agency procedures, but more clearly describes the existing procedures where a State houses multiple local FEP agencies. For the same reasons, there is good cause to provide for an immediate effective date. See 5 U.S.C. 553(d)(3).

Regulatory Procedures

Executive Order 12866

The Commission has complied with the principles in section 1(b) of Executive Order 12866, Regulatory Planning and Review. This rule is not a ''significant regulatory action'' under section 3(f) of the Executive Order and does not require an assessment of potential costs and benefits under section 6(a)(3)(B)(ii) of the Executive Order.

Paperwork Reduction Act

This final rule contains no new information collection requirements subject to review by the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) only requires a regulatory flexibility analysis when the APA requires notice and comment procedures, or the agency otherwise issues such a notice. As stated above, notice and comment procedures are neither required nor being used for this rule. Accordingly, the Regulatory Flexibility Act does not apply.

Unfunded Mandates Reform Act of 1995

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

Congressional Review Act

This regulation does not substantially affect the rights or obligations of non-agency parties and, accordingly, is not a ''rule'' as that term is used by the Congressional Review Act (Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996). Therefore, the reporting requirement of 5 U.S.C. 801 does not apply.

List of Subjects in 29 CFR Part 1601

Administrative practice and procedure, Equal employment opportunity.

Accordingly, for the reasons set forth in the preamble, the Equal Employment Opportunity Commission amends 29 CFR part 1601 as follows:

PART 1601–PROCEDURAL REGULATIONS

■ 1. The authority citation for part 1601 continues to read as follows:

Authority: 42 U.S.C. 2000e to 2000e–17; 42 U.S.C. 12111 to 12117; 42 U.S.C. 2000ff to 2000ff–11; 42 U.S.C. 2000gg to 2000gg–6; 28 U.S.C. 2461 note, as amended; Pub. L. 104–134, Sec. 31001(s)(1), 110 Stat. 1373.

§ 1601.70 [Amended]

■ 2. In § 1601.70, amend paragraph (d) by adding the words ''the State and local agencies'' after the word ''both'' in the second sentence.

■ 3. Amend § 1601.71 by revising paragraph (a) to read as follows:

§ 1601.71 FEP agency notification.

(a) When the Commission determines that an agency or authority meets the criteria outlined in section 706(c) of title VII and § 1601.70, the Commission shall so notify the agency by letter and shall notify the public by publication of an updated list of FEP agencies on the Commission's public website, *https://www.eeoc.gov/fair-employment-practices-agencies-fepas-and-dual-filing*.

* * * * *

§ 1601.74 [Removed and Reserved]

■ 4. Remove and reserve § 1601.74.

■ 5. Amend § 1601.75 by revising paragraph (c) to read as follows:

§ 1601.75 Certification of designated FEP agencies.

* * * * *

(c) Upon Commission approval of a designated FEP agency for certification, it shall notify the agency of its certification and shall effect such certification by publication of an updated list of FEP agencies on the Commission's public website at *https://www.eeoc.gov/fair-employment-practices-agencies-fepas-and-dual-filing*.

■ 6. Amend § 1601.79 by revising the last sentence to read as follows:

§ 1601.79 Revocation of certification.

* * * The revocation shall be effected by publication of an updated list of FEP agencies on the Commission's public website at *https://www.eeoc.gov/fair-employment-practices-agencies-fepas-and-dual-filing*.

§ 1601.80 [Removed and Reserved]

■ 7. Remove and reserve § 1601.80.

For the Commission,

Dated: July 10, 2026.

Andrea R. Lucas,

Chair.

[FR Doc. 2026–14303 Filed 7–15–26; 8:45 am]

BILLING CODE 6570–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 310

[Docket ID: DoD–2024–OS–0112]

RIN 0790–AL45

Privacy Act of 1974; Implementation

AGENCY: Office of the Secretary of Defense (OSD), Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The Department of Defense (Department or DoD) is issuing a final rule to amend its regulations to exempt portions of DoD–0024, ''Catch a Serial Offender (CATCH) Program Records,'' system of records from certain provisions of the Privacy Act of 1974. Specifically, the rule exempts portions of the CATCH Program Records from certain provisions of the Privacy Act to avoid interference during the conduct of criminal, civil, or administrative actions or investigations and to protect the identity of confidential sources pertaining to adult sexual assault allegations.

DATES: This rule is effective on August 17, 2026.

FOR FURTHER INFORMATION CONTACT: Ms. Rahwa Keleta, Chief, Privacy and Civil Liberties Division, Oversight and Compliance Directorate, 4800 Mark Center Drive, Attn: Mailbox #24, Suite 05F16, Alexandria, VA 22350–1700, *osd.mc-alex.odam.mbx.pcld-sorn@mail.mil*; (703) 571–0070.

SUPPLEMENTARY INFORMATION:

Discussion of Comments and Changes

The proposed rule was published in the **Federal Register** (89 FR 85892–85895) on October 29, 2024. Comments were accepted until December 30, 2024. The Department received five public comments. Commenters were generally supportive of the rule and the program; two commenters raised questions and concerns regarding the implementation of the CATCH Program Records system, including victim eligibility, the assurance of accurate records, and the selection of Privacy Act exemptions.

With respect to victim eligibility, eligibility criteria are established by sexual assault prevention and response policy rather than this Privacy Act rulemaking. Regarding the assurance of the accuracy of information, the CATCH Program Records system records information voluntarily submitted by victims. Because the system is intended to generate investigative leads rather than serve as an evidentiary database, determinations of accuracy and credibility are made through established investigative and adjudicative processes.

Concerning Privacy Act exemptions, DoD notes that the exemptions are consistent with the Privacy Act of 1974 and are necessary to preserve the integrity of the system by preventing subjects of reports from accessing or altering information in ways that could compromise ongoing investigative efforts.

After careful consideration of all comments, DoD has determined that the existing eligibility criteria, safeguards, and exemptions adequately address the concerns raised. Accordingly, no changes to the final rule text are required.

This final rule adds to the DoD's Privacy Act exemptions for Department-wide systems of records found in 32 CFR 310.13(e)(16). *Note:* When the proposed rule was published, the intended location of the exemption rule was 32 CFR 310.13(e)(15); because an exemption rule for a different SORN has since been added to that location, this final rule will now be codified at 32 CFR 310.13(e)(16).

I. Background

In finalizing this rule, DoD exempts portions of this system of records titled, ''CATCH a Serial Offender Program Records,'' DoD–0024 from certain provisions of the Privacy Act. This system of records covers DoD's maintenance of records used to collect and compare sexual assault reports for the purpose of identifying alleged serial sexual assault offenders. These records will consist of information voluntarily submitted into the CATCH system by eligible victims who elect to participate in the CATCH program and provide information about an alleged adult sexual assault incident, without identifying such victims, through established CATCH processes.

II. Privacy Act Exemption

The Privacy Act allows Federal agencies to exempt eligible records in a system of records from certain provisions of the Act, including those that provide individuals with a right to request access to and amendment of their own records. If an agency intends to exempt a particular system of records, it must first go through the rulemaking process pursuant to 5 U.S.C. 553(b)(1)–(3), (c), and (e). The DoD is amending 32 CFR part 310 to add a new Privacy Act exemption rule for the DoD–0024, CATCH a Serial Offender Program Records, system of records. The DoD is adding an exemption for this system of records pursuant to 5 U.S.C. 552a(j)(2) to prevent the harms articulated in this rule from occurring. The DoD is claiming an exemption from several provisions of the Privacy Act, including various access, amendment, disclosure of accounting, and certain recordkeeping and notice requirements, to avoid, among other harms, frustrating the underlying purposes for which the information was gathered.

III. Regulatory Analysis

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. It has been determined that this rulemaking is not a significant regulatory action.

Executive Order 14192, ''Unleashing Prosperity Through Deregulation''

This rule is not subject to Executive Order 14192, because this rule is not a significant regulatory action under Executive Order 12866.

Congressional Review Act (5 U.S.C. 804(2))

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the

Congress and to the Comptroller General of the United States. DoD will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States. A major rule may take effect no earlier than 60 calendar days after Congress receives the rule report or the rule is published in the **Federal Register**, whichever is later. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

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

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532(a)) requires agencies to assess anticipated costs and benefits before issuing any rule whose mandates may result in the expenditure by State, local and Tribal governments in the aggregate, or by the private sector, in any one year of $100 million in 1995 dollars, updated annually for inflation. This rulemaking will not mandate any requirements for State, local, or Tribal governments, nor will it affect private sector costs.

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

The Director of Administration and Management has certified that this rulemaking is not subject to the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. This rulemaking is concerned only with the administration of Privacy Act systems of records within the DoD. Therefore, the Regulatory Flexibility Act, as amended, does not require DoD to prepare a regulatory flexibility analysis.

Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. 3501 et seq.)

The Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) was enacted to minimize the paperwork burden for individuals; small businesses; educational and nonprofit institutions; Federal contractors; State, local and Tribal governments; and other persons resulting from the collection of information by or for the Federal Government. The Act requires agencies obtain approval from the Office of Management and Budget before using identical questions to collect information from ten or more persons. This rulemaking does not impose reporting or recordkeeping requirements on the public.

Executive Order 13132, ''Federalism''

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

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

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

List of Subjects in 32 CFR Part 310

Privacy.

Accordingly, 32 CFR part 310 is amended as follows:

PART 310—PROTECTION OF PRIVACY AND ACCESS TO AND AMENDMENT OF INDIVIDUAL RECORDS UNDER THE PRIVACY ACT OF 1974

■ 1. The authority citation for 32 CFR part 310 continues to read as follows:

Authority: 5 U.S.C. 552a.

■ 2. Amend § 310.13 by adding paragraph (e)(16) to read as follows:

§ 310.13 Exemptions for DoD-wide systems.

* * * * *

(e) * * *

(16) *System identifier and name.* DoD–0024, ''CATCH a Serial Offender Program Records.''

(i) *Exemptions.* This system of records is exempt from 5 U.S.C. 552a (c)(3) and (4); (d)(1), (2), (3), and (4); (e)(1); (e)(2); (e)(3); (e)(4)(G), (H), and (I); (e)(5); (e)(8); (f) and (g).

(ii) *Authority.* 5 U.S.C. 552a (j)(2).

(iii) *Exemption from the particular subsections.* Exemption from the particular subsections is justified pursuant to 5 U.S.C. 552a(j)(2) for the following reasons:

(A) *Subsection (c)(3), (d)(1), and (d)(2).* Records in this system of records may contain investigatory material compiled for criminal law enforcement purposes to include information identifying criminal offenders and alleged offenders, information compiled for the purpose of criminal investigation, or reports compiled during criminal law enforcement proceedings. Application of exemption (j)(2) may be necessary as access to, amendment of, or release of the accounting of disclosures of such records could inform a record subject of an investigation of the existence, nature, or scope of an actual or potential law enforcement or disciplinary investigation, and thereby seriously impede law enforcement or prosecutorial efforts by permitting the record subject and other persons to whom he might disclose the records to avoid criminal penalties or disciplinary measures; access to, amendment of, or release of the accounting of disclosures could also reveal confidential sources who might not have otherwise come forward to assist in an investigation and thereby hinder DoD's ability to obtain information from future confidential sources and result in an unwarranted invasion of the privacy of others.

(B) *Subsection (c)(4), (d)(3) and (4).* These subsections are inapplicable to the extent that an exemption is being claimed from subsections (d)(1) and (2).

(C) *Subsection (e)(1).* In the collection of information for investigatory or law enforcement purposes, it is not always possible to conclusively determine the relevance and necessity of particular information in the early stages of the investigation or adjudication. In some instances, it will be only after the collected information is evaluated in light of other information that its relevance and necessity for effective investigation and adjudication can be assessed. Collection of such information permits more informed decision-making by the Department when making required disciplinary and prosecutorial determinations.

(D) *Subsection (e)(2).* To collect information from the subject individual could serve notice that he or she is the subject of a criminal investigation and thereby present a serious impediment to such investigations. Collection of information only from the individual accused of criminal activity or misconduct could also subvert discovery of relevant evidence and subvert the course of justice. Accordingly, application of exemption (j)(2) may be necessary.

(E) *Subsection (e)(3).* To inform individuals as required by this subsection could reveal the existence of a criminal investigation and compromise investigative efforts. Accordingly, application of exemption (j)(2) may be necessary.

(F) *Subsection (e)(4)(G) and (H).* These subsections are inapplicable to the extent exemption is claimed from subsections (d)(1) and (2).

(G) *Subsection (e)(4)(I).* To the extent that this provision is construed to require more detailed disclosure about record sources than the broad, generic information currently published in the system notice, an exemption from this provision is necessary to protect the confidentiality of sources of information and to protect privacy and physical safety of witnesses and informants. Accordingly, application of exemption (j)(2) may be necessary.

(H) *Subsection (e)(5).* It is often impossible to determine in advance if investigatory records contained in this system are accurate, relevant, timely and complete, but, in the interests of effective law enforcement, it is necessary to retain this information to maintain an accurate record of the investigatory activity to preserve the integrity of the investigation and satisfy various Constitutional and evidentiary requirements, such as mandatory disclosure of potentially exculpatory information in the investigative file to a defendant. It is also necessary to retain this information to aid in establishing patterns of activity and provide investigative leads. With the passage of time, seemingly irrelevant or untimely information may acquire new significance as further investigation brings new details to light and the accuracy of such information can only be determined through judicial processes. Accordingly, application of exemption (j)(2) may be necessary.

(I) *Subsection (e)(8).* To serve notice could give persons sufficient warning to evade investigative efforts. Accordingly, application of exemption (j)(2) may be necessary.

(J) *Subsection (f).* To the extent that portions of the system are exempt from the provisions of the Privacy Act concerning individual access and amendment of records, DoD is not required to establish rules concerning procedures and requirements relating to such provisions. Accordingly, application of exemptions (j)(2) may be necessary.

(K) *Subsection (g).* This subsection is inapplicable to the extent that the system is exempt from other specific subsections of the Privacy Act to which the civil remedies provisions pertain.

(iv) *Exempt records from other systems.* In the course of carrying out the overall purpose for this system, exempt records from other systems of records may in turn become part of the records maintained in this system. To the extent that copies of exempt records from those other systems of records are maintained in this system, the DoD claims the same exemptions for the records from those other systems that are entered into this system, as claimed for the prior system(s) of which they are a part, provided the reason for the exemption remains valid and necessary.

Dated: July 14, 2026.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026–14368 Filed 7–15–26; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2026–0424]

Special Local Regulations; Marine Events Within the Southwest District

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce special local regulations for the Dutch Shoe Regatta on July 17, 2026, to provide for the safety of life on navigable waterways during this event. Our regulation for marine events within Coast Guard Southwest District identifies the regulated area for this event in San Diego, CA. During the enforcement periods, the operator of any vessel in the regulated area must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.1101, Table 1 to § 100.1101, Item No. 4, will be enforced from 8 a.m. to 7 p.m. on July 17, 2026.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, email Lieutenant Shelley Turner, Waterways Management, U.S. Coast Guard Sector San Diego, CA; telephone (619) 278–7033, email *D11MarineEventsSD@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce special local regulations in 33 CFR 100.1101 for the Dutch Shoe Regatta regulated area from 8 a.m. to 7 p.m. on July 17, 2026. This action is being taken to provide for the safety of life on navigable waterways during this event. Our regulation for Southern California Annual Marine Events for the San Diego Captain of the Port Zone, § 100.1101, line 4, specifies the location of the regulated area for the Dutch Shoe Regatta which encompasses portions of the San Diego Bay. During the enforcement periods, as reflected in § 100.1101(b), if you are the operator of a vessel in the regulated area you must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard plans to provide notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts.

R.C. Tucker,

Captain, U.S. Coast Guard, Captain of the Port San Diego.

[FR Doc. 2026–14315 Filed 7–15–26; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2026–0942]

Special Local Regulations; Marine Events in the Coast Guard Sector Detroit Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Notification of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulation (SLR) for the annual St. Clair River Classic Power Boat Race. This action is necessary to safely control vessel movements in the vicinity of the race and provide for the safety of the general boating public. During the enforcement period, the operator of any vessel in the regulated areas must comply with directions from the Patrol Commander or any Official Patrol displaying a Coast Guard ensign.

DATES: The regulations in 33 CFR 100.911, Table 1, Event 7, will be in effect from 11 a.m. on July 25, 2026, until 7 p.m. on July 26, 2026. This regulation will be enforced from 11 a.m. through 5 p.m. on July 25, 2026, and from 10 a.m. through 7 p.m. on July 26, 2026.

FOR FURTHER INFORMATION CONTACT: If you have questions about this notification of enforcement, call or email Tracy Girard, Prevention Department, U.S. Coast Guard; telephone (313) 347–3007, email *Tracy.M.Girard@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local

regulation in 33 CFR 100.911, Table 1, Event 7, for the St. Clair River Classic Power Boat Race from 11 a.m. through 7 p.m. on July 25, 2026, and from 10 a.m. through 7 p.m. on July 26, 2026. This action is being taken to provide for safe control of vessel movements in the vicinity of the race and provide for the safety of the general boating public. Our regulation in § 100.911, Table 1, Event 7, specifies the location of the regulated area for the St. Clair River Classic Power Boat Race. During the enforcement period, no vessel may enter the regulated area without prior approval from the Coast Guard's designated Patrol Commander (PATCOM). The PATCOM may restrict vessel operation within the regulated area to vessels having particular operating characteristics. Vessels desiring to transit the regulated area may do so only with prior approval of the PATCOM and when so directed by that officer. The PATCOM may be contacted on Channel 16 (156.8 MHZ) by the call sign ''Coast Guard Patrol Commander.'' Vessels permitted to transit the regulated area will operate at no wake speed and in a manner which will not endanger participants in the event or any other craft.

In addition to this notification of enforcement in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via Broadcast Notice to Mariners or Local Notice to Mariners. If the Captain of the Port determines that any of these special local regulations need not be enforced for the full duration stated in this document, he or she may suspend such enforcement and notify the public of the suspension via Broadcast Notice to Mariners.

Caren C. Damon,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. 2026–14316 Filed 7–15–26; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2026–3764; FRL–13384–01–R3]

Air Plan Approval; Pennsylvania; Interim Final Determination To Stay and Defer Sanctions Related to Reasonably Available Control Technology Requirements (RACT) for Volatile Organic Compounds (VOC) Control Technique Guidelines (CTG) Under the 2008 Ozone National Ambient Air Quality Standards (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Interim final determination.

SUMMARY: The Environmental Protection Agency (EPA) is making an interim final determination (IFD) that Pennsylvania has submitted revisions to the state implementation plan (SIP) that satisfy the requirements under the Clean Air Act (CAA) to implement Reasonably Available Control Technology (RACT) for volatile organic compounds (VOC) Control Technique Guidelines (CTG) for the 2008 ozone national ambient air quality standards (NAAQS). The effect of this IFD is to stay emission offset sanctions and defer the imposition of highway funding sanctions triggered by an August 16, 2024 EPA disapproval of a prior Pennsylvania SIP addressing VOC CTG RACT requirements for the 2008 ozone NAAQS. This IFD is consistent with a proposed action, published elsewhere in this issue of the **Federal Register**, in which the EPA is proposing approval of revisions to Pennsylvania's SIP, as submitted on May 10, 2023, January 20, 2026, February 17, 2026 and April 10, 2026 to address VOC CTG RACT requirements for the 2008 and 2015 NAAQS.

DATES: This interim final determination is effective on July 16, 2026. However, comments will be accepted until August 17, 2026.

ADDRESSES: The EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2026–3764. All documents in the docket are listed on the *www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Sean Silverman, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1600 John F Kennedy Boulevard, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–5511. Mr. Silverman can also be reached via electronic mail at *silverman.sean@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On August 16, 2024, the EPA took final action to disapprove portions of the Pennsylvania SIP revisions submitted on August 13, 2018 that, among other things, certified the Commonwealth had satisfied its VOC CTG RACT obligations for the 2008 ozone NAAQS.[1] The EPA's August 16, 2024 final disapproval (August 2024 disapproval) started a sanctions clock under CAA section 179 and 40 CFR 52.31. The two-to-one new source emissions offset sanctions took effect on March 16, 2026 (18 months following the September 16, 2024 effective date of the August 2024 disapproval), while highway funding sanctions will take effect on September 16, 2026, unless the State submits, and the EPA approves, SIP revisions that correct the deficiencies identified in the August 2024 disapproval.

On May 10, 2023, January 20, 2026, February 17, 2026 and April 10, 2026, PADEP submitted SIP revisions to address the deficiencies identified in the August 2024 disapproval. In the Proposed Rules section in this issue of the **Federal Register**, the EPA is concurrently proposing to approve these SIP revisions. There, the EPA proposes to find that Pennsylvania's current SIP-approved regulations, newly submitted regulations for certain CTG categories, and incorporated limits from permits for four facilities meet the Commonwealth's VOC CTG RACT Requirements for the 2008 and 2015 ozone NAAQS. The proposed determination is based on the EPA's analysis of Pennsylvania's SIP revisions, including supplemental technical support provided by the EPA. Accordingly, the EPA is proposing that these SIP revisions address the deficiencies identified in the EPA's August 2024 disapproval with respect to 2008 ozone VOC CTG RACT

[1] *See* 89 FR 66599.

requirements, which started the sanctions clock for offset and highway sanctions in Pennsylvania.

II. What action is the EPA taking?

The EPA is making an IFD to stay the application of the offset sanctions and defer the application of the highway sanctions associated with the EPA's August 2024 disapproval of certain VOC CTG RACT requirements for the 2008 ozone NAAQS for Pennsylvania. This determination is based on the EPA's concurrent proposal (referenced above) to approve the Pennsylvania SIP revisions regarding VOC CTG RACT for the 2008 (and 2015) ozone NAAQS, which resolve the deficiencies that triggered sanctions under section 179 of the CAA.

Based on the EPA's proposed approval that determines that the aforementioned Pennsylvania VOC CTG RACT SIP revisions address the deficiencies identified in the August 2024 disapproval and are likely approvable, relief from sanctions should be provided as quickly as possible. This interim final determination is consistent with the requirements of the Administrative Procedure Act (APA) [2] for Federal agency rulemaking. Generally, under the APA, agency rulemaking affecting the rights of individuals must comply with certain minimum procedural requirements, including publishing a notice of proposed rulemaking in the **Federal Register** and providing an opportunity for the public to submit written comments on the proposal, before the rulemaking can have final effect. The EPA will not be providing an opportunity for public comment before those deferrals or stays are effective. However, the EPA will provide an opportunity to comment on the proposed approval that is the basis for this IFD and will provide an opportunity, after the fact, for the public to comment on the IFD. Thus, an opportunity for comment will be provided before any sanctions clock is permanently stopped or any already applied sanctions are permanently lifted. In the context of the proposed approval, and with respect to the interim final rule, the public would have an opportunity to comment on the appropriateness of the EPA's interim final determination that the State had corrected the deficiencies and on whether the State should remain subject to sanctions, even though the deferral or stay is already effective.

Section 553(b)(4)(B) of the APA provides that the notice and opportunity for comment requirements do not apply when the Agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' In this instance, the EPA believes it would be both impracticable and contrary to the public interest to have to propose and provide an opportunity to comment before any relief is provided from the effect of sanctions. The EPA has reviewed Pennsylvania's SIP submissions addressing the August 2024 disapproval and, through its proposed action, is indicating that it is more likely than not that the SIP submissions correct the deficiencies that were the basis for the disapproval action that started the sanctions clock. Therefore, it is not in the public interest to apply sanctions. The EPA believes that it is necessary to use the interim final rulemaking process to stay the application of the offset sanctions and defer the application of the highway funding sanctions while we complete our rulemaking process on the approvability of Pennsylvania's SIP revisions intended to address the VOC CTG RACT requirements for the 2008 (and 2015) ozone NAAQS.

Consistent with 5 U.S.C. 553(d)(1) of the APA, the EPA finds there is good cause for this action to become effective immediately upon publication. Section 553(d)(1) of the APA provides that final rules shall not become effective until 30 days after publication in the **Federal Register** ''except . . . a substantive rule which grants or recognizes an exemption or relieves a restriction.'' The purpose of this provision is to ''give affected parties a reasonable time to adjust their behavior before the final rule takes effect.'' *Omnipoint Corp.*v. *Fed. Commc'n Comm'n,* 78 F.3d 620, 630 (D.C. Cir. 1996); see also United States v. Gavrilovic, 551 F.2d 1099, 1104 (8th Cir. 1977) (quoting legislative history). However, when the agency grants or recognizes an exemption or relieves a restriction, affected parties do not need a reasonable time to adjust because the effect is not adverse. Because this rule relieves a restriction, the EPA finds good cause under 5 U.S.C. 553(d)(1) for this action to become effective on the date of publication of this action.

As noted in this document, in the Proposed Rules section in this issue of the **Federal Register**, the EPA has proposed to find that Pennsylvania's SIP Revisions submitted on May 10, 2023, January 20, 2026, February 17, 2026 and April 10, 2026 address the deficiencies identified by the EPA in its August 2024 disapproval. In accordance with 40 CFR 52.31(d)(2)(ii), when a State has submitted a revised plan to correct the deficiency, and the EPA proposes to approve the plan and issues an IFD that the revised plan corrects the deficiency after 18 months but before 24 months from the beginning of the sanctions clock, application of the new source emission offset sanction shall be stayed and application of the highway sanction shall be deferred. However, if issues are raised during the public comment period of the proposed plan approval which cannot be addressed and the revised plan is ultimately disapproved, the new source offset sanction shall reapply immediately and the highway sanction shall apply immediately on the date of the final disapproval if that date is more than six months after the date the offset sanctions became effective. In Pennsylvania, the offset sanction was imposed on March 16, 2026, and the highway sanction, if not deferred, would be imposed on September 16, 2026.

III. Statutory and Executive Order Reviews

A. General Requirements

This action defers sanctions and imposes no additional requirements. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not an Executive Order 14192 (90 FR 9065, February 6, 2025) regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement

[2] 5 U.S.C. 551 *et seq.*

Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act

This action does not have Tribal implications, as specified in Executive Order 13175. This action stays and defers application of sanctions and imposes no new requirements. In addition, this action does not apply on any Indian reservation land or in any other area where the EPA or an Indian Tribe has demonstrated that a tribe has jurisdiction, and will not impose substantial direct costs on Tribal governments or preempt Tribal law. Thus, Executive Order 13175 does not apply to this action.

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2026. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Amy Van Blarcom-Lackey,

Regional Administrator, Region III.

[FR Doc. 2026–14326 Filed 7–15–26; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2025–0056; FRL–12601–03–R9]

Air Plan Revisions; California; Antelope Valley Air Quality Management District; New Source Review; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing an approval of seven permitting rules as a revision to the Antelope Valley Air Quality Management District (AVAQMD or ''District'') portion of the California State Implementation Plan (SIP). These revisions concern the District's New Source Review (NSR) permitting program for new and modified sources of air pollution under part D of title I of the Clean Air Act (CAA or ''Act''). The revised rules address deficiencies identified in a previous limited disapproval action, correct a newly identified deficiency for one permitting rule, and incorporate other revisions related to NSR requirements. This action updates the District's portion of the California SIP with the revised rules.

DATES: This rule is effective August 17, 2026.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R09–OAR–2025–0056. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information. If you need assistance in a language other than English or if you are a person with a disability who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Cecelia Working, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105; by phone: (213) 244–1911; or by email to *working.cece@epa.gov.*

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

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I. Proposed Action
II. Public Comments and EPA Responses
III. EPA Action
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. Proposed Action

On March 26, 2025 (90 FR 13719), the EPA proposed approval of six rules and a limited approval and limited disapproval of one rule that were submitted for incorporation into the California SIP.

The EPA had finalized this action on July 3, 2023 (88 FR 42621). Table 1 of this preamble lists the rules in the current SIP with the dates they were adopted or amended by the AVAQMD, submitted by the California Air Resources Board (CARB), the governor's designee for California SIP submittals, and approved by the EPA.

TABLE 1—CURRENT SIP RULES

District rule number	Title/subject	State effective date	Epa approval date
1300	New Source Review General	7/20/2021	7/3/2023 (88 FR 42621)
1301	New Source Review Definitions	7/20/2021	7/3/2023 (88 FR 42621)
1302 (except 1302(C)(5) and1302(C)(7)(c))	New Source Review Procedure	7/20/2021	7/3/2023 (88 FR 42621)
1303	New Source Review Requirements	7/20/2021	7/3/2023 (88 FR 42621)
1304	New Source Review Emissions Calculations	7/20/2021	7/3/2023 (88 FR 42621)
1305	New Source Review Emissions Offsets	7/20/2021	7/3/2023 (88 FR 42621)

TABLE 1—CURRENT SIP RULES—Continued

District rule number	Title/subject	State effective date	Epa approval date
1306	New Source Review for Electric Energy Generating Facilities.	7/20/2021	7/3/2023 (88 FR 42621)
1309	Emission Reduction Credit Banking	7/20/2021	7/3/2023 (88 FR 42621)

CARB submitted the rules that are listed in table 2 of this preamble to replace the EPA-approved rules currently in the SIP as listed in table 1 of this preamble. CARB also intended the submitted rules to: satisfy the minor NSR and nonattainment NSR (NNSR) requirements of section 110(a)(2)(C) and part D of title I of the Act; satisfy the EPA's implementing regulations at title 40 of the Code of Federal Regulations (CFR) part 51; and resolve deficiencies identified in our July 3, 2023 final NSR action (''2023 NSR Action'') [1] that included a limited disapproval of Rules 1301, 1302, 1303, 1304, 1305, and 1309, as amended on July 20, 2021.

TABLE 2—SUBMITTED RULES

District rule number	Title/subject	Amended or adopted	Amendment or adoption date	Submittal date [a]
1301	New Source Review Definitions	Amended	12/30/2024	1/7/2025
1302 [b] (except 1302(C)(5) and 1302(C)(7)(c)).	New Source Review Procedures	Amended	12/30/2024	1/7/2025
1303	State New Source Review Requirements	Amended	12/30/2024	1/7/2025
1304	State New Source Review Emissions Calculations.	Amended	12/30/2024	1/7/2025
1305	State New Source Review Emissions Offsets.	Amended	12/30/2024	1/7/2025
1309	Emission Reduction Credit Banking	Amended	12/30/2024	1/7/2025
1314	Federal Nonattainment New Source Review for Ozone Precursors.	Adopted (New Rule)	7/15/2025 [c]	10/1/2025 [c]

[a] The submittal for Rules 1301, 1302, 1303, 1304, 1305, 1309, and 1314 was transmitted to the EPA via a letter from CARB dated January 6, 2025. We note that no revisions were submitted for Rules 1300 and 1306, therefore, they will not be replaced.
[b] Subsections 1302(C)(5)(d) and 1302(C)(7)(c)(iii) of Rule 1302 specifically state that subsections 1302(C)(5) and 1302(C)(7)(c) are not submitted to the EPA and are not intended to be included as part of the California SIP.
[c] As we explain in this rule and in our March 23, 2026 proposed rulemaking (91 FR 13797), CARB submitted an amended version of Rule 1314 for inclusion in the SIP.

In our March 26, 2025 (90 FR 13719) proposed action, we proposed approval of CARB's January 7, 2025 submittal of Rules 1301, 1302, 1303, 1304, 1305, and 1309 as authorized under section 110(k)(3) of the Act. We determined that these submitted rules satisfy the statutory and regulatory requirements in part D of the Act (including sections 172, 173, 182(c)(6), and 182(d)), and in the relevant provisions of sections 110(a)(2) and 302(z) of the Act, as well as 40 CFR 51.160 through 51.165, and 51.307, and they address the deficiencies previously identified by the EPA.[2] On the same day, we also made an interim final determination (IFD) (90 FR 13702, March 26, 2025) that the submittal from CARB corrected the SIP deficiencies we identified in the 2023 NSR Action, allowing us to stay the application of the offset sanction and to defer the application of the highway sanction resulting from that action.

In our March 26, 2025 (90 FR 13719) proposed action, we also proposed a limited approval and limited disapproval of Rule 1314 as authorized in sections 110(k)(3) and 301(a) of the Act,[3] because although the version of AVAQMD Rule 1314 that CARB submitted on January 7, 2025, fulfilled most of the relevant CAA requirements and strengthened the SIP, it did not include the reasonable possibility requirements in 40 CFR 51.165(a)(6) and (7). We determined that this was a deficiency that the AVAQMD could resolve by including the requirements in 40 CFR 51.165(a)(6) and (7) in Rule 1314.

Following the EPA's March 26, 2025 (90 FR 13719) proposed limited approval and limited disapproval of Rule 1314, on October 16, 2025, CARB submitted to the EPA an amended Rule 1314 (hereafter referred to as the ''October 2025 submittal'').[4] Locally amended Rule 1314 supersedes the version of Rule 1314 that CARB submitted to the EPA on January 7, 2025. In our March 23, 2026 proposal, we proposed approval of Rule 1314 as submitted in the October 2025 submittal as authorized in section 110(k)(3) of the Act. We simultaneously withdrew our proposed limited approval and limited disapproval of Rule 1314 from the March 2025 Proposed Action (91 FR 13797, March 23, 2026).

II. Public Comments and EPA Responses

The EPA's March 26, 2025 (90 FR 13719), and March 23, 2026 proposed actions each provided a 30-day public comment period, as did the March 26, 2025 (90 FR 13702) IFD. The public

[1] 88 FR 42621.

[2] 88 FR 42621 (July 3, 2023), and 90 FR 13719 (March 26, 2025). The EPA's proposal and technical support document (TSD), which can be found in the docket for this action, contain a more detailed discussion of the District's submitted rules that form the basis for our proposed action.

[3] CAA sections 110(k)(3) and 301(a) authorize the EPA to issue a limited approval and limited disapproval action that will strengthen the SIP and require the State to correct a deficient provision.

[4] The AVAQMD locally amended Rule 1314 on July 15, 2025. Documentation of AVAQMD's adoption of amendments is included in the docket for this action.

comment periods for the March 26, 2025 (90 FR 13719) proposed action and IFD began on the date of their publication in the **Federal Register** and closed on April 25, 2025. During this period, the EPA received one comment letter from an anonymous commenter concerning the IFD (Comment 1). The public comment period for the March 23, 2026 proposed action began on March 23, 2026, its date of publication in the **Federal Register**, and closed on April 22, 2026. During this period, the EPA received one comment letter from an anonymous commenter (Comment 2).

Comment 1: The commenter expressed concern with the EPA's use of an interim final rule to delay sanctions before giving the public any chance to provide input or react. The commenter wrote that clean air is a human right, which is something that should not be taken lightly because it affects everybody and delaying action without public input seems unstable. The commenter also questioned AVAQMD Rule 1314's limited approval, stating that the limited approval begs the question of whether or not the alterations are enough to meet Federal standards. The commenter wrote that if the issues from 2023 are not fully addressed, pausing sanctions would be the wrong decision. The commenter concluded by encouraging the EPA to follow through with a more transparent and just final review that includes meaningful public feedback and a readiness to reinstate sanctions if the rules fall short during final review.

Response to Comment 1: EPA acted consistently with notice and comment requirements in publishing the March 26, 2025 (90 FR 13719), IFD, which stayed and deferred offset and highway sanctions, respectively, in the AVAQMD. As we explained in section II, ''EPA Evaluation and Action'' of the IFD, we preliminarily determined that the State corrected the deficiencies we identified in the 2023 NSR Action and relief from sanctions should be provided as quickly as possible.[5] In delaying sanctions, the IFD invoked the Administrative Procedure Act good cause exception, which allows Federal agencies to bypass standard notice-and-comment procedures under certain circumstances including bypassing public notice and comment before an action takes effect. However, the IFD stated that we were providing the public with an opportunity to comment on the EPA's determination after the effective date of the March 26, 2025 IFD. The IFD also stated that we would consider any comments received in deciding the appropriateness of such determination. As discussed in the IFD, the IFD itself stayed the offset sanction and deferred the highway sanction.[6] It did not terminate those sanctions—the sanctions would not be terminated until the effective date of a final full approval.[7]

As we explained in the IFD, we believe that notice-and-comment rulemaking before the effective date of that action was impracticable and contrary to the public interest.[8] When we proposed action on March 26, 2025, we had reviewed the State's submittal and found that it was more likely than not that the State had corrected the deficiencies that were the basis for the limited disapproval in the 2023 NSR Action that started the sanctions clocks.[9] Therefore, we stated that it was not in the public interest to apply sanctions.[10] We did not receive any comments from the public to change our understanding that the submitted rules satisfy CAA requirements and resolve the deficiencies we identified in the 2023 NSR Action.

The commenter's statement that they ''question Rule 1314's limited approval which begs the question if the alterations are enough to meet Federal standards'' may be based on the commenter's misunderstanding of the substance of the rulemaking, which the EPA can clarify here. In the March 26, 2025 rulemaking, the EPA proposed that the rules CARB submitted as part of the January 7, 2025 submittal package resolved the deficiencies the EPA identified in the 2023 NSR Action. Separately, the EPA identified a deficiency in Rule 1314. The deficiency we identified and explained in the March 26, 2025 rulemaking was unrelated to the deficiencies that were the basis for the disapproval in the 2023 NSR Action. That deficiency would not affect the sanctions clocks associated with the 2023 NSR Action.[11] Thus, there is nothing that changes our understanding that the District's rules satisfy the CAA requirements.

As the EPA explained in our 1994 rulemaking on the sequence of sanctions for findings made pursuant to section 179 of the CAA, we believe that it is consistent with CAA section 179 to treat proposed full approvals following disapprovals as the basis for deferring or staying the application of sanctions, while not permanently stopping the sanctions clock or permanently lifting sanctions.[12] Here, the District fixed all of the deficiencies that the EPA identified in the 2023 NSR Action. The proposed full approval then forms the basis for the EPA to issue an IFD, which the EPA publishes in a separate action in the **Federal Register**, as we did here.[13] As we explained in 1994, we believe this approach is consistent with the requirements of Administrative Procedures Act section 553 because the opportunity for comment is provided before any sanctions clock is permanently stopped, while in the meantime enabling the EPA to pause sanctions that would unnecessarily risk potential disruption in government programs and the marketplace after EPA has determined it is more likely than not that the State has corrected the deficiency.[14]

For the reasons described here, the EPA's position is that the March 26, 2025 IFD provided the public with the opportunity to comment on the stay of the offset sanction and deferral of the highway sanction, which the EPA correctly paused on the basis that the State more likely than not had corrected the deficiencies that were the reason for the sanctions. No comments were submitted that changed our understanding.

Comment 2: The commenter stated that they did not understand the summary of the EPA's proposed action.

Response to Comment 2: The EPA summary was meant to provide an overview of the proposed action and how it will impact the AVAQMD portion of the California SIP.

The comment letters can be found in the docket for this action and are accessible at *www.regulations.gov*.

III. EPA Action

None of the submitted comments change our assessment of the submitted rules as described in our proposed actions. Although we initially proposed a limited approval and limited disapproval of Rule 1314, the District amended Rule 1314 on July 15, 2025. CARB submitted the amended rule to the EPA on October 16, 2025, which superseded the January 1, 2025 submittal of that rule.

As authorized in section 110(k)(3) of the Act, the EPA is fully approving the

[5] 90 FR 13702, 13703 (March 26, 2025).

[6] Id.

[7] Id.

[8] Id.

[9] Id.

[10] Id.

[11] In any event, the District fixed the deficiency we identified in the March 26, 2025 (90 FR 13719) proposed action and CARB submitted the amended rule to supersede the January 7, 2025 submittal. As we explain in section I of this preamble, we proposed to fully approve amended Rule 1314 in our March 23, 2026 proposed action (91 FR 13797).

[12] 59 FR 39832, 39849 (August 4, 1994).

[13] Id.

[14] Id. at 39849–50.

submitted versions of Rules 1301, 1302 (except 1302(C)(5) and 1302(C)(7)(c)), 1303, 1304, 1305, 1309 and 1314 into the California SIP. The December 30, 2024 version of Rules 1301, 1302 (except 1302(C)(5) and 1302(C)(7)(c)), 1303, 1304, 1305, and 1309 will replace the previously approved versions of rules 1301, 1302 (except 1302(C)(5) and 1302(C)(7)(c)), 1303, 1304, 1305, and 1309 in the SIP. New Rule 1314, locally amended on July 15, 2025, will also be incorporated into the SIP.

This approval resolves all deficiencies that formed the basis for our previous limited disapprovals in the 2023 NSR Action of Rules 1301, 1302 (except 1302(C)(5) and 1302(C)(7)(c)), 1303, 1304, 1305, and 1309. As a result of this action, the sanctions that were stayed and deferred in our March 26, 2025 IFD are now terminated, and a Federal implementation plan to resolve the deficiency is no longer required under section 110(c) of the Act.

IV. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference the AVAQMD rules described in table 2 of this preamble. These rules implement the District's NSR permitting program for new and modified sources of air pollution under part D of title I of the CAA. The EPA has made, and will continue to make, these materials available through *https://www.regulations.gov* and in hard copy at the EPA Region IX Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not an Executive Order 14192 (90 FR 9065, February 6, 2025) regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2026. Filing a petition for reconsideration by the Administrator for this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See CAA section 307(b)(2).)

List of Subjects in 40 CFR Part 52

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

Dated: July 6, 2026.

Michael Martucci,

Acting Regional Administrator, Region 9.

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

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart F—California

■ 2. Amend § 52.220a, paragraph (c), table 5, under the heading ''Regulation XIII—New Source Review'' by:

■ a. Revising the entries for ''1301'', ''1302 (except 1302(C)(5) and 1302(C)(7)(c))'', ''1303'', ''1304'', ''1305'', and ''1309''; and

■ b. Adding an entry for ''1314'' in numerical order.

The revisions and addition read as follows:

§ 52.220a Identification of plan–in part.

* * * * *

(c) * * *

TABLE 5—EPA-APPROVED ANTELOPE VALLEY AIR QUALITY MANAGEMENT DISTRICT REGULATIONS; LOS ANGELES COUNTY AIR POLLUTION CONTROL DISTRICT REGULATIONS; SOUTHERN CALIFORNIA AIR POLLUTION CONTROL DISTRICT REGULATIONS; SOUTH COAST AIR QUALITY MANAGEMENT DISTRICT REGULATIONS [APPLICABLE IN ANTELOPE VALLEY]

District citation	Title subject	State effective date	EPA approval date	Additional explanation
*	*	*	*	*
Regulation XIII—New Source Review				
*	*	*	*	*
1301	New Source Review Definitions.	December 30, 2024	7/16/2026, 91 FR [INSERT **Federal Register** PAGE WHERE THE DOCUMENT BEGINS].	Submitted by CARB on January 7, 2025.
1302 (except 1302(C)(5) and 1302(C)(7)(c)).	New Source Review Procedures.	December 30, 2024	7/16/2026, 91 FR [INSERT **Federal Register** PAGE WHERE THE DOCUMENT BEGINS].	Submitted by CARB on January 7, 2025.
1303	State New Source Review Requirements.	December 30, 2024	7/16/2026, 91 FR [INSERT **Federal Register** PAGE WHERE THE DOCUMENT BEGINS].	Submitted by CARB on January 7, 2025.
1304	State New Source Review Emissions Calculations.	December 30, 2024	7/16/2026 , 91 FR [INSERT **Federal Register** PAGE WHERE THE DOCUMENT BEGINS].	Submitted by CARB on January 7, 2025.
1305	State New Source Review Emissions Offsets.	December 30, 2024	7/16/2026 , 91 FR [INSERT **Federal Register** PAGE WHERE THE DOCUMENT BEGINS].	Submitted by CARB on January 7, 2025.
*	*	*	*	*
1309	Emission Reduction Credit Banking.	December 30, 2024	7/16/2026, 91 FR [INSERT FEDERAL REGISTER PAGE WHERE THE DOCUMENT BEGINS].	Submitted by CARB on January 7, 2025.
1314	Federal Nonattainment New Source Review for Ozone Precursors.	July 15, 2025	7/16/2026, 91 FR [INSERT FEDERAL REGISTER PAGE WHERE THE DOCUMENT BEGINS].	Submitted by CARB on October 16, 2025.
*	*	*	*	*

* * * * *

[FR Doc. 2026–14317 Filed 7–15–26; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 70

[EPA–R07–OAR–2026–1156; FRL–13242–02–R7]

Air Plan Approval; Iowa; Revisions to Iowa Air Quality Regulations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve revisions to the Iowa State Implementation Plan (SIP) and the Operating Permit Program to incorporate recent changes to the Iowa Administrative Code (IAC). The revisions include removal of the Voluntary Operating Permit (VOP) Program language; removal of the Emission Reduction Program language; new and renumbered rules; replacement of duplicative language with references to state statute and federal regulations; updated definitions; consolidation of 14 chapters into 8 chapters; and minor clarifications to language and grammar. The EPA is also finalizing corrections to the erroneous incorporation of several rules into the Iowa SIP pursuant to the Clean Air Act (CAA). These revisions do not decrease the stringency of the SIP or have an adverse effect on air quality. The EPA's final approval of this rule revision is in accordance with the requirements of the CAA.

DATES: This final rule is effective on August 17, 2026.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2026–1156. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional information.

FOR FURTHER INFORMATION CONTACT: Allyson Prue, Environmental Protection Agency, Region 7 Office, Air Quality

Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7277; email address *prue.allyson@epa.gov*.

SUPPLEMENTARY INFORMATION:

Throughout this document ''we,'' ''us,'' and ''our'' refer to EPA.

Table of Contents

I. What is being addressed in this document?
II. Have the requirements for approval of SIP and operating permit program revisions been met?
III. The EPA's Response to Comments
IV. What action is the EPA taking?
V. Incorporation by Reference
VI. Statutory and Executive Order Reviews

I. What is being addressed in this document?

The EPA is finalizing approval of revisions to the Iowa SIP and Title V Operating Permit Program received on July 26, 2024. All revisions were completed due to an administrative process required by Executive Order 10 (E.O.–10), issued by the Iowa Governor in January 2023. The revisions are to section 567—Iowa Air Quality Regulations. The EPA is finalizing the following revisions to the SIP-approved chapters:

Chapter 20—SCOPE OF TITLEmndash;DEFINITIONS is rescinded.

Chapter 21—COMPLIANCE is retitled COMPLIANCE, EXCESS EMISSIONS, AND MEASUREMENT OF EMISSIONS. Revisions to this chapter include the removal of the Emission Reduction Program language; adoption by reference of federal language; incorporation of rules from the now-removed Chapters 24, 25, 26, and 29; removal of numerous definitions; updated citations; and minor revisions to grammar and wording.

Chapter 22—CONTROLLING POLLUTION—PERMITS is retitled CONTROLLING AIR POLLUTION—CONSTRUCTION PERMITTING. Revisions to SIP-approved text include the removal of the VOP Program; incorporation of rules from the now-removed Chapters 20 and 28; language relocation; updated citations; and minor revisions to grammar and wording.

Chapter 23–EMISSION STANDARDS is retitled AIR EMISSION STANDARDS. Revisions to this chapter include removal of redundant language; updated citations; and minor revisions to grammar and wording.

Chapter 24–EXCESS EMISSIONS is retitled OPERATING PERMITS. Revisions to SIP-approved sections are administrative in nature and include updated citations and minor revisions to grammar and wording.

Chapter 25—MEASUREMENT OF EMISSIONS is rescinded.

Chapter 26—PREVENTION OF AIR POLLUTION EMERGENCY EPISODES is rescinded.

Chapter 28—AMBIENT AIR QUALITY STANDARDS is rescinded.

Chapter 29—QUALIFICATIONS IN VISUAL DETERMINATION OF THE OPACITY OF EMISSIONS is rescinded.

Chapter 31—NONATTAINMENT AREAS is retitled NONATTAINMENT NEW SOURCE REVIEW. Revisions to this chapter include the removal of language referencing nonattainment areas, because Iowa no longer has any areas designated nonattainment prior to May 18, 1998; updated citations; and minor revisions to grammar and wording.

Chapter 33—SPECIAL REGULATIONS AND CONSTRUCTION PERMIT REQUIREMENTS FOR MAJOR STATIONARY SOURCES—PREVENTION OF SIGNIFICANT DETERIORATION (PSD) OF AIR QUALITY is retitled CONSTRUCTION PERMIT REQUIREMENTS FOR MAJOR STATIONARY SOURCES—PREVENTION OF SIGNIFICANT DETERIORIATION (PSD). Revisions to this chapter include numerous adoptions by reference of federal language, removal of redundant language, updated citations, and minor revisions to grammar and wording.

The EPA is finalizing the following revisions to the Title V Operating Permit Program:

Chapter 22—CONTROLLING POLLUTION—PERMITS is retitled CONTROLLING AIR POLLUTION—CONSTRUCTION PERMITTING. Revisions include language relocation, updated citations, and minor revisions to grammar and wording. Additionally, numerous definitions from IAC 567—22.1 and IAC 567—22.10(1) are retained in the Title V Operating Permit Program.

Chapter 23—EMISSION STANDARDS is retitled AIR EMISSION STANDARDS. The EPA is finalizing approval of Iowa's request to incorporate the definitions at IAC 567—23.1(4) into the Title V Operating Permit Program. The terms were previously approved into the Title V Operating Permit Program but were relocated to IAC 567—23.1(4).

Chapter 24—EXCESS EMISSIONS is retitled OPERATING PERMITS. Revisions to this chapter include removal of the (VOP) Program language; numerous adoptions by reference of federal language; removal of redundant language and of provisions requiring that copies of Title V operating permit applications be submitted to EPA Region 7; updated citations; and minor revisions to grammar and wording.

Chapter 30—FEES is retained. Revisions to this chapter include addition of clarifying language, removal of redundant language, and updated citations.

The revisions to the Iowa SIP and Title V Operating Permit Program are described in more detail in the proposed rulemaking located in this docket.

Additionally, the EPA is finalizing removal of IAC 567—Chapter 27, IAC 567—22.1(3)''b''(8), IAC 567–23.1(1), and IAC 567–25.1(12) from the Iowa SIP under the authority of CAA 110(k)(6). The EPA determined these provisions were approved into the Iowa SIP in error because they are not required by the CAA for implementation, maintenance, or enforcement of the NAAQS. The full text of the rule revisions as well as the EPA's analysis of the revisions can be found in the technical support documents (TSDs) which are part of this docket.

II. Have the requirements for approval of SIP and operating permit program revisions been met?

The State's submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice on this SIP revision from December 27, 2023, to January 30, 2024, and received no comments. In addition, as explained above and in more detail in the TSDs which are part of this docket, the revisions meet the substantive SIP requirements of the CAA, including section 110 and implementing regulations.

III. The EPA's Response to Comments

The public comment period on the EPA's proposed rule opened March 26, 2026, the date of its publication in the **Federal Register** and closed on April 27, 2026 (91 FR 14658). During this period, the EPA received four comments. One anonymous comment was overall supportive of this action, and one citizen comment was blank. The EPA acknowledges the blank submission.

The EPA is responding to the anonymous supportive comment and the two additional citizen comments. Summaries of these comments and the EPA's responses are provided below. All comments are available for review in the docket for this action.

Comment 1: Commenter 1 states that, although the proposal is framed as administrative cleanup (reorganization, elimination of certain chapters, elimination of the voluntary operating permit program, and correction of prior incorporation errors), administrative

restructuring is not neutral. The commenter requests that the EPA critically evaluate and transparently disclose the practical effects of the revisions on how requirements are applied, understood, and enforced, rather than treating them as purely ministerial changes.

Response 1: The EPA disagrees with the commenter's assertion that the EPA did not critically evaluate and transparently disclose the practical effects of the revisions. The EPA notes that the commenter provides broad high-level observations and recommendations and does not cite or engage with the docket materials, including the EPA's technical support documents that describe the EPA's evaluation of the revisions to the Iowa SIP that it proposes to approve. The EPA summarizes and responds to the commenter's significant comments below, identified as Comments 1A through 1D.

Comment 1A: The commenter stated the EPA should demonstrate that removal of chapters and the VOP program did not result in reduced compliance obligations or enforceability; less rigorous oversight; or the loss of regulatory tools without replacement. Absent this clarity, the commenter views the removals as subtraction rather than streamlining.

Response 1A: The EPA disagrees with commenter's assertion that the removal of certain chapters and the voluntary operating permit program constitutes a subtraction of protections in Iowa's SIP. The docket for this rulemaking includes a state provided crosswalk, titled ''EO10_AQB_Rules_Crosswalk_06192024'' and each TSD includes a redline/strikeout showing how provisions were reorganized and where functions are retained or relocated. The EPA reviewed these materials and determined that all substantive SIP requirements remain legally enforceable and that the restructuring does not change emission limits, compliance obligations, or enforceability.

This comment also referenced the removal of the VOP program language. The full technical analysis of the removal of the VOP program language is in the TSD titled ''(3) IA–194_TSD_Chapters 23, 24,'' and includes references to other state regulations that provide similar mechanisms to the VOP program. As detailed in the TSD and the Voluntary Operating Permit Background and Summary document in the docket, Iowa's VOP program was discontinued by the State in 2015 after Iowa determined that its construction permitting program could provide federally enforceable synthetic minor limits. The VOP program is not required under the Title V Operating Permit Program or section 110 of the CAA. Discontinuation of the State's VOP program does not change federal applicability thresholds or permitting obligations under New Source Review (NSR), Prevention of Significant Deterioration (PSD), or title V, does not alter any source's status, and does not void any existing federally enforceable permit conditions where limiting conditions are needed (*e.g.,* to establish synthetic minor status). Under IAC 567–Chapter 22, a source seeking to limit potential to emit below major thresholds remains subject to PSD until it receives a construction permit that caps the project below PSD thresholds, and IAC 567–22.3(6) authorizes IDNR to limit hazardous air pollutant (HAP) potential to emit below major source thresholds. Prior to removing the VOP rules from the Iowa Administrative Code, IDNR either modified existing construction permits or issued new construction permits for VOP facilities, as needed, to establish the same federally enforceable operational limits and maintain synthetic minor status in lieu of a VOP permit.

The EPA finds that Iowa's Chapter 22 construction permit rules provide adequate authority to establish and enforce synthetic minor limits for criteria pollutants and HAPs; accordingly, removal of the VOP regulations does not reduce the scope or enforceability of applicable requirements, does not shift any facilities into less rigorous oversight pathways, and does not retire necessary regulatory tools. Therefore, the EPA concludes that these changes are streamlining measures that do not reduce the scope or enforceability of applicable requirements and satisfy CAA section 110(l).

Comment 1B: While generally supportive of the EPA's correction of past incorporation errors, the commenter requested the EPA clearly distinguish between true clerical or technical corrections as well as changes that alter the legal status, applicability, or enforceability of provisions, in relation to the CAA 110(k)(6) error corrections. If a provision previously treated as enforceable is no longer incorporated, the commenter asserts this is a substantive regulatory change that should be identified and justified.

Response 1B: The EPA disagrees with commenter's assertion that it did not fully evaluate the impact of its proposed CAA 110(k)(6) error corrections, and notes that the commenter does not identify a specific concern with the EPA's proposed error corrections. The EPA thoroughly reviewed each amendment, and each analysis distinguishes between clerical and technical corrections for each revision. Additionally, the EPA provided a technical analysis of each CAA 110(k)(6) error correction. The full analysis of IAC 567–Chapter 27 can be found in the TSD titled ''(1) IA–194_TSD_Chapters 21, 27, 31, 33.'' The full analysis of IAC 567–22.1(3)''b''(8) and IAC 567–25.1(12) can be found in the TSD titled ''(2) IA–194_TSD_Chapters 22, 30.'' The full analysis of IAC–23.1(1) can be found in the TSD titled ''(3) IA–194_TSD_Chapters 23, 24.''

In the TSDs, the EPA identifies discrete prior approvals that were mistaken because they were administrative or not related to CAA section 110 criteria pollutant programs. Examples include: (1) removing Chapter 27 (Local Program Acceptance) from the SIP because it is administrative and not required for NAAQS implementation or enforcement; (2) removing IAC 567–23.1(1) from the SIP because it pertains to New Source Performance Standards and National Emission Standards for Hazardous Air Pollutants references (CAA sections 111 and 112) requirements and cites non-SIP regulations, thus it should not have been approved into the SIP; (3) removing IAC 567–22.1(3)''b''(8) (case-by-case maximum achievable control technology (MACT)) and IAC 567–22.7(2)''f'' (a continuous emissions monitoring requirement tied to an alternative emission control program not approved into the SIP) because they concern hazardous air pollutants or non-enforceable SIP constructs and therefore were erroneously included in the SIP.

Across the TSDs, the EPA emphasizes that CAA section 110(k)(6) corrections are limited to addressing prior errors, such as approval of state-only or administrative provisions, cross-reference problems, or content outside the scope of CAA section 110, and are not used to make discretionary policy changes or to relax federally enforceable requirements. The EPA documents that each correction maintains the SIP's stringency and does not diminish monitoring, reporting, recordkeeping, compliance, or enforcement obligations, and therefore does not decrease the stringency of the SIP or have an adverse effect on air quality.

Comment 1C: The commenter acknowledges that there are usability improvements that can be gained for the regulated community in the consolidation of rules, but that this can hinder the public's ability to track obligations and violations. The

commenter requested that the EPA ensure that the revised structure does not obscure regulatory requirements and that enforcement pathways remain clear and accessible, not buried in reorganized frameworks.

Response 1C: The EPA acknowledges that regulations should be clear and traceable for both regulated entities and the public, and concludes that the proposed revisions to the Iowa SIP preserve both. The docket includes a state provided crosswalk, titled ''EO10_AQB_Rules_Crosswalk_06192024,'' and each TSD includes a redline/strikeout which shows how provisions were reorganized and where functions are retained or relocated. The TSDs also describe that the revisions streamline duplicative text and consolidate 14 chapters into 8 without reducing stringency, and they list differences between the previously approved SIP and the updated chapters, thereby functioning as a crosswalk to where prior requirements now reside and indicate what was removed. The EPA verified that cross-references were updated and requirements remain accessible. As demonstrated by the EPA's analysis in the TSDs, the EPA finds the revisions do not obscure regulatory requirements, preserve public-facing traceability, and maintain clear, accessible enforcement pathways.

Comment 1D: The commenter stated that EPA should explicitly analyze and disclose the net effect of these revisions, not just their individual justifications. The commenter also stated that the EPA should affirm, in plain terms, that no emission limits are relaxed; that monitoring, reporting, and enforcement mechanisms are not weakened; and that the revisions do not introduce compliance gaps or delays in enforcement. The commenter further states that if the EPA cannot make these assurances, that it should reconsider its approval.

Response 1D: The EPA agrees that evaluating cumulative effects is important, and, as documented across the TSDs, concludes that the revisions maintain overall stringency, and enforceability without creating compliance gaps. The EPA thoroughly analyzed each revision in this rulemaking and concluded in the proposed rulemaking (91 FR 14658) that these revisions do not decrease the stringency of the Iowa SIP or have an adverse effect on air quality. The four TSDs for this rulemaking clearly demonstrate and state in plain terms that no emission limitations were relaxed; compliance and enforcement mechanisms were not weakened; and that the revisions do not introduce compliance gaps or delays in enforcement. The EPA has determined that each revision is administrative or clarifying and does not change any emission limit, compliance obligation, or enforcement mechanism without equivalent replacement, as applicable. Furthermore, as documented in the TSDs, the EPA has demonstrated that its CAA section 110(k)(6) error corrections and the proposed revisions to the Iowa SIP streamline organization while preserving federally enforceable requirements and oversight consistent with the requirements of the Clean Air Act. Accordingly, the EPA finds that reconsideration of its proposed approval is unwarranted.

Comment 2: The commenter stated that removing the case-by-case MACT provisions from the Iowa SIP as a CAA section 110(k)(6) error correction could weaken federal oversight of HAP limits, make enforcement of HAPs more difficult, and create regulatory gaps that may affect public health through exposure to HAPs. The commenter encouraged the EPA to reconsider the removal of the case-by-case MACT provisions from the Iowa SIP.

Response 2: The EPA disagrees that removing case-by-case MACT provisions from the Iowa SIP weakens federal oversight of hazardous air pollutants. This action corrects a prior SIP inclusion error and does not remove or relax any HAP emission limits or alter federal or state enforcement authorities.

The EPA provided a thorough technical analysis of the removal of the case-by-case MACT determination language in the TSD titled ''(2) IA–194_TSD_Chapters 22, 30.'' As explained in the TSD, because case-by-case MACT determinations involve HAPs and not criteria pollutants, they are not a requirement of CAA section 110 and are therefore not a required component of SIPs. Case-by-case MACT determinations are implemented and enforced under Clean Air Act section 112 (including sections 112(g) and 112(j) and 40 CFR part 63). The EPA generally does not approve HAP-only requirements into SIPs; when states adopt procedures to implement CAA section 112(g)/(j), the EPA approves them under section 112(l), and resulting MACT limits are federally enforceable through construction permits and Title V operating permits. The State of Iowa's incorporation by reference of 40 CFR part 63, subpart B in IAC 567-Chapter 23.1(4) provides it with adequate authority to conduct case-by-case MACT determinations. As a result, case-by-case MACT requirements applicable to sources in Iowa will continue to apply and be federally enforceable under section 112 and associated permits, ensuring no regulatory gaps in air toxics oversight. Therefore, no changes have been made in response to this comment.

Comment 3: A commenter expresses overall support for the proposed approval, stating that the revisions appear to reorganize, update, and clean up the rules without reducing protections. The commenter agrees with removal of provisions that were erroneously included in the SIP, provided that doing so does not weaken air quality protections. The commenter also requests that the EPA continue to monitor implementation to ensure that the removal of older programs does not create problems in permitting or pollution monitoring.

Response 3: The EPA appreciates the commenter's support for the proposed action. Under CAA section 110(k), the EPA may approve SIP revisions only if they meet all applicable CAA requirements, and, consistent with CAA section 110(l), the EPA may not approve a SIP revision that would interfere with attainment or maintenance of the NAAQS, reasonable further progress, or any other applicable requirement; where relevant, CAA section 193 also prohibits relaxation of certain pre-1990 nonattainment measures absent equivalent or greater emissions reductions. Consistent with the EPA's statutory and regulatory authorities, the EPA's approval of these revisions is based on a determination, explained in this action, that the revisions do not relax emissions limits or weaken monitoring, reporting, recordkeeping, compliance certification, or enforcement mechanisms, and that corrections do not reduce federally enforceable protections. The EPA will continue to exercise its oversight authorities to ensure that implementation of Iowa's SIP and title V program remains consistent with the Clean Air Act.

IV. What action is the EPA taking?

The EPA is taking final action to amend the Iowa SIP and Title V Operating Permit Program by approving the State's request to revise section 567, Title II-Iowa Air Quality Regulations. Additionally, the EPA is finalizing multiple CAA 110(k)(6) error corrections.

V. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, and as discussed in section I. of this preamble, the EPA is finalizing the incorporation by reference of section

567, Title II of the Iowa Air Quality Administrative Regulations:

- Chapter 21—Compliance, Excess Emissions, and Measurement of Emissions, which provides provisions for air quality compliance, excess emissions, and measurement of emissions;
- Chapter 22—Controlling Air Pollution, which provides provisions for air quality construction permitting as well as applicable air quality definitions;
- Chapter 23—Air Emission Standards, which provides provisions for air emission standards as well as applicable air quality definitions;
- Chapter 24—Operating Permits, which includes provisions for Title V Operating Permits, Acid Rain Permits, and Small Source Operating Permits;
- Chapter 30—Fees, which defines specific air quality fees owed by air contaminant sources;
- Chapter 31—Nonattainment New Source Review, which provisions for the preconstruction review and permitting program applicable to new or modified major sources of air pollutants in areas that do not meet the National Ambient Air Quality Standards (NAAQS); and
- Chapter 33—Construction Permit Requirements for Major Stationary Sources-Prevention of Significant Deterioration (PSD), which provides provisions for the preconstruction permitting program applicable to new or modified major stationary sources of air pollutants.

The state effective date of these rules is June 19, 2024. The EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region 7 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

Therefore, these materials have been approved by the EPA for inclusion in the State Implementation Plan, have been incorporated by reference by the EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

Also, in this document, the EPA is finalizing removal of rules that were previously incorporated by reference from the Iowa SIP. In accordance with the requirements of 1 CFR 51.5, the EPA is removing IAC 567—Chapter 27, IAC 567–22.1(3)''b''(8), IAC 567–23.1(1), and IAC 567–25.1(12) discussed in section I of this preamble and as set forth below in the revision to 40 CFR part 52.

VI. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993);
- Is not an Executive Order 14192 (90 FR 9065, February 6, 2025) regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

This action is subject to the Congressional Review Act (CRA), and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2026. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects

40 CFR Part 52

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

40 CFR Part 70

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

Dated: July 6, 2026.

James Macy,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA amends 40 CFR parts 52 and 70 as set forth below:

[1] 62 FR 27968, May 22, 1997.

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart Q—Iowa

■ 2. In § 52.820, in the table in paragraph (c):

■ a. Remove the center heading ''Chapter 20-Scope of Title-Definitions'' and the entries ''567–20.1'', ''567–20.2'', and ''567–20.3''.

■ b. Revise the center heading ''Chapter 21-Compliance'' to read ''Chapter 21-Compliance, Excess Emissions, and Measurement of Emissions'' and the entries ''567–21.1'', ''567–21.2'', ''567–21.3'', ''567–21.4'', ''567–21.5'', and ''567–21.6'' and add the entries ''567–21.7'', ''567–21.8'', ''567–21.10'', ''567–21.13'', ''567–21.14'', ''567–21.15'', ''567–21.16'', and ''567–21.17''.

■ c. Revise the center heading ''Chapter 22-Controlling Pollution'' to read ''Chapter 22-Controlling Air Pollution'' and the entries ''567–22.1'', 567–22.2'', ''567–22.3'', 567–22.4'', ''567–22.5'', ''567–22.8'', ''567–22.9'', and ''567–22.10''; add the entry ''567–22.11''; and remove the entries ''567–22.105'', ''567–22.200'', ''567–22.201'', ''567–22.202'', ''567–22.203'', ''567–22.204'', ''567–22.205'', ''567–22.206'', ''567–22.207'', ''567–22.208'', ''567–22.209'', and ''567–22.300''.

■ d. Revise the center heading ''Chapter 23-Emission Standards for Contaminants'' to read ''Chapter 23-Air Emission Standards'' and the entries ''567–23.1'', ''567–23.2'', ''567–23.3'', and ''567–23.4''.

■ e. Revise the center heading ''Chapter 24-Excess Emissions'' to read ''Chapter 24-Operating Permits''; remove the entries ''567–24.1'' and 567–24.2''; and add the entries ''567–24.105'' and ''567–24.300''.

■ f. Remove the center heading ''Chapter 25-Measurement of Emissions'' and the entry ''567–25.1''.

■ g. Remove the center heading ''Chapter 26-Prevention of Air Pollution Emergency Episodes'' and the entries ''567–26.1'', ''567–26.2'', ''567–26.3'', and ''567–26.4''.

■ h. Remove the center heading ''Chapter 27-Certificate of Acceptance'' and the entries ''567–27.1'', ''567–27.2'', ''567–27.3'', ''567–27.4'', and ''567–27.5''.

■ i. Remove the center heading ''Chapter 28-Ambient Air Quality Standards'' and the entry ''567–28.1''.

■ j. Remove the center heading ''Chapter 29-Qualification in Visual Determination of the Opacity of Emissions'' and the entry ''567–29.1''.

■ k. Revise the center heading ''Chapter 31-Nonattainment Areas'' to read ''Chapter 31-Nonattainment New Source Review'' and the entries ''567–31.1'', ''567–31.3'', ''567–31.4'', ''567–31.9'', and ''567–31.10'' and remove entries ''567–31.2 and 567–31.20''.

■ l. Revise the center heading ''Chapter 33-Special Regulations and Construction Permit Requirements for Major Stationary Sources-Prevention of Significant Deterioration (PSD) of Air Quality'' to read ''Chapter 33-Construction Permit Requirements for Major Stationary Sources-Prevention of Significant Deterioration (PSD)'' and the entries ''567–33.1'', ''567–33.3'', ''567–33.9'', and 567–33.10''.

The revisions and additions read as follows:

§ 52.820 Identification of plan.

* * * * *

(c) * * *

EPA—APPROVED IOWA REGULATIONS

Iowa citation	Title	State effective date	EPA approval date	Explanation
Iowa Department of Natural Resources Environmental Protection Commission [567]				
*	*	*	*	*
Chapter 21—Compliance, Excess Emissions, and Measurement of Emissions				
567–21.1	Definitions and compliance requirements.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.2	Variances	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.4	Circumvention of rules	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.5	Evidence used in establishing that a violation has occurred or is occurring.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.6	Temporary electricity generation for disaster situations.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.7	Excess emission reporting	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.8	Maintenance and repair requirements.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.10	Testing and sampling of new and existing equipment.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.13	Methodology and qualified observer.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	

EPA—APPROVED IOWA REGULATIONS—Continued

Iowa citation	Title	State effective date	EPA approval date	Explanation
567–21.14	Prevention of air pollution emergency episodes—general.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.15	Episode criteria	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.16	Preplanned abatement strategies	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–21.17	Actions taken during episodes	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
Chapter 22—Controlling Air Pollution				
567–22.1	Definitions and permit requirements for new or existing stationary sources.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	The definitions for ''anaerobic lagoon,'' ''odor,'' ''odorous substance,'' ''odorous substance source'' are not SIP approved.
567–22.2	Processing permit applications	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–22.3	Issuing permits	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	Subrule 22.3(6) is not SIP approved.
567–22.4	Major stationary sources located in areas designated attainment or unclassified (PSD).	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–22.5	Major stationary sources located in areas designated nonattainment.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–22.8	Permit by rule	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–22.9	Special requirements for visibility protection.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–22.10	Permitting requirements for country grain elevators, country grain terminal elevators, grain terminal elevators and feed mill equipment.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
.				
567–22.11	Ambient air quality standards	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
Chapter 23—Air Emission Standards				
567–23.1	Emission standards	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	Subrules 23.1(1)–(5) are not SIP approved
567–23.2	Open burning	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	Subrule 23.2(3)j is not SIP approved. Variances from opening burning rule 23.2(2) are subject to EPA approval.
567–23.3	Specific contaminants	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	Subrule 23.3(3)''(d)'' is not SIP approved.
567–23.4	Specific processes	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	Subrule 23.4(10) is not SIP approved.
Chapter 24–Operating Permits				
567–24.105	Title V permit applications	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	Only subparagraph 24.105(2)i(5) is SIP approved.

EPA—APPROVED IOWA REGULATIONS—Continued

Iowa citation	Title	State effective date	EPA approval date	Explanation
567–24.300	Operating permit by rule for small sources.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
Chapter 31—Nonattainment New Source Review				
567–31.1	Permit requirements relating to nonattainment area.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–31.3	Nonattainment new source review (NNSR) requirements for areas designated nonattainment.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–31.4	Preconstruction review permit program.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–31.9	Actuals PALs	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–31.10	Validity of rules	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
Chapter 33—Construction Permit Requirements for Major Stationary Sources—Prevention of Significant Deterioration (PSD)				
567–33.1	Purpose	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–33.3	PSD construction permit requirements for major stationary sources.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	Provisions of the 2010 $PM_{2.5}$ PSD-Increments, SILs, and SMCs rule are excluded from 33.3(20) and are not SIP approved.
567–33.9	Plantwide applicability limitations ..	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
567–33.10	Exceptions to adoption by reference.	6/19/2024	7/16/2026, 91 FR [insert **Federal Register** page where the document begins].	
*	*	*	*	*	*	*

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PART 70—STATE OPERATING PERMIT PROGRAMS

■ 3. The authority citation for part 70 continues to read as follows:

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

■ 4. Appendix A to part 70 is amended by adding paragraph (aa) under ''Iowa'' to read as follows:

Appendix A to Part 70-Approval Status of State and Local Operating Permits Programs

* * * * *

Iowa

* * * * *

(aa) The Iowa Department of Natural Resources submitted for program approval revisions to rules 567-Chapter 22 and 567–30.4 on July 26, 2024. Rules 567–22.100 through 567–22.300(12) are now located in Chapter 24 and are referred to as 567–24.100 through 567–24.300(12). Rules 567–22.117 through 567–22.119 (now 567–24.117 through 567–24.119) as well as rules 567–22.210 through 567–22.299 (now 567–24.210 through 567–24.299) remain reserved and are not part 70 approved. Previously part 70 approved rules 567–22.200 through 567–22.209 (now 567–24.200 through 567–24.209) have been reserved as a part of this approval and are no longer part 70 approved. Revisions were also made to rule 567–30.4. Numerous definitions located in 576–22.1, 567–22.10(1), and 567–23.1(4) retain part 70 approval. The state effective date is June 19, 2024. This revision is effective August 17, 2026.

* * * * *

[FR Doc. 2026–14322 Filed 7–15–26; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA–R05–OAR–2024–0461; EPA–R05–OAR–2025–0222; FRL–13226–02–R5]

Air Plan Approval and Air Quality Designation; Ohio; Attainment Plan and Redesignation of the Canton Area to Attainment of the 2008 Lead Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA or Agency) is approving the attainment plan and comprehensive emissions inventory for the Canton Nonattainment Area for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS) submitted by the Ohio Environmental Protection Agency (Ohio EPA or Ohio) on

September 19, 2024. Additionally, the EPA is determining that the Canton Nonattainment Area has attained the 2008 Pb NAAQS and is approving Ohio's April 25, 2025, maintenance plan for continued attainment. With these approvals, the EPA is acting in accordance with Ohio's request to redesignate the Canton Nonattainment Area from nonattainment to attainment of the 2008 Pb NAAQS. The EPA is taking these actions in accordance with the Clean Air Act (CAA) and the Agency's implementation regulations regarding the 2008 Pb NAAQS. The EPA proposed these actions on March 27, 2026, with publication in the **Federal Register** on April 10, 2026, and we received no adverse comments.

DATES: This final rule is effective on July 16, 2026.

ADDRESSES: The EPA has established two dockets for this action under Docket ID Nos. EPA–R05–OAR–2024–0461 and EPA–R05–OAR–2025–0222.[1] All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available either through *https://www.regulations.gov* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional information.

FOR FURTHER INFORMATION CONTACT: Alisa Liu, Air and Radiation Division (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, telephone number: (312) 353–3193, email address: *liu.alisa@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean the EPA. We use multiple acronyms and terms in this preamble. While this list may not be exhaustive, to ease the reading of this preamble and for reference purposes, the EPA defines the following terms and acronyms here:

CAA Clean Air Act
CBI Confidential Business Information
EPA Environmental Protection Agency
NAAQS National Ambient Air Quality Standard
Ohio EPA Ohio Environmental Protection Agency
μg/m³ Micrograms per cubic meter
NPRM Notice of Proposed Rulemaking
Pb Lead
PBI Proprietary Business Information
SIP State Implementation Plan

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I. Executive Summary

a. What action is the EPA taking?

The EPA is approving the attainment plan for the Canton Nonattainment Area for the 2008 Pb NAAQS and the comprehensive Pb emissions inventory submitted by Ohio EPA on September 19, 2024. Additionally, the EPA is determining that the Canton Nonattainment Area has attained the 2008 Pb NAAQS and is approving Ohio's April 25, 2025, maintenance plan for continued attainment. With these approvals, the EPA is also acting in accordance with Ohio's request to redesignate the Canton Nonattainment Area from nonattainment to attainment of the 2008 Pb NAAQS.

b. What is the legal authority and requirements?

The EPA is taking these actions in accordance with the CAA sections 107(d)(3)(E) and 172 in determining whether the State met all requirements applicable to the Canton Nonattainment Area under CAA sections 110(a)(2)(D)(i)(I), 110(a)(2)(I), 110(a)(2)(K), 110(l), 172(c)(3), 175A, 191, and 192(a), and the Agency's implementation regulations regarding the 2008 Pb NAAQS at 40 CFR part 50, appendix R, 40 CFR part 51, subparts F and G, and 40 CFR part 58.

II. Background

On April 10, 2023, the EPA redesignated portions of the Canton-Stark County, Ohio area from an unclassifiable/attainment area to a nonattainment area for the 2008 Pb NAAQS pursuant to CAA section 107(d)(3).[2] The redesignation was based on ambient air quality monitoring from a source-oriented monitor near the Republic Steel-Canton Plant, which manufactured leaded steel products at the time, that resulted in a 2019–2021 design value that exceeded the 2008 Pb NAAQS of 0.15 micrograms per cubic meter (μg/m³).[3] The Canton Nonattainment Area includes the Republic Steel-Canton Plant site and encompasses the portions of Stark County that are bounded on the north by State Route OH–153 (12th Street NE; Mahoning Road), on the east by Broadway Avenue, on the south by State Route OH–172 (Tuscarawas Street E; Lincoln Street E), and the west by State Route OH–43-Northbound (Cherry Avenue NE).

On September 10, 2023, the parent company of Republic Steel, Grupo Simec, announced the permanent closure of the Republic Steel-Canton Plant, and all associated air permits were terminated effective July 26, 2024. By the end of 2024, ambient air monitoring demonstrated that airborne Pb levels had declined to 0.00 μg/m³ and that the three-year design value for 2022–2024 for the Canton Nonattainment Area had achieved 0.15 μg/m³, thereby meeting the 2008 Pb NAAQS.

III. Summary of Ohio's Submittals

The redesignation of the Canton, Ohio area from unclassifiable/attainment to nonattainment for the 2008 Pb NAAQS imposed certain planning requirements on the State of Ohio to reduce Pb concentrations within this area.[4] On September 19, 2024, Ohio submitted a revision to its SIP for the 2008 Pb NAAQS in the Canton Nonattainment Area, which was comprised of an attainment plan with ambient air monitoring data, emissions inventory, attainment demonstration, and contingency measures. Then, on April 25, 2025, Ohio provided the first 10-year maintenance plan for keeping the Canton Nonattainment Area in attainment and submitted a request to the EPA to redesignate the Canton Nonattainment Area to attainment.

IV. The EPA's Evaluation of Ohio's Submittals

On March 27, 2026, the EPA proposed to approve Ohio's September 19, 2024, attainment plan and comprehensive Pb emissions inventory for the Canton Nonattainment Area for the 2008 Pb NAAQS. Based on complete, quality-assured ambient air monitoring data for 2022–2024, the EPA also proposed to determine that the Canton Area had attained the 2008 Pb NAAQS and to approve Ohio's April 25, 2025, maintenance plan for continued attainment. With these elements of

[1] Docket ID No. EPA–R05–OAR–2024–0461 relates to Ohio's attainment demonstration, and Docket ID No. EPA–R05–OAR–2025–0222 relates to Ohio's redesignation request and maintenance plan.

[2] 88 FR 14920; 14921 (March 10, 2023).

[3] 88 FR 14920; 14922 (March 10, 2023).

[4] 88 FR 14920; 14921 (March 10, 2023).

Ohio's State Implementation Plan (SIP) in place, EPA proposed to act in accordance with Ohio's request to redesignate the area to attainment.[5] In taking these separate, but related, actions, we note that the EPA has previously determined that approval actions on SIP elements for a nonattainment area and the associated redesignation may occur simultaneously.[6] [7]

An explanation of the CAA requirements, a detailed analysis of Ohio's submittals, and the EPA's reasons for proposing approval and redesignation were provided in the notice of proposed rulemaking [8] and the Agency's December 11, 2025, Technical Support Document, which are included in the dockets for this rulemaking, and will not be fully restated here.

In that proposal, based on complete, quality-assured ambient air monitoring data, we proposed to find that the area had achieved a design value of 0.15 μg/m [3] for the most recent three-year period 2022–2024, thereby meeting the 2008 Pb NAAQS of 0.15 μg/m [3]. While the EPA proposed to determine that the Canton Nonattainment Area had monitored attainment of the 2008 Pb NAAQS, we noted that this, in and of itself, did not constitute a redesignation to attainment. We identified the five criteria for redesignating an area from nonattainment to attainment found in CAA section 107(d)(3)(E) and addressed how Ohio's submittals effectively met each of the criteria:

(i) the Administrator determines that the area has attained the NAAQS;

(ii) the Administrator has fully approved the applicable implementation plan for the area under CAA section 110(k);

(iii) the Administrator determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable implementation plan and applicable Federal air pollutant control regulations and other permanent and enforceable reductions;

(iv) the Administrator has fully approved a maintenance plan for the area as meeting the requirements of CAA section 175A; and

(v) the State containing such area has met all requirements applicable to the area under CAA section 110 and part D of CAA title 1.[9]

II. Public Comments

The public comment period for this proposed rule ended on May 11, 2026. During the comment period, the EPA received two comment letters that were supportive of the Agency's proposed actions. All comments received are included in the dockets for this rulemaking.

III. Conclusion

The EPA is approving all of Ohio's required SIP elements herein simultaneously in conjunction with acting in accordance with Ohio's request to redesignate the Canton Nonattainment Area from nonattainment to attainment of the 2008 Pb NAAQS. Specifically, the EPA is taking the following separate, but related, actions:

1. Approving Ohio's September 19, 2024, Canton Pb SIP Revision as meeting the applicable requirements of CAA sections 110(a)(2)(D)(i)(I), 110(a)(2)(I), 110(a)(2)(K), 110(l), 172, 191, and 192(a) and 40 CFR 51 subparts F and G.

2. Determining that the Canton Nonattainment Area is attaining the 2008 Pb NAAQS.

3. Approving Ohio's comprehensive Pb emissions inventory for the Canton Nonattainment Area as meeting the applicable requirements of CAA section 172(c)(3).

4. Approving Ohio's 2025 Canton Pb Maintenance Plan as meeting the applicable requirements of CAA section 175A.

5. Determining that Ohio's 2024 Canton Pb SIP Revision as well as Ohio's 2025 Canton Pb Maintenance Plan and Redesignation Request have met the applicable requirements for the EPA to redesignate the Canton Nonattainment Area from nonattainment to attainment of the 2008 Pb NAAQS under CAA section 107(d)(3)(E).

6. Acting in accordance with Ohio's April 25, 2025, Canton Pb Redesignation Request and redesignating the Canton Nonattainment Area from nonattainment to attainment of the 2008 Pb NAAQS in accordance with CAA section 107(d)(3)(E)(i) through (v).

IV. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not an Executive Order 14192 (90 FR 9065, February 6, 2025) regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian Tribe has demonstrated that a Tribe has jurisdiction. In those areas of Indian country, the rule does not have Tribal implications and will not impose substantial direct costs on Tribal

[5] 91 FR 18372 (April 10, 2026).

[6] *See* section 2 of ''Procedures for Processing Requests to Redesignate Areas to Attainment,'' Memorandum from John Calcagni, Director, EPA Air Quality Management Division, September 4, 1992, (1992 Calcagni Redesignations Memo), which is publicly available at *https://www.epa.gov/sites/default/files/2016-03/documents/calcagni_memo_-_procedures_for_processing_requests_to_redesignate_areas_to_attainment_090492.pdf* .

[7] *See* 66 FR 53096 (October 19, 2001) for Pittsburgh-Beaver Valley, Pennsylvania; 65 FR 37879 (June 19, 2000) for Cincinnati-Hamilton, Ohio; 61 FR 20458 (May 7, 1996) for Cleveland-Akron-Lorain, Ohio; 60 FR 37366 (July 20, 1995) and 61 FR 31832–31833 (June 21, 1996) for Grand Rapids, Michigan; and 68 FR 25413 (May 12, 2003) and 68 FR 25418 (May 12, 2003) for St. Louis, Missouri.

[8] 91 FR 18372 (April 10, 2026).

[9] *See* 91 FR 18372; 18381–18382 (April 10, 2026) and the EPA's December 11, 2025, Technical Support Document.

governments or preempt Tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

This action is subject to the Congressional Review Act, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2026. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (*See* section 307(b)(2).)

List of Subjects

40 CFR Part 52

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

40 CFR Part 81

Environmental protection, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: July 8, 2026.

Anne Vogel,

Regional Administrator, Region 5.

For the reasons stated in the preamble, title 40 CFR parts 52 and 81 are amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. In § 52.1870, the table in paragraph (e) is amended:

■ a. Under the heading ''Summary of Criteria Pollutant Attainment Plans'', by adding an entry for ''Lead (2008)'' before the first entry for ''Ozone (8-Hour, 2015)''; and

■ b. Under the heading ''Summary of Criteria Pollutant Maintenance Plan'', by adding an entry for ''Lead (2008)'' after the first entry for ''Lead (2008)'' (with the State date of 10/29/2013).

The additions read as follows:

§ 52.1870 Identification of plan.

* * * * *

(e) * * *

EPA-APPROVED OHIO NONREGULATORY AND QUASI-REGULATORY PROVISIONS

Title	Applicable geographical or non-attainment area	State date	EPA approval	Comments
*	*	*	*	*
Summary of Criteria Pollutant Attainment Plans				
Lead (2008)	Canton (partial Stark County)	9/19/2024	7/16/2026, 91 FR [INSERT **Federal Register** PAGE WHERE THE DOCUMENT BEGINS].	Includes approval of the 2020 lead base year emissions inventory.
*	*	*	*	*
Summary of Criteria Pollutant Maintenance Plan				
*	*	*	*	*
Lead (2008)	Canton (partial Stark County)	4/25/2025	7/16/2026, 91 FR [INSERT **Federal Register** PAGE WHERE THE DOCUMENT BEGINS].	
*	*	*	*	*

* * * * *

PART 81—DESIGNATION OF AREAS FOR AIR QUALITY PLANNING PURPOSES

■ 3. The authority citation for part 81 continues to read as follows:

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

■ 4. In § 81.336, the table titled ''Ohio-2008 Lead NAAQS'' is amended by revising the entry for ''Canton-Stark County, OH:'' to read as follows:

§ 81.336 Ohio.

* * * * *

OHIO—2008 LEAD NAAQS

Designated area	Designation for the 2008 NAAQS [a]	
	Date [1]	Type
*	*	*
Canton-Stark County, OH:	7/16/2026	Attainment.
Stark County (part)		

OHIO—2008 LEAD NAAQS—Continued

Designated area	Designation for the 2008 NAAQS [a]	
	Date [1]	Type
Attainment area is bounded by the following roadways: North: State Route OH–153 (12th Street NE; Mahoning Road). East: Broadway Avenue. South: State Route OH–172 (Tuscarawas Street E; Lincoln Street E). West: State Route OH–43-Northbound (Cherry Avenue NE)		
* * * * * * *		

[a] Includes Indian Country located in each county or area, except as otherwise specified.
[1] December 31, 2011, unless otherwise noted.

* * * * *

[FR Doc. 2026–14318 Filed 7–15–26; 8:45 am]
BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 60

[EPA–HQ–OAR–2024–0419; FRL–11542.1–02–OAR]

New Source Performance Standards Review for Stationary Combustion Turbines and Stationary Gas Turbines; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Correcting amendments.

SUMMARY: The U.S. Environmental Protection Agency (EPA) is making corrections to the New Source Performance Standards Review for Stationary Combustion Turbines and Stationary Gas Turbines final rule (''Final NSPS Rule'') that published in the **Federal Register** (FR) on January 15, 2026, and became effective on January 15, 2026. After publication, the EPA identified inadvertent technical and typographical errors in the **Federal Register** regulatory text and is correcting those errors.

DATES: Effective on August 17, 2026.

ADDRESSES: The EPA established a docket for this action under Docket ID No. EPA–HQ–OAR–2024–0419. The docket lists all documents at *https://www.regulations.gov.* Although listed, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The EPA does not place certain other material, such as copyrighted material, on the internet; this material is publicly available only as portable document format (PDF) versions accessible only on EPA computers in the docket office reading room. The public cannot download certain databases and physical items from the docket but may request these items by contacting the docket office at (202) 566–1744. The docket office has 10 business days to respond to such requests. With the exception of such material, publicly available docket materials are available electronically at *https://www.regulations.gov* or on EPA computers in the docket office reading room at the EPA Docket Center, WJC West Building, Room Number 3334, 1301 Constitution Ave. NW, Washington, DC. The Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m. Eastern Time (ET), Monday through Friday (except Federal holidays). The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the EPA Docket Center is (202) 566–1742.

FOR FURTHER INFORMATION CONTACT: For information about this action, contact U.S. EPA, Attn.: John Ashley, Industrial Processing and Power Division (D243–02), 109 T.W. Alexander Drive, P.O. Box 12055, Research Triangle Park, North Carolina 27711; telephone number: (919) 541–1458; and email address: *ashley.john@epa.gov.*

SUPPLEMENTARY INFORMATION: The EPA is correcting the Final NSPS Rule, New Source Performance Standards Review for Stationary Combustion Turbines and Stationary Gas Turbines, which was published in the **Federal Register** at 91 FR 1910 on January 15, 2026. Following publication of this document, the EPA identified inadvertent technical and typographical errors in the regulatory text of new 40 Code of Federal Regulations (CFR) part 60, subpart KKKKa (''Subpart KKKKa''), as well as regulatory text amended by the Final NSPS Rule in existing 40 CFR part 60, subparts KKKK and GG (''Subpart KKKK'' and ''Subpart GG,'' respectively).

With this action, the EPA is correcting the following errors in FR Document Number (FR Doc) 2026–00677 and appearing at 91 FR 1910 in the **Federal Register** of January 15, 2026:

- At 91 FR 1975, third column, 40 CFR part 60, subpart GG. Final NSPS Rule instruction 3 amended § 60.330 by revising paragraph (a) and adding paragraphs (c) through (e). The EPA corrects the regulatory text in paragraph (e) to read as being applicable to a ''gas turbine'' instead of a ''combustion turbine.'' The EPA is making this correction for consistency with Subpart GG, which applies to the stationary gas turbines source category.
- At 91 FR 1978, third column, 40 CFR part 60, subpart KKKK. Final NSPS Rule instruction 9 amended § 60.4305 by revising paragraphs (a) and (b) and adding paragraphs (c) through (e). The EPA corrects the regulatory text in paragraph (e) to read as being applicable to ''combustion turbines'' instead of ''stationary gas turbines.'' The EPA is making this correction for consistency with Subpart KKKK, which applies to the stationary combustion turbines source category. In addition, the EPA removes the word ''stationary'' from the same phrase in paragraph (e) because turbines subject to title II of the Clean Air Act (CAA) are not stationary sources.
- At 91 FR 1979, second column, 40 CFR part 60, subpart KKKK. Final NSPS Rule instruction 14 added § 60.4331. In § 60.4331 paragraphs (a) through (e), the EPA listed the requirements for operating a stationary temporary combustion turbine. The EPA corrects paragraph (a) to add the phrases ''owners or operators of'' and ''may elect to be a temporary combustion turbine and'' in the first sentence. These additions are necessary to clarify that the stationary temporary combustion turbine subcategory is optional for qualifying combustion turbines. Furthermore, the EPA adds the phrase ''as an alternative to the otherwise applicable emission standards and monitoring, recordkeeping, and

reporting requirements of this subpart'' to the end of paragraph (a) to clarify that only those that elect to own or operate a stationary temporary combustion turbine must comply with the requirements in paragraphs (b) through (e) of this section. As conforming edits, the EPA deletes the phrases ''you may operate,'' ''so long as you,'' and ''all of'' from paragraph (a). In paragraph (c) introductory text and paragraph (d), the EPA deletes the phrase ''Unless you elect to demonstrate compliance through the otherwise applicable monitoring, recordkeeping, and reporting requirements of this subpart'' because this notice adds that phrase to paragraph (a). The EPA adds the word ''combustion'' before ''turbine'' in the first sentence of paragraph (e)(1) for consistency.

- At 91 FR 1982, third column, 40 CFR part 60, subpart KKKK. Final NSPS Rule instruction 23 amended § 60.4380 by revising paragraph (b)(3). The EPA corrects the regulatory text in paragraph (b)(3) to reflect the use of an arithmetic average to determine the applicable nitrogen oxide (NO_X) standard for averaging periods during which multiple NO_X emission standards apply. The Final NSPS Rule inadvertently incorporated regulatory text from Subpart KKKKa that specified the use of a heat input weighted average.
- At 91 FR 1982, third column, 40 CFR part 60, subpart KKKK. Final NSPS Rule instruction 24 amended § 60.4395 by revising the introductory text. The EPA corrects the heading of this section to read ''When must I submit my reports?'' instead of ''What must I submit my reports?''
- At 91 FR 1984, third column, 40 CFR part 60, subpart KKKK. Final NSPS Rule instruction 28 amended § 60.4420 by adding and revising certain definitions. The EPA is making an editorial change to the last sentence of the ''stationary combustion turbine'' definition. The EPA adds the word ''combustion'' before the word ''turbine'' for consistency and moves the phrase ''all related requirements'' to before the phrase ''promulgated pursuant to title II of the Clean Air Act'' for grammatical correctness.
- At 91 FR 1985, table 1, second column, 40 CFR part 60, subpart KKKK. Final NSPS Rule instruction 29 amended Table 1 to Subpart KKKK of Part 60—Nitrogen Oxide Emission Limits for New Stationary Combustion Turbines. In the second column of the table, ''Combustion turbine heat input at peak load (HHV),'' the EPA amended the threshold for the subcategories of ''Turbines located north of the Arctic Circle (latitude 66.5 degrees north), turbines operating at less than 75 percent of peak load, modified and reconstructed offshore turbines, and turbines operating at temperatures less than 0 °F.'' Specifically, the EPA amended the size threshold for these subcategories by including a heat input-based threshold of 300 million British thermal units per hour (MMBtu/h) in addition to the existing 30 megawatts (MW) output-based threshold. The EPA is making a technical correction to revert to the 30 MW output-based threshold in Subpart KKKKa. As a conforming edit and for consistency across the subparts, the EPA revises table 1 of Subpart KKKK by reverting to the previous output-based threshold of 30 MW alone for these subcategories of turbines. Because the EPA retained the 30 MW metric as part of the size threshold in Subpart KKKK in the Final NSPS Rule, this change in Subpart KKKK has no practical effect. All combustion turbines with outputs greater than 30 MW also have base load ratings of greater than 300 MMBtu/h, so the added 300 MMBtu/h metric had no applicability implications.
- At 91 FR 1985, table 1, first column, 40 CFR part 60, subpart KKKK. Final NSPS Rule instruction 29 amended Table 1 to Subpart KKKK of Part 60—Nitrogen Oxide Emission Limits for New Stationary Combustion Turbines. In the last row of the table, the EPA added a subcategory for ''Combustion turbines bypassing the heat recovery unit.'' The EPA adds the phrase ''firing natural gas'' to the first column of this row. The EPA is making this correction for consistency with the previous applicable emission standards for units firing non-natural gas fuels in Subpart KKKK. The EPA restores those previous emission standards in Subpart KKKK by clarifying that this subcategory's NO_X emission standard applies only to units firing natural gas.
- At 91 FR 1985, table 1, first column, 40 CFR part 60, subpart KKKK. Final NSPS Rule instruction 29 amended Table 1 to Subpart KKKK of Part 60—Nitrogen Oxide Emission Limits for New Stationary Combustion Turbines. The EPA corrects an omission from the table and lists subcategories for stationary temporary combustion turbines firing natural gas and firing fuels other than natural gas. These additional rows at the end of the table include the associated NO_X emission standards for these subcategories, consistent with the discussion in the preamble at 91 FR 1925. The Final NSPS Rule inadvertently omitted these rows.
- At 91 FR 1986, second column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4310a paragraph (d), the EPA identified ''stationary gas turbines'' as not being subject to this subpart if they are subject to title II of the CAA. The EPA corrects paragraph (d) to read as being applicable to ''combustion turbines'' instead of ''stationary gas turbines.'' The EPA is making this correction for consistency with Subpart KKKKa, which applies to the stationary combustion turbines source category. In addition, the EPA removes the word ''stationary'' from the same phrase in paragraph (d) because turbines subject to title II of the CAA are not stationary sources.
- At 91 FR 1987, third column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4331a paragraphs (a) through (e), the EPA listed the requirements for operating a stationary temporary combustion turbine. The EPA corrects paragraph (a) to add the phrases ''owners or operators of'' and ''may elect to be a temporary combustion turbine and'' in the first sentence. This addition is necessary to clarify that the stationary temporary combustion turbine subcategory is optional for qualifying combustion turbines. Furthermore, the EPA adds the phrase ''as an alternative to the otherwise applicable emission standards and monitoring, recordkeeping, and reporting requirements of this subpart'' to the end of paragraph (a) to clarify that only those that elect to own or operate a stationary temporary combustion turbine must comply with the requirements in paragraphs (b) through (e) of this section. As conforming edits, the EPA deletes the phrases ''you may operate,'' ''so long as you,'' and ''all of'' from paragraph (a). In paragraph (c) introductory text and paragraph (d), the EPA deletes the phrase ''Unless you elect to demonstrate compliance through the otherwise applicable monitoring, recordkeeping, and reporting requirements of this subpart'' because this notice adds that phrase to paragraph (a). The EPA adds the word ''combustion'' before ''turbine'' in the first sentence of paragraph (e)(1) for consistency.
- At 91 FR 1988, second column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4333a paragraph (b)(1), the EPA listed the general requirements for complying with the NO_X emission standards. In paragraph (b)(1), the EPA corrects the stated interval between performance

tests to 14-calendar-months instead of 12-calendar-months. The EPA is making this correction to align performance testing requirements in paragraph (b)(1) with the Agency's response to public comments, which states, ''The language in 40 CFR 60.4333a(b) has been updated to be consistent with the 14- and 26-calendar-month testing gaps prescribed in subpart KKKK.'' [1]

- At 91 FR 1989, first column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4333a paragraph (d)(3), the EPA listed the methods that an owner or operator of a stationary combustion turbine must use to demonstrate compliance with a sulfur dioxide (SO_2) emission standard. The Final NSPS Rule inadvertently omitted a reference to § 60.4372a, which contains the additional acceptable method of using fuel records of the total sulfur content for the combusted fuel to demonstrate compliance. The EPA corrects the last sentence of § 60.4333a paragraph (d)(3) by adding a reference to § 60.4372a to clarify—consistent with the intent of the Final NSPS Rule—that maintaining records is an option for demonstrating compliance with the applicable SO_2 emission standard.
- At 91 FR 1991, third column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4350a, the EPA listed instructions for determining excess NO_X emissions using continuous emission monitoring system (CEMS) data. In § 60.4350a paragraph (d), the EPA explained the proper procedure for estimating emissions for hours with missing data. The EPA adds the phrase ''of this chapter'' after ''part 75'' in the first sentence of paragraph (d) for consistency. In addition, the EPA replaces the phrase ''of the hour of'' in the second sentence with ''of the hourly load value of'' after ''± 10 percent.'' The EPA is making this change to clarify the proper procedure for estimating emissions.
- At 91 FR 1992, third column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4350a paragraph (f)(1), the EPA provided equation 1 for calculating the hourly average NO_X emissions rate, including a list that defines the variables used in the equation. For variable T, the second sentence describes a calculation that ''consists of useful thermal output on an annual basis.'' The EPA corrects this description to clarify that variable T ''consists of useful thermal output on a 12-calendar-month basis'' instead of an ''annual'' basis, which could be confused with calendar-years. The EPA is making this change for consistency with the intent of the Final NSPS Rule, which bases emissions standards on a 12-calendar-month rolling average.
- At 91 FR 1995, third column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4374a paragraph (g)(2), the EPA provided equation 2 for calculating the hourly average NO_X emissions rate, including a list that defines the variables used in the equation. For variable T, the second sentence describes a calculation that ''consists of useful thermal output on an annual basis.'' The EPA corrects this description to clarify that variable T ''consists of useful thermal output on a 12-calendar-month basis'' instead of an ''annual'' basis, which could be confused with calendar-years. The EPA is making this change for consistency with the intent of Final NSPS Rule, which bases emissions standards on a 12-calendar-month rolling average.
- At 91 FR 2000, first column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4400a, the EPA listed instructions for conducting performance tests to demonstrate compliance with the NO_X emissions standards without using a NO_X CEMS. The EPA corrects paragraph (d) introductory text to specify that owners or operators must conduct the performance test at any load condition within ± 30 percent of 100 percent of the base load rating and may perform testing at the highest achievable load point if they cannot achieve at least 70 percent of the base load rating in practice. The percentages listed in paragraph (d) introductory text of the Final NSPS Rule inadvertently included ± 25 percent and 75 percent from Subpart KKKK. Subpart KKKKa defines ''full load'' as greater than or equal to 70 percent of the base load rating of the turbine. Therefore, the correct percentages are ''± 30 percent'' instead of ''± 25 percent'' and ''70 percent'' instead of ''75 percent.'' The EPA makes the same corrections to § 60.4400a paragraph (d)(2).
- At 91 FR 2000, second column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4405a, the EPA listed instructions for conducting performance tests to demonstrate compliance with the NO_X emissions standards using a NO_X CEMS. The EPA corrects paragraph (b)(1) to specify that owners or operators must conduct the performance test at a single load level, within ± 30 percent of 100 percent of the base load rating, and owners or operators may perform testing at the highest achievable load point if they cannot achieve at least 70 percent of the base load rating in practice. The percentages listed in paragraph (b)(1) of the Final NSPS Rule inadvertently included ± 25 percent and 75 percent from Subpart KKKK. Subpart KKKKa defines ''full load'' as greater than or equal to 70 percent of the base load rating of the turbine. Therefore, the correct percentages are ''± 30 percent'' instead of ''± 25 percent'' and ''70 percent'' instead of ''75 percent.''
- At 91 FR 2000, third column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4415a paragraph (a) and paragraph (b) introductory text, the EPA listed instructions for owners or operators to conduct performance tests to demonstrate compliance with the SO_2 emissions standard. The EPA corrects § 60.4415a paragraph (a) to clarify that ''you may submit fuel records, . . .'' instead of ''must submit fuel records,'' because using fuel records is not the only acceptable method of demonstrating compliance. Similarly, in § 60.4415a paragraph (b) introductory text, the EPA inadvertently omitted the phrase ''and are not using fuel records, you . . .'' Accordingly, the EPA corrects the introductory text to read: ''If you are an owner or operator of an affected facility complying with the SO_2 emissions standard and are not using fuel records, you must conduct the performance test by measuring the SO_2 emissions in the stationary combustion turbine exhaust gases using the methods in either paragraph (b)(1) or (2) of this section.''
- At 91 FR 2001, second column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Subpart KKKKa consisting of sections 60.4300a to 60.4420a. In § 60.4420a, the Final NSPS Rule included definitions that apply to this subpart. The EPA removes the definitions of ''annual capacity factor,'' ''high-utilization source,'' and ''low-utilization source''

[1] See the document ''Summary of Public Comments and Responses: Review of New Source Performance Standards for Stationary Combustion Turbines and Stationary Gas Turbines,'' Section 8.5.2 Continuous emission monitoring, available in the docket (EPA Docket ID No. EPA–HQ–OAR–2024–0419) for this rulemaking at *https://www.regulations.gov*.

because Subpart KKKKa does not use those terms. In addition, the EPA revises the definition of ''gross energy output'' in paragraph (3) to specify a ''12-calendar-month'' instead of an ''annual'' basis, the definition of ''stationary combustion turbine'' to move ''all related requirements'' before the phrase ''promulgated pursuant to title II of the Clean Air Act'' for grammatical correctness, and the definition of ''turbine tuning'' to clarify that Subpart KKKKa limits turbine tuning to 30 hours per 12-calendar-month period. The use of the phrase ''12-calendar-month'' instead of the word ''annual'' in the ''gross energy output'' and ''turbine tuning'' definitions is necessary to ensure consistency with the 12-calendar-month basis for emission standards and the intent of the Final NSPS Rule. Furthermore, the EPA adds the definition of ''utilization'' because that term is relevant for subcategorization purposes.

• At 91 FR 2004, table 1, second column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Table 1 to Subpart KKKKa of Part 60—Nitrogen Oxide Emission Standards for Stationary Combustion Turbines. In the second column of the table, ''Combustion turbine base load rated heat input (HHV),'' the EPA set a heat-input threshold for the subcategories of turbines ''Located north of the Arctic Circle (latitude 66.5 degrees north), operating at ambient temperatures less than 0 °F (-18 °C), modified or reconstructed offshore turbines, operated during periods of turbine tuning, byproduct-fired turbines, and/or operating at less than 70 percent of the base load rating.'' Specifically, the EPA set the threshold for this subcategory as a heat input-based threshold of 300 MMBtu/h. The EPA intended for this threshold in Subpart KKKKa to be equivalent to the output-based threshold of 30 MW in Subpart KKKK. The EPA attempted to align the combustion turbine size subcategories in both subparts with heat input-based thresholds for associated NO_X standards for consistency.[2] The EPA did not intend to effectuate a substantive change in the size threshold for these subcategories.[3] However, the EPA is now aware that these two forms of threshold are not equivalent for all combustion turbines in these subcategories that could be subject to Subpart KKKKa, and this change inadvertently substantively altered this threshold, which was not the Agency's intent.[4] Therefore, the EPA corrects this unintended error in table 1 to Subpart KKKKa by reverting to the output-based threshold of 30 MW in Subpart KKKK for these subcategories of turbines in Subpart KKKKa.

• At 91 FR 2004, table 1, first column, 40 CFR part 60, subpart KKKKa. Final NSPS Rule instruction 30 added Table 1 to Subpart KKKKa of Part 60—Nitrogen Oxide Emission Standards for Stationary Combustion Turbines. To better clarify the NO_X emission standards applicable to stationary temporary combustion turbines consistent with the discussion in the preamble,[5] the EPA adds the subcategories of temporary turbines firing natural gas and temporary turbines firing fuels other than natural gas to the end of the table in separate rows. The EPA removes the reference to temporary turbines from the subcategory of ''New, firing natural gas, either offshore turbines, turbines bypassing the heat recovery unit, and/or temporary turbines'' as a conforming edit and inserts ''and/or'' before the phrase ''turbines bypassing the heat recovery unit.''

Section 553 of the Administrative Procedure Act provides that when an agency for good cause finds that notice and public procedure are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment.[6] The EPA has determined that there is good cause for making this rule final without prior proposal and opportunity for comment because the changes to the rule are minor, noncontroversial in nature, and correct inadvertent typographical and technical errors. These changes align regulatory text with the EPA's expressed intent in the Final NSPS Rule preamble and do not substantively change the requirements of the Final NSPS Rule except to the extent necessary to align the regulatory text with the EPA's intent, which the preamble expressly states. Thus, the corrected regulatory text in this action has already had notice and opportunity for public comment, rendering further notice and opportunity for public comment unnecessary. The EPA finds that this constitutes good cause under 5 U.S.C. 553(b)(B).

List of Subjects in 40 CFR Part 60

Environmental protection, Administrative practice and procedures, Air pollution control, Reporting and recordkeeping requirements.

Accordingly, 40 CFR part 60 is corrected by making the following correcting amendments:

PART 60—STANDARDS OF PERFORMANCE FOR NEW STATIONARY SOURCES

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

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

Subpart GG—Standards of Performance for Stationary Gas Turbines

■ 2. Amend § 60.330 by revising paragraph (e) to read as follows:

§ 60.330 Applicability and designation of affected facility.

* * * * *

(e) A gas turbine that is subject to this subpart and is not a ''major source'' or located at a ''major source'' (as that term is defined at 42 U.S.C. 7661 (2)) is exempt from the requirements of 42 U.S.C. 7661a(a).

Subpart KKKK—Standards of Performance for Stationary Combustion Turbines

■ 3. Amend § 60.4305 by revising paragraph (e) to read as follows:

§ 60.4305 Does this subpart apply to my stationary combustion turbine?

* * * * *

(e) Combustion turbines subject to title II of the Clean Air Act are not subject to this subpart.

■ 4. Amend § 60.4331 by revising paragraph (a), paragraph (c) introductory text, and paragraphs (d) and (e)(1) to read as follows:

§ 60.4331 What are the requirements for operating a stationary temporary combustion turbine?

(a) Notwithstanding any other provision of this subpart, owners or operators of a small- or medium-size stationary combustion turbine (*i.e.,* a combustion turbine with a base load rating less than or equal to 850 MMBtu/h) at a single location for up to 24 consecutive months, may elect to be a temporary combustion turbine and comply with the requirements in paragraphs (b) through (e) of this section as an alternative to the otherwise

[2] *See* 91 FR 1928 (January 15, 2026).

[3] *Id.*

[4] See the petition for reconsideration filed with the EPA by the American Petroleum Institute (API), available in the rulemaking docket under Docket ID # EPA–HQ–OAR–2024–0419–0246. It is the Agency's expectation that this correction fully resolves the issue raised in this petition for reconsideration.

[5] *See* 91 FR 1925 (January 15, 2026).

[6] 5 U.S.C. 553(b)(B).

applicable emission standards and monitoring, recordkeeping, and reporting requirements of this subpart.

* * * * *

(c) Compliance with the NO_X emissions standard must be demonstrated through maintaining the documentation in paragraphs (c)(1) and (2) of this section on-site:

* * * * *

(d) Compliance with the SO_2 emissions standard must be demonstrated through complying with the provisions in § 60.4365.

(e) * * *

(1) The combustion turbine may only be located at the same stationary source (or group of stationary sources located within a contiguous area and under common control) for a total period of 24 consecutive months. This is the total period of residence time allowed after the turbine commences operation at the location, regardless of whether the turbine is in operation for the entire 24-consecutive-month period.

* * * * *

■ 5. Amend § 60.4380 by revising paragraph (b)(3) to read as follows:

§ 60.4380 How are excess emissions and monitor downtime defined for NO_X?

* * * * *

(b) * * *

(3) For averaging periods during which multiple emissions standards apply, the applicable standard for the averaging period is the arithmetic average of the applicable standards during each hour. For hours with multiple emission standards, the applicable standard for that hour is determined based on the condition that corresponded to the highest emissions standard.

* * * * *

■ 6. Amend § 60.4395 by revising the section heading to read as follows:

§ 60.4395 When must I submit my reports?

* * * * *

■ 7. Amend § 60.4420 by revising the definition of ''Stationary combustion turbine'' to read as follows:

§ 60.4420 What definitions apply to this subpart?

* * * * *

Stationary combustion turbine means all equipment, including but not limited to the turbine, the fuel, air, lubrication and exhaust gas systems, control systems (except emissions control equipment), heat recovery system, and any ancillary components and sub-components comprising any simple cycle stationary combustion turbine, any regenerative/recuperative cycle stationary combustion turbine, any combined cycle combustion turbine, and any combined heat and power combustion turbine based system. Stationary means that the combustion turbine is not self-propelled or intended to be propelled while performing its function. It may, however, be mounted on a vehicle for portability. Portable combustion turbines are excluded from the definition of ''stationary combustion turbine,'' and not regulated under this part, if the combustion turbine meets the definition of ''nonroad engine'' under title II of the Clean Air Act and applicable regulations and is certified to meet emission standards and all related requirements promulgated pursuant to title II of the Clean Air Act.

* * * * *

■ 8. Revise table 1 to subpart KKKK of part 60 to read as follows:

TABLE 1 TO SUBPART KKKK OF PART 60—NITROGEN OXIDE EMISSION LIMITS FOR NEW STATIONARY COMBUSTION TURBINES

Combustion turbine type	Combustion turbine heat input at peak load (HHV)	NO_X emission standard
New turbine firing natural gas, electric generating	≤50 MMBtu/h	42 ppm at 15 percent O_2 or 290 ng/J of useful output (2.3 lb/MWh).
New turbine firing natural gas, mechanical drive	≤50 MMBtu/h	100 ppm at 15 percent O_2 or 690 ng/J of useful output (5.5 lb/MWh).
New turbine firing natural gas	>50 MMBtu/h and ≤850 MMBtu/h.	25 ppm at 15 percent O_2 or 150 ng/J of useful output (1.2 lb/MWh).
New, modified, or reconstructed turbine firing natural gas	>850 MMBtu/h	15 ppm at 15 percent O_2 or 54 ng/J of useful output (0.43 lb/MWh).
New turbine firing fuels other than natural gas, electric generating.	≤50 MMBtu/h	96 ppm at 15 percent O_2 or 700 ng/J of useful output (5.5 lb/MWh).
New turbine firing fuels other than natural gas, mechanical drive.	≤50 MMBtu/h	150 ppm at 15 percent O_2 or 1,100 ng/J of useful output (8.7 lb/MWh).
New turbine firing fuels other than natural gas	>50 MMBtu/h and ≤850 MMBtu/h.	74 ppm at 15 percent O_2 or 460 ng/J of useful output (3.6 lb/MWh).
New, modified, or reconstructed turbine firing fuels other than natural gas.	>850 MMBtu/h	42 ppm at 15 percent O_2 or 160 ng/J of useful output (1.3 lb/MWh).
Modified or reconstructed turbine	≤50 MMBtu/h	150 ppm at 15 percent O_2 or 1,100 ng/J of useful output (8.7 lb/MWh).
Modified or reconstructed turbine firing natural gas	>50 MMBtu/h and ≤850 MMBtu/h.	42 ppm at 15 percent O_2 or 250 ng/J of useful output (2.0 lb/MWh).
Modified or reconstructed turbine firing fuels other than natural gas.	>50 MMBtu/h and ≤850 MMBtu/h.	96 ppm at 15 percent O_2 or 590 ng/J of useful output (4.7 lb/MWh).
Turbines located north of the Arctic Circle (latitude 66.5 degrees north); turbines operating at less than 75 percent of peak load; modified and reconstructed offshore turbines; and turbines operating at temperatures less than 0 °F.	≤30 MW output	150 ppm at 15 percent O_2 or 1,100 ng/J of useful output (8.7 lb/MWh).
Turbines located north of the Arctic Circle (latitude 66.5 degrees north); turbines operating at less than 75 percent of peak load; modified and reconstructed offshore turbines; and turbines operating at temperatures less than 0 °F.	>30 MW output	96 ppm at 15 percent O_2 or 590 ng/J of useful output (4.7 lb/MWh).

TABLE 1 TO SUBPART KKKK OF PART 60—NITROGEN OXIDE EMISSION LIMITS FOR NEW STATIONARY COMBUSTION TURBINES—Continued

Combustion turbine type	Combustion turbine heat input at peak load (HHV)	NO_X emission standard
Heat recovery units operating independent of the combustion turbine.	All sizes	54 ppm at 15 percent O_2 or 110 ng/J of useful output (0.86 lb/MWh).
Combustion turbines bypassing the heat recovery unit firing natural gas.	>50 MMBtu/h	25 ppm at 15 percent O_2 or 150 ng/J of useful output (1.2 lb/MWh).
Temporary turbine firing natural gas	≤850 MMBtu/h	25 ppm at 15 percent O_2 or 150 ng/J of useful output (1.2 lb/MWh).
Temporary turbine firing fuels other than natural gas	≤850 MMBtu/h	74 ppm at 15 percent O_2 or 460 ng/J of useful output (3.6 lb/MWh).

Subpart KKKKa—Standards of Performance for Stationary Combustion Turbines

■ 9. Amend § 60.4310a by revising paragraph (d) to read as follows:

§ 60.4310a What stationary combustion turbines are not subject to this subpart?

* * * * *

(d) Combustion turbines subject to title II of the Clean Air Act are not subject to this subpart.

■ 10. Amend § 60.4331a by revising paragraph (a), paragraph (c) introductory text, and paragraphs (d) and (e)(1) to read as follows:

§ 60.4331a What are the requirements for operating a stationary temporary combustion turbine?

(a) Notwithstanding any other provision of this subpart, owners or operators of a small- or medium-size stationary combustion turbine (*i.e.,* a combustion turbine with a base load rating less than or equal to 850 MMBtu/h) at a single location for up to 24 consecutive months, may elect to be a temporary combustion turbine and comply with the requirements in paragraphs (b) through (e) of this section as an alternative to the otherwise applicable emission standards and monitoring, recordkeeping, and reporting requirements of this subpart.

* * * * *

(c) Compliance with the NO_X emissions standard must be demonstrated through maintaining the documentation in paragraphs (c)(1) and (2) of this section on-site:

* * * * *

(d) Compliance with the SO_2 emissions standard must be demonstrated through complying with the provisions in § 60.4372a.

(e) * * *

(1) The combustion turbine may only be located at the same stationary source (or group of stationary sources located within a contiguous area and under common control) for a total period of 24 consecutive months. This is the total period of residence time allowed after the turbine commences operation at the location, regardless of whether the turbine is in operation for the entire 24-consecutive-month period.

* * * * *

■ 11. Amend § 60.4333a by revising paragraphs (b)(1) and (d)(3) to read as follows:

§ 60.4333a What are my general requirements for complying with this subpart?

* * * * *

(b) * * *

(1) Except as provided for in paragraphs (b)(2) through (5) of this section, you must conduct subsequent performance tests within 14 calendar months of the date that the previous performance test was conducted.

* * * * *

(d) * * *

(3) Conduct an initial performance test according to § 60.8 and use the applicable methods in § 60.4415a. Thereafter, maintain records (such as a current, valid purchase contract, tariff sheet, or transportation contract) documenting that total sulfur content for the initial and subsequent fuel combusted in your stationary combustion turbine at all times does not exceed applicable conditions specified in § 60.4370a or § 60.4372a; or

* * * * *

■ 12. Amend § 60.4350a by revising paragraph (d) and equation 1 to paragraph (f)(1) to read as follows:

§ 60.4350a How do I use the NO_X CEMS data to determine excess emissions?

* * * * *

(d) Data used to meet the requirements of this subpart shall not include substitute data values derived from the missing data procedures of part 75 of this chapter, nor shall the data be bias adjusted according to the procedures of part 75 of this chapter. For units complying with the 12-calendar-month mass-based standard, emissions for hours of missing data shall be estimated by using the average emissions rate of non-out-of-control hours within ±10 percent of the hourly load value of missing data within the 12-calendar-month period. If non-out-of-control data is not available, the maximum hourly emissions rate during the 12-calendar-month period shall be used.

* * * * *

(f) * * *

(1) * * *

Equation 1 to Paragraph (f)(1)

$$P = \frac{(Pe)_t}{T} + \frac{(Pe)_c}{T} - Pe_A + P_s + P_o \quad \text{(Eq. 1)}$$

Where:

P = Gross or net energy output of the stationary combustion turbine system in MWh;

$(Pe)_t$ = Electrical or mechanical energy output of the combustion turbine engine in MWh;

$(Pe)_c$ = Electrical or mechanical energy output (if any) of the steam turbine in MWh;
Pe_A = Electric energy used for any auxiliary loads in MWh (only applicable to owners/operators electing to demonstrate compliance on a net output basis);
P_s = Useful thermal energy of the steam, measured relative to ISO conditions, not used to generate additional electric or mechanical output, in MWh;
P_o = Other useful heat recovery, measured relative to ISO conditions, not used for steam generation or performance enhancement of the stationary combustion turbine; and
T = Electric Transmission and Distribution Factor. Equal to 0.95 for CHP combustion turbine where at least 20.0 percent of the total gross useful energy output consists of electric or direct mechanical output and 20.0 percent of the total gross useful energy output consists of useful thermal output on a 12-calendar-month basis. Equal to 1.0 for all other combustion turbines.

* * * * *

■ 13. Amend § 60.4374a by revising equation 2 to paragraph (g)(2) to read as follows:

§ 60.4374a How do I demonstrate compliance with my SO_2 emissions standard and determine excess emissions using a SO_2 CEMS?

* * * * *

(g) * * *

(2) * * *

Equation 2 to Paragraph (g)(2)

$$P = \frac{(Pe)_t}{T} + \frac{(Pe)_c}{T} - Pe_A + P_s + P_o \quad \text{(Eq. 2)}$$

Where:

P = Gross energy output of the stationary combustion turbine system in MWh;
$(Pe)_t$ = Electrical or mechanical energy output of the stationary combustion turbine in MWh;
$(Pe)_c$ = Electrical or mechanical energy output (if any) of the steam turbine in MWh;
Pe_A = Electric energy used for any auxiliary loads in MWh;
P_s = Useful thermal energy of the steam, measured relative to ISO conditions, not used to generate additional electric or mechanical output, in MWh;
P_o = Other useful heat recovery, measured relative to ISO conditions, not used for steam generation or performance enhancement of the stationary combustion turbine; and
T = Electric Transmission and Distribution Factor. Equal to 0.95 for CHP combustion turbine where at least 20.0 percent of the total gross useful energy output consists of electric or direct mechanical output and 20.0 percent of the total gross useful energy output consists of useful thermal output on a 12-calendar-month basis. Equal to 1.0 for all other combustion turbines.

* * * * *

■ 14. Amend § 60.4400a by revising paragraph (d) introductory text and paragraph (d)(2) to read as follows:

§ 60.4400a How do I conduct performance tests to demonstrate compliance with my NO_X emissions standard if I do not have a NO_X CEMS?

* * * * *

(d) The performance test must be done at any load condition within ±30 percent of 100 percent of the base load rating. You may perform testing at the highest achievable load point, if at least 70 percent of the base load rating cannot be achieved in practice. You must conduct three separate test runs for each performance test. The minimum time per run is 20 minutes.

* * * * *

(2) For a combined cycle or CHP combustion turbine with supplemental heat (duct burner), you must measure the total NO_X emissions downstream of the duct burner. The duct burner must be in operation within ±30 percent of 100 percent of the base load rating of the duct burners or the highest achievable load if at least 70 percent of the base load rating of the duct burners cannot be achieved during the performance test.

* * * * *

■ 15. Amend § 60.4405a by revising paragraph (b)(1) to read as follows:

§ 60.4405a How do I conduct a performance test if I use a NO_X CEMS?

* * * * *

(b) * * *

(1) Perform a minimum of nine RATA reference method runs, with a minimum time per run of 21 minutes, at a single load level, within ±30 percent of 100 percent of the base load rating while the source is combusting the fuel that is a normal primary fuel for that source. You may perform testing at the highest achievable load point, if at least 70 percent of the base load rating cannot be achieved in practice. The ambient temperature must be greater than 0 °F during the RATA runs. The Administrator or delegated authority may approve performance testing below 0 °F if the timing of the required performance test and environmental conditions make it impractical to test at ambient conditions greater than 0 °F.

* * * * *

■ 16. Amend § 60.4415a by revising paragraph (a) and paragraph (b) introductory text to read as follows:

§ 60.4415a How do I conduct performance tests to demonstrate compliance with my SO_2 emissions standard?

(a) If you are an owner or operator of an affected facility complying with the fuel-based standard, you may submit fuel records (such as a current, valid purchase contract, tariff sheet, transportation contract, or results of a fuel analysis) to satisfy the requirements of § 60.8.

(b) If you are an owner or operator of an affected facility complying with the SO_2 emissions standard and are not using fuel records, you must conduct the performance test by measuring the SO_2 emissions in the stationary combustion turbine exhaust gases using the methods in either paragraph (b)(1) or (2) of this section.

* * * * *

■ 17. Amend § 60.4420a by:
■ a. Removing the definition of ''Annual capacity factor'';
■ b. Revising the definition of ''Gross energy output'';
■ c. Removing the definitions of ''High-utilization source'' and ''Low-utilization source'';
■ d. Revising the definitions of ''Stationary combustion turbine'' and ''Turbine tuning''; and
■ e. Adding the definition of ''Utilization'' in alphabetical order.

The revisions and addition read as follows:

§ 60.4420a What definitions apply to this subpart?

* * * * *

Gross energy output means:

(1) For simple cycle and combined cycle combustion turbines, the gross useful work performed is the gross electrical or direct mechanical output from both the combustion turbine engine and any associated steam turbine(s).

(2) For a CHP combustion turbine, the gross useful work performed is the gross electrical or direct mechanical output from both the combustion turbine engine and any associated steam turbine(s) plus any useful thermal output measured relative to ISO

conditions that is not used to generate additional electrical or mechanical output or to enhance the performance of the unit (*i.e.,* steam delivered to an industrial process).

(3) For a CHP combustion turbine where at least 20.0 percent of the total gross useful energy output consists of useful thermal output on a 12-calendar-month basis, the gross useful work performed is the gross electrical or direct mechanical output from both the combustion turbine engine and any associated steam turbine(s) divided by 0.95 plus any useful thermal output measured relative to ISO conditions that is not used to generate additional electrical or mechanical output or to enhance the performance of the unit (*i.e.,* steam delivered to an industrial process).

(4) For a district energy CHP combustion turbine where at least 20.0 percent of the total gross useful energy output consists of useful thermal output on a 12-calendar-month basis, the gross useful work performed is the gross electrical or direct mechanical output from both the combustion turbine engine and any associated steam turbine(s) divided by 0.95 plus any useful thermal output measured relative to ISO conditions that is not used to generate additional electrical or mechanical output or to enhance the performance of the unit (*e.g.,* steam delivered to an industrial process) divided by 0.95.

* * * * *

Stationary combustion turbine means all equipment including, but not limited to, the combustion turbine engine, the fuel, air, lubrication and exhaust gas systems, control systems (except post combustion emissions control equipment), heat recovery system (including heat recovery steam generators and duct burners); steam turbine; fuel compressor and/or pump, any ancillary components and sub-components comprising any simple cycle stationary combustion turbine, any combined cycle combustion turbine, and any combined heat and power combustion turbine based system; plus any integrated equipment that provides electricity or useful thermal output to the combustion turbine engine (*e.g.,* onsite photovoltaics), heat recovery system, or auxiliary equipment. Stationary means that the combustion turbine is not self-propelled or intended to be propelled while performing its function. It may, however, be mounted on a vehicle for portability. Portable combustion turbines are excluded from the definition of ''stationary combustion turbine,'' and not regulated under this part, if the combustion turbine meets the definition of ''nonroad engine'' under title II of the Clean Air Act and applicable regulations and is certified to meet emissions standards and all related requirements promulgated pursuant to title II of the Clean Air Act.

* * * * *

Turbine tuning means planned maintenance or parameter performance testing of a combustion turbine engine involving adjustment of the operating configuration to maintain proper combustion dynamics or testing machine operating performance. Turbine tuning is limited to 30 hours per 12-calendar-month period.

* * * * *

Utilization means the ratio between the actual heat input to a combustion turbine engine (not including any heat input to an HRSG) during a 12-calendar-month period and the potential heat input to the combustion turbine engine had it operated at the base load rating for every hour during the 12-calendar-month period. Heat input during a system emergency as defined in this section is excluded when determining the utilization rate. Actual and potential heat input derived from non-combustion sources (*e.g.,* solar thermal) are not included when calculating the utilization.

* * * * *

■ 18. Revise table 1 to subpart KKKKa of part 60 to read as follows:

TABLE 1 TO SUBPART KKKKa OF PART 60—NITROGEN OXIDE EMISSION STANDARDS FOR STATIONARY COMBUSTION TURBINES

Combustion turbine type	Combustion turbine base load rated heat input (HHV)	Input-based NO_X emission standard [1]	Optional output-based NO_X standard [2]
New, firing natural gas with utilization rate >45 percent.	>850 MMBtu/h	5 ppm at 15 percent O_2 or 7.9 ng/J (0.018 lb/MMBtu).	0.054 kg/MWh-gross (0.12 lb/MWh-gross) 0.055 kg/MWh-net (0.12 lb/MWh-net).
New, firing natural gas with utilization rate ≤45 percent and with design efficiency ≥38 percent.	>850 MMBtu/h	25 ppm at 15 percent O_2 or 40 ng/J (0.092 lb/MMBtu).	0.38 kg/MWh-gross (0.83 lb/MWh-gross) 0.39 kg/MWh-net (0.85 lb/MWh-net).
New, firing natural gas with utilization rate ≤45 percent and with design efficiency <38 percent.	>850 MMBtu/h	9 ppm at 15 percent O_2 or 14 ng/J (0.033 lb/MMBtu).	0.17 kg/MWh-gross (0.37 lb/MWh-gross) 0.17 kg/MWh-net (0.38 lb/MWh-net).
New, modified, or reconstructed, firing non-natural gas.	>850 MMBtu/h	42 ppm at 15 percent O_2 or 70 ng/J (0.16 lb/MMBtu).	0.45 kg/MWh-gross (1.0 lb/MWh-gross) 0.46 kg/MWh-net (1.0 lb/MWh-net).
Modified or reconstructed, firing natural gas, at all utilization rates, with design efficiency ≥38 percent.	>850 MMBtu/h	25 ppm at 15 percent O_2 or 40 ng/J (0.092 lb/MMBtu).	0.38 kg/MWh-gross (0.83 lb/MWh-gross) 0.39 kg/MWh-net (0.85 lb/MWh-net).
Modified or reconstructed, firing natural gas, at all utilization rates, with design efficiency <38 percent.	>850 MMBtu/h	15 ppm at 15 percent O_2 or 24 ng/J (0.055 lb/MMBtu).	0.28 kg/MWh-gross (0.62 lb/MWh-gross) 0.29 kg/MWh-net (0.30 lb/MWh-net).
New, firing natural gas, at utilization rate >45 percent.	>50 MMBtu/h and ≤850 MMBtu/h.	15 ppm at 15 percent O_2 or 24 ng/J (0.055 lb/MMBtu).	0.20 kg/MWh-gross (0.43 lb/MWh-gross) 0.20 kg/MWh-net (0.44 lb/MWh-net).
New, firing natural gas, at utilization rate ≤45 percent.	>50 MMBtu/h and ≤850 MMBtu/h.	25 ppm at 15 percent O_2 or 40 ng/J (0.092 lb/MMBtu).	0.54 kg/MWh-gross (1.2 lb/MWh-gross) 0.56 kg/MWh-net (1.2 lb/MWh-net).
Modified or reconstructed, firing natural gas	>20 MMBtu/h and ≤850 MMBtu/h.	42 ppm at 15 percent O_2 or 67 ng/J (0.15 lb/MMBtu).	0.91 kg/MWh-gross (2.0 lb/MWh-gross) 0.92 kg/MWh-net (2.0 lb/MWh-net).

TABLE 1 TO SUBPART KKKKa OF PART 60—NITROGEN OXIDE EMISSION STANDARDS FOR STATIONARY COMBUSTION TURBINES—Continued

Combustion turbine type	Combustion turbine base load rated heat input (HHV)	Input-based NO_X emission standard [1]	Optional output-based NO_X standard [2]
New, firing non-natural gas	>50 MMBtu/h and ≤850 MMBtu/h.	74 ppm at 15 percent O_2 or 120 ng/J (0.29 lb/MMBtu).	1.6 kg/MWh-gross (3.6 lb/MWh-gross) 1.6 kg/MWh-net (3.7 lb/MWh-net).
Modified or reconstructed, firing non-natural gas.	>20 MMBtu/h and ≤850 MMBtu/h.	96 ppm at 15 percent O_2 or 160 ng/J (0.37 lb/MMBtu).	2.1 kg/MWh-gross (4.7 lb/MWh-gross) 2.2 kg/MWh-net (4.8 lb/MWh-net).
New, firing natural gas	≤50 MMBtu/h	25 ppm at 15 percent O_2 or 40 ng/J (0.092 lb/MMBtu).	0.64 kg/MWh-gross (1.4 lb/MWh-gross) 0.65 kg/MWh-net (1.4 lb/MWh-net).
New, firing non-natural gas	≤50 MMBtu/h	96 ppm at 15 percent O_2 or 160 ng/J (0.37 lb/MMBtu).	2.4 kg/MWh-gross (5.3 lb/MWh-gross) 2.5 kg/MWh-net (5.4 lb/MWh-net).
Modified or reconstructed, all fuels	≤20 MMBtu/h	150 ppm at 15 percent O_2 or 240 ng/J (0.55 lb/MMBtu).	3.9 kg/MWh-gross (8.7 lb/MWh-gross) 4.0 kg/MWh-net (8.9 lb/MWh-net).
New, firing natural gas, either offshore turbines and/or turbines bypassing the heat recovery unit.	>50 MMBtu/h	25 ppm at 15 percent O_2 or 40 ng/J (0.092 lb/MMBtu).	N/A.
Located north of the Arctic Circle (latitude 66.5 degrees north), operating at ambient temperatures less than 0 °F (−18 °C), modified or reconstructed offshore turbines, operated during periods of turbine tuning, byproduct-fired turbines, and/or operating at less than 70 percent of the base load rating.	≤30 MW output	150 ppm at 15 percent O_2 or 240 ng/J (0.55 lb/MMBtu).	N/A.
Located north of the Arctic Circle (latitude 66.5 degrees north), operating at ambient temperatures less than 0 °F (−18 °C), modified or reconstructed offshore turbines, operated during periods of turbine tuning, byproduct-fired turbines, and/or operating at less than 70 percent of the base load rating.	> 30 MW output	96 ppm at 15 percent O_2 or 150 ng/J (0.35 lb/MMBtu).	N/A.
Heat recovery units operating independent of the combustion turbine.	All sizes	54 ppm at 15 percent O_2 or 86 ng/J (0.20 lb/MMBtu).	N/A.
Temporary turbines firing natural gas	≤850 MMBtu/h	25 ppm at 15 percent O_2 or 40 ng/J (0.092 lb/MMBtu).	N/A.
Temporary turbines firing non-natural gas	≤850 MMBtu/h	74 ppm at 15 percent O_2 or 120 ng/J (0.29 lb/MMBtu).	N/A.

[1] Input-based standards are determined on a 4-operating-hour rolling average basis.
[2] Output-based standards are determined on a 30-operating-day average basis.

Aaron Szabo,

Assistant Administrator,Office of Air and Radiation.

[FR Doc. 2026–14371 Filed 7–15–26; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R07–OAR–2026–4952; FRL–13457–02–R7]

Approval and Promulgation of State Plan (Negative Declaration) for Designated Facilities and Pollutants; Nebraska; Commercial and Industrial Solid Waste Incineration Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to accept a negative declaration submitted by the Nebraska Department of Water, Energy, and Environment (NDWEE) to satisfy the emission guidelines and associated compliance times requirements for Commercial and Industrial Solid Waste Incineration (CISWI) units for the State of Nebraska. The negative declaration certifies that there are no existing sources within the jurisdiction of Nebraska that must comply with the rule. This action is being taken in accordance with the Clean Air Act (CAA) requirements for emission guidelines and state plans for existing sources.

DATES: This direct final rule will be effective September 14, 2026, without further notice, unless the EPA receives adverse comment by August 17, 2026. If the EPA receives adverse comment, we

will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2026–4952, to *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Allyson Prue, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7277; email address: *prue.allyson@epa.gov.*

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

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I. What is a CAA 111(d) Plan?

Sections 111(d) and 129 of the CAA require states to submit plans to control certain pollutants (designated pollutants) at existing solid waste combustor facilities (designated facilities) whenever standards of performance have been established under CAA section 111(b) for new sources of the same type, and the EPA has established emission guidelines for such existing sources. Section 129 of the CAA is specific to solid waste combustion and requires the EPA to establish the new source performance standards (NSPS) and emission guidelines for existing sources for each category of solid waste incineration units, which include CISWI units, as addressed in this action. Under CAA section 129, the NSPS and emission guidelines must contain numerical emissions limitations for particulate matter (total and fine), opacity (as appropriate), sulfur dioxide, hydrogen chloride, oxides of nitrogen, carbon monoxide, lead, cadmium, mercury, and dioxins and dibenzofurans. While the NSPS are directly applicable to affected facilities, emission guidelines for existing units are intended for states to use to develop a state plan to submit to the EPA. Once approved by the EPA, the state plan becomes federally enforceable. If a state does not submit an approvable state plan to the EPA, the EPA is responsible for developing, implementing, and enforcing a federal plan. The regulations at 40 CFR part 60, subpart B, contain general provisions applicable to the adoption and submittal of state plans for controlling designated pollutants. The regulations at 40 CFR part 62, subpart A, provide the procedural framework by which the EPA will approve or disapprove such plans submitted by a state.

However, 40 CFR 60.23(b) and 62.06 provide that if a state does not have any existing solid waste incineration units for the relevant emission guidelines, the state shall submit a letter to the EPA certifying that no such units exist within the state (*i.e.,* a negative declaration) in lieu of a state plan. A negative declaration exempts the state from the provisions of subpart B regarding the submittal of a CAA section 111(d)/129 plan.

II. What are the Regulatory Requirements for CISWIs?

On December 1, 2000, the EPA originally promulgated the NSPS and emission guidelines to reduce air pollution from CISWI units, which are codified at 40 CFR part 60, subparts CCCC and DDDD, respectively. *See* 65 FR 75338. These rulemakings underwent a number of revisions and amendments throughout the 2000s, with the most recent amendments being finalized on June 23, 2016. *See* 81 FR 40956. Due to significant changes to applicability in the March 21, 2011 CISWI rulemaking, the EPA required states to resubmit state plans for existing source CISWI. *See* 76 FR 15704 and 78 FR 9112. Existing source CISWI units are those which have commenced construction on or before June 4, 2010, or were modified no later than August 7, 2013. The emission guidelines for existing source CISWI are codified at 40 CFR part 60, subpart DDDD.

States subject to 40 CFR part 60, subpart DDDD (subpart DDDD) must submit a state plan to the EPA that implements the CISWI emission guidelines as per 40 CFR 60.2505. A state with no existing units submits a negative declaration letter in place of a state plan in accordance with 40 CFR 60.2510. The Nebraska Department of Water, Energy, and Environment, formerly the Nebraska Department of Environmental Quality at the time of submission, submitted a negative declaration to the EPA on March 26, 2018, certifying that there are no existing sources in the State of Nebraska subject to the requirements of subpart DDDD. On May 21, 2026, the EPA received confirmation from the NDWEE that the 2018 negative declaration is current and that there continues to be no existing sources in the State subject to the requirements of subpart DDDD.

III. Why is this Action Necessary?

In this final rule, the EPA will amend 40 CFR part 62 to reflect receipt of the negative declaration letter for the State of Nebraska, certifying that there are no existing CISWI units within its jurisdiction subject to 40 CFR part 60, subpart DDDD, in accordance with section 111(d) of the CAA.

If a designated facility is later found within the mentioned jurisdictions after publication of the final action, then the facility will become subject to the requirements of the federal plan for that designated facility, including the compliance schedule. The federal plan will no longer apply if we subsequently receive and approve a CAA section 111(d)/129 plan from the jurisdiction with the overlooked facility.

We are publishing this direct final rule without prior proposed rule because we view this as a noncontroversial action and anticipate no adverse comment. However, in the ''Proposed Rules'' section of this **Federal Register**, we are publishing a separate document that will serve as the proposed rule to approve the negative declaration if adverse comments are received on this direct final rule. We will not institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information about commenting on this rule, see the **ADDRESSES** section of this document. If the EPA receives adverse comment, we will publish a timely withdrawal in the **Federal Register** informing the public that this direct final rule will not take effect. We will address all public comments in any subsequent final rule based on the proposed rule.

IV. Statutory and Executive Order Reviews

Under the CAA, the Administrator has the authority to approve a 111(d) negative declaration in lieu of a state plan that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7411(d); 42 U.S.C. 7429; 40 CFR part 60, subparts B and DDDD; and 40 CFR part 62, subpart A. Thus, in reviewing 111(d) negative declaration letters, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993);
- Is not an Executive Order 14192 (90 FR 9065, February 6, 2025) regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA.

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

This action is subject to the Congressional Review Act (CRA), and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by September 14, 2026. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Commercial and industrial solid waste incinerators, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: July 6, 2026.

James Macy,

Regional Administrator, Region 7.

For the reasons stated in the preamble, the EPA amends 40 CFR part 62 as set forth below:

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

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

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

Subpart CC—Nebraska

■ 2. Revise § 62.6916 to read as follows:

§ 62.6916 Identification of plan-negative declaration.

On March 26, 2018, the State of Nebraska Department of Environmental Quality submitted a letter certifying no Commercial and Industrial Solid Waste Incineration units subject to 40 CFR part 60, subpart DDDD operate within the State's jurisdiction.

[FR Doc. 2026–14330 Filed 7–15–26; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 635

[Docket No. 220919–0193; RTID 0648–XF881]

Atlantic Highly Migratory Species; Atlantic Bluefin Tuna Fisheries; Harpoon Category Quota Transfer

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS is transferring 6.4 metric tons (mt) of Atlantic bluefin tuna (BFT) quota from the Reserve category to the Harpoon category resulting in an adjusted Harpoon category quota 65.6 mt and a Reserve category quota of 1 mt. This action is intended to provide further harvest opportunities for Harpoon category fishermen, based on consideration of the regulatory determination criteria regarding inseason adjustments and applies to Atlantic Tunas Harpoon category (commercial) permitted vessels. The Harpoon category fishery will remain open until November 15, 2026, or until the adjusted Harpoon quota is reached, whichever comes first.

DATES: The quota transfer is effective July 14, 2026, through November 15, 2026.

FOR FURTHER INFORMATION CONTACT: Larry Redd, Jr., *larry.redd@noaa.gov*, or Becky Curtis, *becky.curtis@noaa.gov*, or by email or phone at 301–427–8503.

SUPPLEMENTARY INFORMATION: Atlantic BFT fisheries are managed under the 2006 Consolidated Atlantic Highly Migratory Species (HMS) Fishery Management Plan (FMP) and its amendments, pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act; 16 U.S.C. 1801 *et seq.*) and consistent with the Atlantic Tunas Convention Act (ATCA; 16 U.S.C. 971 *et seq.*). HMS implementing regulations are at 50 CFR part 635. Section 635.27(a) divides the U.S. BFT quota, established by the International Commission for the Conservation of Atlantic Tunas (ICCAT) and as implemented by the United States among the various domestic fishing categories, per the allocations established in the HMS FMP and its amendments. NMFS is required under the Magnuson-Stevens Act at 16 U.S.C. 1854(g)(1)(D) to provide U.S. fishing

vessels with a reasonable opportunity to harvest quotas under relevant international fishery agreements such as the ICCAT Convention, which is implemented domestically pursuant to ATCA.

As described in § 635.27(a), the current baseline U.S. BFT quota is 1,316.14 mt (not including the 25 mt ICCAT allocated to the United States to account for bycatch of BFT in pelagic longline fisheries in the Northeast Distant Gear Restricted Area per § 635.27(a)(3)). The baseline quotas for the Harpoon and Reserve categories are 59.2 mt and 38.2 mt, respectively. To date, NMFS has published one action that adjusted the Reserve category quota (91 FR 5855, February 10, 2026). The current adjusted Reserve category quota is 7.4 mt. As described under § 635.27(a)(4), the Harpoon category quota is available from June 1 through November 15 of each year.

Separate from this action, NMFS published a proposed rulemaking that would implement the 2025 ICCAT recommendation (Recommendation 25–05) regarding western BFT management (91 FR 24789, May 7, 2026). Consistent with that recommendation, that proposed rule, would increase the baseline U.S. BFT quota from 1,316.14 mt to 1,509.98 mt and adjust all the subquotas accordingly. In that proposed rule, the Harpoon category baseline quota would increase from 59.2 mt to 67.9 mt and the Reserve category baseline quota would increase from 38.2 mt to 43.8 mt. The comment period on that proposed rule ended on June 8, 2026. Any final rule implementing ICCAT Recommendation 25–05 would likely be effective in mid-2026 or later.

Transfer From the Reserve Category to the Harpoon Category Fishery

Under § 635.27(a)(8), NMFS has the authority to transfer quota among fishing categories or subcategories after considering the determination criteria provided under § 635.27(a)(7). This section focuses on the calculations involved in transferring quota currently available from the 2026 Reserve category to the 2026 Harpoon category quota; the consideration of the determination criteria can be found below after this section.

As stated above, the baseline Harpoon category quota and adjusted Reserve category quota are 59.2 mt and 7.4 mt, respectively. Transferring 6.4 mt from the Reserve category to the Harpoon category, results in an adjusted Harpoon category quota of 65.6 mt (59.2 mt + 6.4 mt = 65.6 mt), and an adjusted Reserve category quota of 1 mt (7.4 mt − 6.4 mt = 1 mt). The Harpoon category quota is available for use by Atlantic Tunas Harpoon category permitted vessels.

In summary, this transfer results in an adjusted Harpoon quota of 65.6 mt and an adjusted Reserve quota of 1 mt. The Harpoon category fishery will remain open until November 15, 2026, or until the adjusted Harpoon quota is reached, whichever comes first.

Consideration of the Relevant Determination Criteria

NMFS has considered all of the relevant determination criteria and their applicability to this inseason quota transfer (§ 635.27(a)(7)). These criteria include, but are not limited to, the following:

Regarding the usefulness of information obtained from catches in the particular category for biological sampling and monitoring of the status of the stock (§ 635.27(a)(7)(i)), biological samples collected from BFT landed by Harpoon category fishermen and provided by BFT dealers continue to provide NMFS with valuable parts and data for ongoing scientific studies of BFT age and growth, migration, and reproductive status. Additional opportunity to land BFT in the Harpoon category would support the continued collection of a broad range of data for these studies and for stock monitoring purposes.

NMFS also considered the catches of the Harpoon category quota to date and the likelihood of closure of the Harpoon category fishery if no adjustment is made (§ 635.27(a)(7)(ii)), as well as daily landing trends and the availability of BFT on fishing grounds (§ 635.27(a)(7)(ix)). To date, preliminary landings data indicate that the Harpoon category has landed approximately 63.1 mt for the Harpoon category. Without a quota transfer at this time, the Harpoon category would very likely exceed the available quota and NMFS would have to stop BFT fishing activities even though commercial-sized BFT remain available in the areas where Harpoon category permitted vessels operate. A quota transfer at this time provides limited additional opportunities to harvest the U.S. BFT quota while avoiding exceeding it.

Regarding the projected ability of the vessels fishing under the Harpoon category to harvest the additional amount of BFT quota transferred before the end of the fishing year (§ 635.27(a)(7)(iii)), NMFS considered Harpoon category landings over the last several years and landings to date this year. Landings are highly variable and depend on access to commercial-sized BFT and fishing conditions, among other factors. By allowing for the current quota transfer, NMFS anticipates that the Harpoon category quota would be used before the end of the fishing season. Additionally, this quota transfer would allow Harpoon category fishermen to take advantage of the current availability of BFT on the fishing grounds and provide a reasonable opportunity to harvest the available U.S. BFT quota.

NMFS also considered the estimated amounts by which quotas for other gear categories of the fishery might be exceeded (§ 635.27(a)(7)(iv)), the ability to account for all 2026 landings and dead discards (§ 635.27(a)(7)(xi)), and the ability to facilitate quota accounting (§ 635.27(a)(7)(xii)). With the exception of 2024, the total U.S. BFT landings in recent years typically have been below the available U.S. quota such that the United States has carried forward the maximum amount of underharvest allowed by ICCAT from one year to the next. When total U.S. BFT landings are above the available U.S. quota, the United States reduces the next year's quota by the overharvest amount (including reducing the various fishing category subquotas by their respective overharvest amounts), as was necessary in 2025 to account for overharvest of the 2024 adjusted U.S. quota, consistent with ICCAT recommendations. NMFS will need to account for 2026 landings and dead discards within the 2026 adjusted U.S. quota, and anticipates having sufficient quota to do so.

NMFS also considered the effects of the transfer on the BFT stock and on accomplishing the objectives of the HMS FMP (§ 635.27(a)(7)(v) and (vi)). This transfer would be within established quotas and subquotas, which are implemented consistent with ICCAT recommendations, ATCA, and the objectives of the HMS FMP and amendments. In establishing these quotas and subquotas and associated management measures, ICCAT and NMFS considered the best scientific information available, objectives for stock management and status, and effects on the stock. This quota transfer is in line with the established management measures and stock status determinations. Another principal consideration is the objective of providing opportunities to harvest the available Harpoon category quota without exceeding the annual quota, based on the objectives of the HMS FMP and its amendments, including to achieve optimum yield on a continuing basis and to allow all permit categories a reasonable opportunity to harvest available BFT quota allocations (related to § 635.27(a)(7)(x)). Finally, we note that the amount remaining in the

Reserve category is sufficient for anticipated exempted fishing and other permitted research needs.

In summary, this transfer results in an adjusted Harpoon quota of 65.6 mt and an adjusted Reserve quota of 1 mt. The Harpoon category fishery will remain open until November 15, 2026, or until the adjusted Harpoon quota is reached, whichever comes first.

Monitoring and Reporting

NMFS will continue to monitor the BFT fishery closely. Per § 635.5(b)(2)(i)(A), dealers are required to submit landing reports within 24 hours of a dealer receiving BFT. Late reporting by dealers compromises NMFS' ability to timely implement actions such as quota and retention limit adjustments, as well as closures, and may result in enforcement actions. Additionally, and separate from the dealer reporting requirement, Harpoon category vessel owners are required per § 635.27(a)(4) to report their own catch of all BFT retained or discarded dead within 24 hours of the landing(s) or end of each trip, by accessing *https://hmspermits.noaa.gov*, using the HMS Catch Reporting app, or calling 888–872–8862 (Monday through Friday from 8 a.m. until 4:30 p.m. Eastern Time).

Depending on the level of fishing effort and catch rates of BFT, NMFS may determine that additional adjustments are necessary to ensure available subquotas are not exceeded in 2026 or to enhance scientific data collection from, and fishing opportunities in, all geographic areas as specified under § 635.27(a)(7). If needed, subsequent adjustments will be published in the **Federal Register**. In addition, fishermen may access *https://hmspermits.noaa.gov/home*, for updates on quota monitoring and inseason adjustments.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act (16 U.S.C. 1855(d)) and regulations at 50 CFR part 635 and this action is exempt from review under Executive Order 12866.

The Assistant Administrator for NMFS (AA) finds that pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice of, and opportunity for public comment on, this action because it is impracticable and contrary to the public interest for the following reasons. Specifically, the regulations implementing the HMS FMP and amendments provide for inseason adjustments and quota transfers to respond to the unpredictable nature of BFT availability on the fishing grounds, the migratory nature of this species, and the regional variations in the BFT fishery. Providing prior notice and an opportunity for public comment is impracticable and contrary to the public interest as this fishery is currently underway and, based on the most recent landings information, the 2026 Harpoon category quota is projected to be reached shortly. Delaying this action could result in BFT landings that exceed the Harpoon category quota. Additionally, a delay in implementing this action would preclude the fishery from harvesting BFT that are currently available on the fishing grounds and that might otherwise become unavailable. This action does not raise conservation and management concerns and would support effective management of the BFT fishery. This action does not affect the overall ICCAT-allocated U.S. BFT quota. NMFS notes that the public had an opportunity to comment on the underlying rulemakings that established the U.S. BFT quota and the inseason adjustment criteria.

For all of the above reasons, the AA finds that pursuant to 5 U.S.C. 553(d)(3), there is good cause to waive the 30-day delay in effective date.

Authority: 16 U.S.C. 971 *et seq.* and 1801 *et seq.*

Dated: July 14, 2026.

Shannon Bettridge,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–14366 Filed 7–14–26; 4:15 pm]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 260209–0039; RTID 0648–XF890]

Fisheries of the Northeastern United States; Summer Flounder Fishery; Quota Transfer From North Carolina to Virginia

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

ACTION: Temporary rule; quota transfer.

SUMMARY: NMFS announces that the State of North Carolina is transferring a portion of its 2026 commercial summer flounder quota to the Commonwealth of Virginia. This adjustment to the 2026 fishing year quota is necessary to comply with the Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP) quota transfer provisions. This announcement informs the public of the revised 2026 commercial quotas for North Carolina and Virginia.

DATES: Effective July 15, 2026, through December 31, 2026.

FOR FURTHER INFORMATION CONTACT: Matthew Rigdon, Fishery Management Specialist, (978) 281–9336.

SUPPLEMENTARY INFORMATION: Regulations governing the summer flounder fishery are found in 50 CFR 648.100 through 648.111. These regulations require annual specification of a commercial quota that is apportioned among the coastal states from Maine through North Carolina. The process to set the annual commercial quota and the percent allocated to each state is described in § 648.102, and the final 2026 allocations were published on February 19, 2026 (91 FR 7896).

The final rule implementing amendment 5 to the FMP, as published in the **Federal Register** on December 17, 1993 (58 FR 65936), provided a mechanism for transferring summer flounder commercial quota from one state to another. Two or more states, under mutual agreement and with the concurrence of the NMFS Greater Atlantic Regional Administrator, can transfer or combine summer flounder commercial quota under § 648.102(c)(2). The Regional Administrator is required to consider three criteria in the evaluation of requests for quota transfers or combinations: (1) the transfers or combinations would not preclude the overall annual quota from being fully harvested; (2) the transfers address an unforeseen variation or contingency in the fishery; and (3) the transfers are consistent with the objectives of the FMP and the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). The Regional Administrator has determined these three criteria have been met for the transfer approved in this notification.

North Carolina is transferring 12,719 pounds (lb; 5,769 kilograms (kg)) of summer flounder to Virginia through a mutual agreement between the states. This transfer was requested to repay landings made by out-of-state permitted vessels under safe harbor agreements. The revised summer flounder quotas for 2026 are: North Carolina, 2,907,006 lb (1,318,596 kg); and Virginia, 2,433,727 lb (1,103,920 kg).

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens

Act. This action is required by 50 CFR 648.102(c)(2)(i) through (iv), which was issued pursuant to section 304(b) of the Magnuson-Stevens Act, and is exempted from review under Executive Order 12866.

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

Dated: July 14, 2026.

Shannon Bettridge,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–14369 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 91, No. 135
Thursday, July 16, 2026

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

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2026–7221; Project Identifier MCAI–2025–01377–T]

RIN 2120–AA64

Airworthiness Directives; Bombardier, Inc., Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Bombardier, Inc., Model BD–700–2A12 airplanes. This proposed AD was prompted by a report that the protective film cover on certain secondary power distribution assemblies (SPDA) might not have been removed. This proposed AD would require an inspection of certain SPDA for the presence of the protective film cover and applicable corrective actions. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this proposed AD by August 31, 2026.

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

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

AD Docket: You may examine the AD docket at *regulations.gov* under Docket No. FAA–2026–7221; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

Material Incorporated by Reference:

- For Transport Canada material identified in this proposed AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca.* You may find this material on the Transport Canada website at *tc.canada.ca/en/aviation.* It is also available at *regulations.gov* under Docket No. FAA–2026–7221.
- You may view this material at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

FOR FURTHER INFORMATION CONTACT: Jonathan Duong, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments using a method listed under the **ADDRESSES** section. Include ''Docket No. FAA–2026–7221; Project Identifier MCAI–2025–01377–T'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend this proposal because of those comments.

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

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Jonathan Duong, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.* Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

Transport Canada, which is the aviation authority for Canada, has issued Transport Canada AD CF–2025–40, dated August 20, 2025 (Transport Canada AD CF–2025–40) (also referred to as the MCAI), to correct an unsafe condition for certain Bombardier, Inc., Model BD–700–2A12 airplanes. The MCAI states that a manufacturing quality escape notice reported that a protective film cover (red protection film) might not have been removed from the bottom face of the No. 1 and No. 2 SPDA. If uncorrected, the blockage of the holes in the mesh on the SPDA could impede proper airflow, adversely affecting cooling performance. This could lead to overheating, operation outside of the normal unit conditions, and eventual SPDA failure, which could result in the loss of any system or combination of systems powered by these units, potentially affecting the safe operation of the airplane.

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

You may examine the MCAI in the AD docket at *regulations.gov* under Docket No. FAA–2026–7221.

Material Incorporated by Reference Under 1 CFR Part 51

Transport Canada AD CF–2025–40 specifies procedures for conducting a visual inspection of the top and bottom faces of the No. 1 and No. 2 SPDA for the presence of the protective film cover and, if applicable, corrective actions to remove the protective film cover. This material is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

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

Proposed AD Requirements in This NPRM

This proposed AD would require accomplishing the actions specified in Transport Canada AD CF–2025–40 described previously, except for any differences identified as exceptions in the regulatory text of this proposed AD.

Explanation of Required Compliance Information

In the FAA's ongoing efforts to improve the efficiency of the AD process, the FAA developed a process to use some civil aviation authority (CAA) ADs as the primary source of information for compliance with requirements for corresponding FAA ADs. The FAA has been coordinating this process with manufacturers and CAAs. As a result, the FAA proposes to incorporate Transport Canada AD CF–2025–40 by reference in the FAA final rule. This proposed AD would, therefore, require compliance with Transport Canada AD CF–2025–40 in its entirety through that incorporation, except for any differences identified as exceptions in the regulatory text of this proposed AD. Material required by Transport Canada AD CF–2025–40 for compliance will be available at *regulations.gov* under Docket No. FAA–2026–7221 after the FAA final rule is published.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 25 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REQUIRED ACTIONS

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
1 work-hours × $85 per hour = $85	$0	$85	$2,125

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

ESTIMATED COSTS OF ON-CONDITION ACTIONS

Labor cost	Parts cost	Cost per product
1 work-hour × $85 per hour = $85	Negligible	$85

The FAA has included all known costs in its cost estimate. According to the manufacturer, however, some or all of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected operators.

Authority for This Rulemaking

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

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

Regulatory Findings

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

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

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

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

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

List of Subjects in 14 CFR Part 39

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

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

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

§ 39.13 [Amended]

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

Bombardier, Inc.: Docket No. FAA–2026–7221; Project Identifier MCAI–2025–01377–T.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by August 31, 2026.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Bombardier, Inc., Model BD–700–2A12 airplanes, certificated in any category, as identified in Transport Canada AD CF–2025–40, dated August 20, 2025 (Transport Canada AD CF–2025–40).

(d) Subject

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

(e) Unsafe Condition

This AD was prompted by a report that the protective film cover might not have been removed from the bottom face of the No. 1 and No. 2 secondary power distribution assemblies (SPDA). The FAA is issuing this AD to address the blockage of the holes in the mesh on the SPDA, which could impede proper airflow, adversely affecting cooling performance. The unsafe condition, if not addressed, could lead to overheating, operation outside of the normal unit conditions, and eventual SPDA failure, which could result in the loss of any system or combination of systems powered by these units, potentially affecting the safe operation of the airplane.

(f) Compliance

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

(g) Requirements

Except as specified in paragraph (h) of this AD: Comply with all required actions and compliance times specified in, and in accordance with, Transport Canada AD CF–2025–40.

(h) Exception to Transport Canada AD CF–2025–40

Where Transport Canada AD CF–2025–40 refers to its effective date, this AD requires using the effective date of this AD.

(i) Additional AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the International Validation Branch, send it to the attention of the person identified in paragraph (j) of this AD and email to: *AMOC@faa.gov.* Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

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

(j) Additional Information

For more information about this AD, contact Jonathan Duong, Aviation Safety Engineer, FAA, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; phone: 516–228–7300; email: *9-avs-nyaco-cos@faa.gov.*

(k) Material Incorporated by Reference

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

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

(i) Transport Canada AD CF–2025–40, dated August 20, 2025.

(ii) [Reserved]

(3) For Transport Canada material identified in this AD, contact Transport Canada, Transport Canada National Aircraft Certification, 159 Cleopatra Drive, Nepean, Ontario K1A 0N5, Canada; telephone 888–663–3639; email *TC.AirworthinessDirectives-Consignesdenavigabilite.TC@tc.gc.ca.* You may find this material on the Transport Canada website at *tc.canada.ca/en/aviation.*

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

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

Issued on July 13, 2026.

Steven W. Thompson,

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

[FR Doc. 2026–14300 Filed 7–15–26; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2026–3764; FRL–13384–02–R3]

Air Plan Approval; Pennsylvania; Reasonably Available Control Technology (RACT) for Volatile Organic Compounds (VOC) Control Technique Guidelines (CTG) Under the 2008 and 2015 Ozone National Ambient Air Quality Standards (NAAQS)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve four state implementation plan (SIP) revisions submitted by the Commonwealth of Pennsylvania received on May 10, 2023, January 20, 2026, February 17, 2026, and April 10, 2026, through the Pennsylvania Department of Environmental Protection (PADEP). The SIP revisions address reasonably available control technology (RACT) requirements for the 2008 and 2015 ozone national ambient air quality standards (NAAQS) relating to control technique guidelines (CTGs) for volatile organic compounds (VOC) via previously adopted CTG regulations, three new CTG regulations and four facilities covered by the CTG for the Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins respectively. This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before August 17, 2026.

ADDRESSES: Submit your comments, identified by Docket ID No EPA–R03–OAR–2026–3764 at *https://www.regulations.gov,* or via email to *gordon.mike@epa.gov.* For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment

contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Sean Silverman, Planning & Implementation Branch (3AD30), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1600 John F Kennedy Boulevard, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–5511. Mr. Silverman can also be reached via electronic mail at *silverman.sean@epa.gov.*

SUPPLEMENTARY INFORMATION: On January 20, 2026 PADEP submitted a revision to its SIP certifying that through a combination of: (1) regulations previously approved into the SIP; (2) regulations proposed to be approved into the SIP; and (3) portions of redacted permits proposed to be incorporated into the SIP that RACT is being implemented for VOC sources covered by a CTG to meet Pennsylvania's RACT requirements under the CAA and implementing regulations for the 2008 and 2015 Ozone NAAQS. PADEP submitted four SIP revisions to accomplish this (herein collectively referred to as the VOC CTG RACT SIP). A description of these submissions is summarized below.

On May 10, 2023, PADEP submitted the first of the four revisions to its SIP establishing RACT requirements to control VOC emissions from sources covered by the following CTGs: (1) Shipbuilding and Ship Repair Operations (Surface Coating), 61 FR 44050 (August 27, 1996);[1] (2) Large Petroleum Dry Cleaners, EPA–450/3–82–009;[2] (3) Control of Volatile Organic Compound Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment, EPA–450/3–83–006;[3] (4) Control of Volatile Organic Compound Emissions from Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry (SOCMI), EPA–450/3–84–015;[4] and (5) Control of Volatile Organic Compound Emissions from Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry, EPA–450/4–91–031.[5]

On January 20, 2026, a second SIP submission was received which contained supporting analysis for all four SIP submissions demonstrating that the submittals meet VOC CTG RACT requirements for the 2008 and 2015 Ozone NAAQS. The bulk of this submission relates to PADEP's previously adopted regulations and associated analysis.

On February 17, 2026, a third SIP submission was received containing portions of three redacted permits for specific facilities. In lieu of adopting new regulations to address VOC CTG RACT from manufacturing high density polyethylene, polypropylene and polystyrene resins (CTG EPA 450–3–83–008, November 1983),[6] PADEP seeks to incorporate by reference into the Pennsylvania SIP portions of redacted permits for each source subject to this CTG. The February 17, 2026 SIP submission certifies that these redacted permits contain conditions that are consistent with or more stringent than the CTG and implement VOC CTG RACT Requirements for these sources for the 2008 and 2015 Ozone NAAQS. The February 17th submission contained the redacted permits for Multiplastic Extrusions Hazelton (permit 40–00083), Rohm & Haas Co Bristol (permit 09–00015), and Shell Chemical Appalachia (permit 04–00740).

On April 10, 2026, a fourth SIP submission was received from PADEP certifying that a permit for the BASF Monaca Plant (permit 04–00306), which was submitted to and approved by the EPA as RACT for the 1997 ozone NAAQS, meets or exceeds the CTG for controlling VOC emissions from manufacturing high density polyethylene, polypropylene and polystyrene resins (EPA–450/3–83–008, November 1983) and remains sufficient to implement VOC CTG RACT for the 2008 and 2015 ozone NAAQS.

As explained below, the EPA is proposing to approve each of these four SIP revisions. Based on this proposed approval, in the Rules and Regulations section in this **Federal Register**, the EPA is simultaneously issuing an interim final determination (IFD) that Pennsylvania's four SIP revisions address the deficiencies cited as the basis of the EPA's August 16, 2024 final disapproval (August 2024 disapproval) of certain portions of Pennsylvania's 2008 VOC CTG RACT regulations. The effect of the IFD is to stay emission offset sanctions and defer the imposition of highway funding sanctions triggered by the EPA's August 2024 disapproval of a prior Pennsylvania SIP submission addressing VOC CTG RACT for the 2008 ozone NAAQS. Comments on the IFD should be submitted in accordance with the instructions in that action.

I. Background

A. Ozone NAAQS and RACT Requirements

On July 18, 1997, the EPA promulgated a revised standard for ground level ozone based on 8-hour average concentrations.[7] The 8-hour averaging period replaced the previous 1-hour averaging period adopted in 1979, and the level of the NAAQS was changed from 0.12 parts per million (ppm) to 0.08 ppm. On March 27, 2008, the EPA further strengthened the 8-hour ozone standards from 0.08 ppm to 0.075 ppm (2008 8-hour ozone NAAQS).[8] On October 26, 2015, the EPA adopted another revision to the ozone standard by strengthening the 8-hour ozone standards to 0.070 ppm (2015 ozone NAAQS), but the 2008 ozone standard remains in effect.[9] This action concerns VOC CTG RACT requirements, described in more detail below, under both the 2008 and 2015 8-hour NAAQS.

The CAA addresses emissions of NO_X and VOC to prevent photochemical reactions that result in ozone formation. Section 182(b)(2) of the CAA requires states with ozone nonattainment areas classified as Moderate or higher to submit a SIP revision requiring the implementation of RACT. The EPA has consistently defined ''RACT'' as the lowest emission limit that a particular source is capable of meeting by the application of the control technology that is reasonably available considering

[1] The CTG for Shipbuilding and Ship Repair Operations (Surface Coating) has no standalone document, it is a combination of the information in 61 FR 44050 (Aug. 27, 1996) and the previously published ACT. Alternative Control Technology Document—Surface Coating Operations at Shipbuilding and Ship Repair Facilities.

[2] Control of Volatile Organic Compound Emissions from Large Petroleum Dry Cleaners.

[3] Control of Volatile Organic Compound Leaks from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.

[4] Control of Volatile Organic Compound Emissions from Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry.

[5] Control of Volatile Organic Compound Emissions from Reactor Processes and Distillation Operations in Synthetic Organic Chemical Manufacturing Industry.

[6] *See* Control of Volatile Organic Compound Emissions from Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins *nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=000029VI.txt.*

[7] *See* 62 FR 38856 (July 18, 1997).

[8] *See* 73 FR 16436 (March 27, 2008).

[9] *See* 80 FR 65292 (Oct. 26, 2015).

technological and economic feasibility.[10]

The CAA requires RACT revisions for three specific categories of sources for the ozone NAAQS. First, CAA section 182(b)(2)(A) requires RACT for each category of VOC sources in the nonattainment area covered by a CTG document issued by the EPA between November 15, 1990 and the date of attainment.[11] Second, CAA section 182(b)(2)(B) requires RACT for all VOC sources in the area covered by any CTG issued before November 15, 1990. Third, CAA section 182(b)(2)(C) requires RACT for all other major stationary sources of VOC located in the nonattainment area. In addition, CAA section 182(f) subjects major stationary sources of NO_X to the same RACT requirements applicable to major stationary sources of VOC.[12] The EPA has not issued any CTGs for categories of NO_X sources, so the effect of CAA section 182(f) is to require that SIPs also mandate RACT for major stationary sources of NO_X in accordance with CAA section 182(b)(2)(C). The ozone RACT requirements under CAA section 182(b)(2) are usually referred to as VOC CTG RACT, non-CTG VOC RACT, and major NO_X RACT. In addition, section 184(a) of the CAA established an Ozone Transport Region (OTR) comprised of 12 eastern states, including all of Pennsylvania, and the District of Columbia. CAA section 184(b)(1)(B) requires implementation of RACT with respect to all sources of VOCs in an OTR state that are covered by a CTG issued before or after November 15, 1990. These OTR RACT requirements for CTG sources apply throughout the Commonwealth of Pennsylvania.

On March 6, 2015, the EPA published a final rule that outlined the obligations related to required SIP requirements for the 2008 8-hour ozone NAAQS.[13] This proposed rulemaking, herein referred to as the ''2008 ozone implementation rule,'' contained, among other things, a description of the EPA's expectations for states with RACT obligations. The 2008 ozone implementation rule indicated that states could meet RACT with: (1) the establishment of new or more stringent requirements that meet RACT control levels; (2) a certification that previously adopted RACT controls in their SIP, under a prior ozone NAAQS, represent adequate RACT control levels for the 2008 8-hour ozone NAAQS; or (3) a combination of these two approaches. In addition, a State could submit a negative declaration in instances where, for a particular CTG, there are no sources within the State covered by that CTG.[14]

In the EPA's 2008 ozone implementation rule, the Agency explains that ''states should refer to the existing CTGs and ACTs for purposes of meeting their RACT requirements, as well as all relevant information (including recent technical information and information received during the public comment period) that is available at the time that they are developing their RACT SIPs. . . .'' [15] The EPA's Implementation Rule for the 2015 ozone NAAQS retains the existing general 2008 RACT requirements.[16]

B. Challenge to Approval, Court Proceedings, Voluntary Remand, Reconsideration and Partial Disapproval

On August 13, 2018, PADEP submitted to the EPA two SIP revisions to satisfy certain RACT requirements for sources of VOC emissions required by sections 182(b)(2) and 184(b)(l)(B) of the CAA and the implementing regulations for the 2008 8-hour ozone NAAQS.[17]

On December 14, 2020, the EPA published a full approval of PADEP's two August 13, 2018 SIP submittals.[18] The approval was challenged in the U.S. Court of Appeals for the Third Circuit, and on September 3, 2021, that court granted the EPA's request for remand without vacatur of the Agency's final full approval.[19]

A petitioner filed litigation in the Eastern District of Pennsylvania on May 16, 2023, arguing the EPA had unreasonably delayed in its reconsideration of the final approval of the August 13, 2018 SIP submittals. On December 15, 2023, the court filed a consent decree requiring that the EPA complete its reconsideration of the December 14, 2020 final rule by November 15, 2024.[20]

After reconsideration, the EPA partially approved and partially disapproved the August 13, 2018 submittals on August 16, 2024 (August 2024 disapproval).[21] Specifically, the EPA approved certain clarifying amendments as well as a negative declaration submitted by PADEP. The EPA disapproved the remainder of both SIP submittals related to CTGs and control of VOC emissions from industrial cleaning solvents for the 2008 8-hour ozone NAAQS. In that disapproval, the EPA determined that it erred in previously approving the VOC CTG RACT portion of PADEP's RACT certification SIP, as the record did not provide sufficient support that the regulations identified by PADEP implemented the VOC CTG RACT requirements of the 2008 8-hour ozone NAAQS. As clarified in the 2008 implementation rule, RACT analyses should consider any technical advances since previous approvals of the RACT rules and provide evidence that other relevant information, including recent technical information and information available at the time of adoption, were considered to determine RACT.[22] PADEP did not provide this analysis in the August 2018 submittals. The EPA therefore concluded that PADEP's SIP submittals did not fully evaluate VOC RACT CTG requirements. See the EPA's Notice of Proposed Rulemaking and Final Rulemaking for that action for a complete discussion of these issues.[23]

The EPA's August 2024 disapproval action commenced a sanctions clock under CAA section 179, providing for emission offset sanctions for new or modified sources within the Commonwealth if the EPA has not fully approved a revised plan within 18 months of the effective date of the final disapproval (March 16, 2026), and providing for highway funding sanctions in affected nonattainment areas if the EPA has not fully approved a revised plan within six months of the imposition of offset sanctions (September 16, 2026). The sanctions clock can be stopped only if the

[10] *See* memorandum from Roger Strelow, Assistant Administrator for Air and Waste Management, to Regional Administrators, ''Guidance for Determining Acceptability of SIP Regulations in Non-Attainment Areas,'' and 44 FR 53761, 53762 (Sept. 17, 1979).

[11] The EPA provides states with guidance concerning what types of controls could constitute RACT for a given source category through the issuance of CTG and alternative control technique (ACT) documents.

[12] A ''major source'' is defined based on the source's potential to emit NO_X or VOC, and the applicable ton per year emission thresholds defining a ''major'' source differ based on the classification of the nonattainment area in which the source is located. *See* sections 182(c) through (f) and 302 of the CAA.

[13] *See* 80 FR 12264 (March 6, 2015).

[14] *See* 80 FR 12264, 12278, 12280 (March 6, 2015).

[15] *See* 80 FR 12264, 12279 (March 6, 2015).

[16] *See* 83 FR 62998, 63007 (Dec. 6, 2018).

[17] *See* 80 FR 12264 (March 6, 2015); 40 CFR part 51, subpart AA.

[18] *See* 85 FR 80616 (Dec. 14, 2020).

[19] A copy of the court order is located in the docket for this action. Docket Id. EPA–R03–OAR–2026–3764 in *regulations.gov*.

[20] A copy of the court order is located in the docket for this action. Docket Id. EPA–R03–OAR–2026–3764 in *regulations.gov*.

[21] *See* 89 FR 66599 (Aug. 16, 2024).

[22] As explained in this document, EPA defines RACT as the lowest emission limit that a particular source is capable of meeting by the application of the control technology that is reasonably available considering technological and economic feasibility.

[23] *See* 89 FR 43359 (May 17, 2024) and 89 FR 66599 (Aug. 16, 2024).

conditions of the EPA's regulations at 40 CFR 52.31 are met.

However, as referenced above, in a separate action concurrent with this proposed approval, the EPA has issued an IFD that Pennsylvania's SIP Revisions submitted on May 10, 2023, January 20, 2026, February 10, 2026 and April 10, 2026 resolve the deficiencies which the EPA cited in the August 2024 disapproval action specific to VOC CTG RACT for the 2008 8-hour ozone NAAQS. The IFD stays the emission offset sanctions and defers the imposition of highway funding sanctions triggered by the EPA's August 2024 disapproval.

Pursuant to CAA section 110(c)(1)(B), August 2024 disapproval also initiated an obligation for the EPA to promulgate a Federal implementation plan (FIP) within 24 months unless PADEP has submitted, and the EPA has fully approved, a plan addressing the applicable VOC CTG RACT requirements.

II. Summary of SIP Revision and the EPA Analysis

A. Certifying Adopted Control Technique Guidelines Regulations as VOC CTG RACT

In this section, the EPA outlines its review, analysis and conclusions regarding PADEP's previously adopted VOC CTG RACT regulations addressed in the January 20, 2026 submission as well as its newly adopted CTG regulations addressed in the May 10, 2023 submission. PADEP performed, and the EPA evaluated and supplemented a RACT due diligence analysis, described in more detail below. The EPA's analysis and supplemented information is available in the EPA's technical support document (TSD). PADEP's original analysis for both the previously adopted and newly adopted regulations is available in appendices A–2 and B–2 of the Commonwealth's January 20, 2026 SIP submission.[24] The EPA has not identified any new control technologies that are reasonably available considering technological and economic feasibility for these sources. Pursuant the EPA's review of PADEP's submissions, the EPA is proposing to determine that the VOC controls for the CTG categories in table 1, in this document, that were addressed in previously adopted regulations, still represent VOC CTG RACT for implementing the 2008 and 2015 ozone NAAQS in the Commonwealth of Pennsylvania.[25]

On October 1, 2024, the EPA approved Pennsylvania's VOC CTG RACT regulation for the Oil and Natural Gas Industry (EPA –453/B–16–001, October, 2016).[26] Pennsylvania submitted this regulation in response to a November 16, 2020, and a December 16, 2021 Finding of Failure to Submit.[27] The EPA's approval occurred after the August 2024 disapproval. This approval satisfies Pennsylvania's Oil and Gas CTG requirements for the 2008 and 2015 Ozone NAAQS, see docket EPA–R03–OAR–2023–0300 for details. As a SIP approved regulation is already in place for this CTG, the EPA will not take action on PADEP's Oil and Gas CTG regulation in this proposed rulemaking.

TABLE 1—PREVIOUSLY APPROVED VOC CTG RACT REGULATIONS IN PENNSYLVANIA

CTG source category	Pa. regulation title 25. environmental protection, chapter 129	RACT basis cocument	SIP revision approved by the EPA (date and citation)
1. Surface Coating of Cans 2. Surface Coating of Coils. 3. Surface Coating of Paper. 4. Surface Coating of Fabrics. 5. Surface Coating of Automobiles and Light Duty-Trucks. 6. Surface Coating of Metal Furniture. 7. Surface Coating for Insulation of Magnet Wire. 8. Surface Coating of Large Appliances. 9. Surface Coating of Miscellaneous Metal Parts and Products.	SOURCES OF VOC: Section 129.52.—Surface coating processes[28].	CTG: Control of Volatile Organic Emissions from Existing Stationary Sources, Volume II: Surface Coating of Cans, Coils, Paper, Fabrics, Automobiles, and Light Duty-Trucks, EPA–450/2–77–008, May 1977. CTG: Control of Volatile Organic Emissions from Existing Stationary Sources, Volume III: Surface Coating of Metal Furniture, EPA–450/2–77–032, December 1977. CTG: Control of Volatile Organic Emissions from Existing Stationary Sources, Volume IV: Surface Coating for Insulation of Magnet Wire, EPA–450/2–77–033, December 1977. CTG: Control of Volatile Organic Emissions from Existing Stationary Sources, Volume V: Surface Coating of Large Appliances, EPA–450/2–77–034, December 1977. CTG: Control of Volatile Organic Emissions from Existing Stationary Sources, Volume VI: Surface Coating of Miscellaneous Metal Parts and Products, EPA–450/2–78–015, June 1978.	7/20/01, 66 FR 37908. 8/24/11, 76 FR 52870. 8/10/18, 83 FR 39600.
10. Large Appliance Coatings (2007) 11. Metal Furniture Coatings (2007)	SOURCES OF VOC: Section 129.52a—Control of VOC emissions from large appliance and metal furniture surface coating processes.	CTG: Control Techniques Guidelines for Large Appliance Coatings U.S. EPA 453/R–07–004 September 2007 CTG: Control Techniques Guidelines for Metal Furniture Coatings, EPA 453/R–07–005, September 2007.	8/24/11, 76 FR 52870.
12. Paper, Film, and Foil Coatings (2007).	SOURCES OF VOC: Section 129.52b—Control of VOC emissions from paper, film and foil surface coating processes.	CTG: Control Techniques Guidelines for Paper, Film, and Foil Coatings EPA 453/R–07–003 September 2007.	3/4/11, 76 FR 11983. 5/23/11, 76 FR 29649.
13. Surface Coating of Flat Wood Paneling (1978). 14. Flat Wood Paneling Coating (2006).	SOURCES OF VOC: Section 129.52c—Control of VOC emissions from flat wood paneling surface coating processes.	CTG: Control of Volatile Organic Emissions from Existing Stationary Sources Volume– VII: Factory Surface Coating of Flat Wood Paneling, EPA–450/2–78–032 June 1978[29]. CTG: Control Techniques Guidelines for Flat Wood Paneling Coatings, EPA 453/R–06–004 September 2006.	6/2/11, 76 FR 31856.

[24] These documents are located in the docket for this action. Docket Id. EPA–R03–OAR–2026–3764 in *regulations.gov.*

[25] See section A of the EPA's TSD located in the docket for this action for supporting analysis.

[26] *See* 89 FR 79752 (Oct. 1, 2024).

[27] The finding of failure to submit for the EPA 2016 Oil and Gas CTG for the 2008 NAAQS was issued and published on Nov. 16, 2020 (85 FR 72963), with an effective date of Dec. 16, 2020, and for the 2015 NAAQS on Dec. 16, 2021 (86 FR 71385), with an effective date of Jan. 18, 2022.

TABLE 1—PREVIOUSLY APPROVED VOC CTG RACT REGULATIONS IN PENNSYLVANIA—Continued

CTG source category	Pa. regulation title 25. environmental protection, chapter 129	RACT basis cocument	SIP revision approved by the EPA (date and citation)
15. Miscellaneous Metal Products Coating (2008). 16. Plastic Parts Coating (2008).	SOURCES OF VOC: Section 129.52d.—Control of VOC emissions from miscellaneous metal parts surface coating processes, miscellaneous plastic parts surface coating processes and pleasure craft surface coatings.	CTG: Control Techniques Guidelines for Miscellaneous Metal Products and Plastic Parts Coatings EPA–453/R–08–003 September 2008.	8/10/18, 83 FR 39604.
17. Automobile and Light Duty-Truck Assembly Coating (2008).	SOURCES OF VOC: Section 129.52e.—Control of VOC emissions from automobile and light duty-truck assembly coating operations and heavier vehicle coating operations.	CTG: Control Techniques Guidelines for Automobile and Light Duty—Truck Assembly Coatings EPA–453/R–08–006 September 2008.	3/23/18, 57 FR 12673.
18. Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds.	SOURCES OF VOC: Section 129.55.—Petroleum refineries—specific sources.	CTG: Control of Refinery Vacuum Producing Systems, Wastewater Separators, and Process Unit Turnarounds, EPA–450/2–77–025, October 1977.	01/19/83, 48 FR 2319.
19. Petroleum Liquid Storage in External Floating Roof Tanks. 20. Petroleum Liquids in Fixed Roof Tanks.	SOURCES OF VOC: Section 129.56.—Storage tanks greater than 40,000 gallons capacity containing VOCs.	CTG: Control of Volatile Organic Emissions from Petroleum Liquid Storage in External Floating Roof Tanks, EPA–450/2–78–047, December 1978. CTG: Control of Volatile Organic Emissions from Storage of Petroleum Liquids in Fixed Roof Tanks, EPA–450/2–77–036, December 1977.	07/26/00, 65 FR 45920.
21. Petroleum Liquid Storage in External Floating Roof Tanks. 22. Petroleum Liquids in Fixed Roof Tanks.	SOURCES OF VOC: Section 129.57.—Storage tanks less than or equal to 40,000 gallons capacity containing VOCs [30].	CTG: Control of Volatile Organic Emissions from Petroleum Liquid Storage in External Floating Roof Tanks, EPA–450/2–78–047, December 1978. CTG: Control of Volatile Organic Emissions from Storage of Petroleum Liquids in Fixed Roof Tanks, EPA–450/2–77–036, December 1977.	01/19/83, 48 FR 2319.
23. Leaks from Petroleum Refinery Equipment.	SOURCES OF VOC: Section 129.58.—Petroleum refineries—fugitive sources.	CTG: Control of Volatile Organic Compound Leaks from Petroleum Refinery Equipment, EPA–450/2–78–036, June 1978.	07/27/84, 49 FR 30183.
24. Tank Truck Gasoline Loading Terminals.	SOURCES OF VOC: Section 129.59.—Bulk gasoline terminals.	CTG: Control of Hydrocarbons from Tank Truck Gasoline Loading Terminals, EPA–450/2–77–026, October 1977.	5/13/93, 58 FR 28362.
25. Equipment Leaks from Natural Gas/Gasoline Processing Plants.	Control of VOC Emissions from Unconventional Oil and Natural Gas Sources Sections 129.121—129.130.. Control of VOC Emissions from Conventional Oil and Natural Gas Sources Sections 129.131–129.140. New Source Performance Standards (NSPS)—Subparts KKK, OOOO, OOOOa, VV, and VVa (as incorporated by reference in 25 Pa. Code Chapter 122).	CTG: Control of Volatile Organic Compound Equipment Leaks from Natural Gas/Gasoline Processing Plants, EPA–450/3–83–007 1983/12. CTG: Control Techniques Guidelines for the Oil and Natural Gas Industry, EPA–453/B–16–001 2016/10.	10/1/24, 89 FR 79752. Notably, this approval satisfying requirements for the 2008 and 2015 Ozone NAAQS was finalized after the August 2024 disapproval. See docket EPA–R03–OAR–2023–0300 for details.
26. Bulk Gasoline Plants	SOURCES OF VOC: Section 129.60.—Bulk gasoline plants.	CTG: Control of Volatile Organic Emissions from Bulk Gasoline Plants, EPA–450/2–77–035, December 1977.	5/13/93, 58 FR 28362.
27. Stage I Vapor Control System	SOURCES OF VOC: Section 129.61.—Small gasoline storage tank control (Stage I control). SOURCES OF VOC: Section 129.61a—Vapor leak monitoring procedures and other requirements for small gasoline storage tank emission control.	CTG: Design Criteria for Stage I Vapor Control Systems—Gasoline Service Stations, November 1975.	5/13/93, 58 FR 28362.
28. Leaks from Gasoline Tank Trucks and Vapor Collection Systems.	SOURCES OF VOC: Section 129.62.—General standards for bulk gasoline terminals, bulk gasoline plants and small gasoline storage tanks.	CTG: Control of Hydrocarbons from Tank Truck Gasoline Loading Terminals, EPA–450/2–77–026, December 1977. CTG: Control of Volatile Organic Compound Leaks from Gasoline Tank Trucks and Vapor Collection Systems, EPA–450/2–78–051, December 1978.	12/22/94, 59 FR 65971.
29. Solvent Metal Cleaning	SOURCES OF VOC: Section 129.63.—Degreasing operations.	CTG: Control of Volatile Organic Emissions from Solvent Metal Cleaning, EPA–450/2–77–022, November 1977.. ACT Document—Halogenated Solvent Cleaners, EPA–450/3–89–030, August 1989.	1/16/03, 68 FR 2208.
30. Industrial Cleaning Solvents (2006)	SOURCES OF VOC: Section 129.63a.—Industrial cleaning solvents.	CTG: Control of Volatile Organic Compounds from the use of Industrial Cleaning Solvents, EPA 453/R–06–001, September 2006.	12/14/20, 85 FR 80624.
31. Cutback Asphalt	SOURCES OF VOC: Section 129.64.—Cutback asphalt paving.	CTG: Control of Volatile Organic Compounds from Use of Cutback Asphalt, EPA–450/2–77–037, December 1977.	7/27/84, 49 FR 30183.
32. Graphic Arts—Rotogravure and Flexography.	SOURCES OF VOC: Section 129.67.—Graphic arts systems.	CTG: Control of Volatile Organic Emissions from Existing Stationary Sources, Volume VIII: Graphic Arts—Rotogravure and Flexography, EPA–450/2–78–033, December 1978.	8/10/18, 83 FR 39600.

TABLE 1—PREVIOUSLY APPROVED VOC CTG RACT REGULATIONS IN PENNSYLVANIA—Continued

CTG source category	Pa. regulation title 25. environmental protection, chapter 129	RACT basis cocument	SIP revision approved by the EPA (date and citation)
33. Flexible Package Printing (2006) ...	SOURCES OF VOC: Section 129.67a.—Control of VOC emissions from flexible packaging printing presses.	Updated: Control Techniques Guidelines for Flexible Package Printing, EPA 453/R–06–003, September 2006.	6/25/2015, 80 FR 36482.
34. Offset Lithographic Printing and Letterpress Printing Materials (2006).	SOURCES OF VOC: Section 129.67b.—Control of VOC emissions from offset lithographic printing presses and letterpress printing presses.	CTG: Control of Volatile Organic Emissions from Offset Lithographic Printing and Letterpress Printing, EPA 453/R–06–002, September 2006.	6/25/16, 80 FR 36482.
35. Manufacture of Synthesized Pharmaceutical Products.	SOURCES OF VOC: Section 129.68.—Manufacture of synthesized pharmaceutical products.	CTG: Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products, 450/2–78–029, December 1978.	5/13/1993, 58 FR 28362.
36. Pneumatic Rubber Tires	SOURCES OF VOC: Section 129.69.—Manufacture of pneumatic rubber tires.	CTG: Control of Volatile Organic Emissions from Manufacture of Pneumatic Rubber Tires, EPA–450/2–78–030, December 1978.	12/22/94, 59 FR 65971
37. Manufacture of High-density-Polyethylene, Polypropylene, and Polystyrene Resins.	SOURCES OF VOC: Section 129.71.—Synthetic organic chemical and polymer manufacturing—fugitive sources.	CTG: Control of Volatile Organic Compound Emissions from Manufacture of High-density-Polyethylene, Polypropylene, and Polystyrene Resins, EPA–450/3–83–008, November 1983.	12/22/94, 59 FR 65971.
38. Fugitive Emissions from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment.		CTG: Control of Volatile Organic Compound Fugitive Emissions from Synthetic Organic Chemical Polymer and Resin Manufacturing Equipment, EPA–450/3–83–006, March 1984.	
39. Aerospace	SOURCES OF VOC: Section 129.73.—Aerospace manufacturing and rework.	CTG: Aerospace (CTG & MACT) (see 59 FR 29216, June 6, 1994); CTG (Final), EPA–453/R–97–004, December 1997.	12/14/20, 85 FR 80624.
40. Fiberglass Boat Manufacturing Materials (2008).	SOURCES OF VOC: Section 129.74.—Control of VOC emissions from fiberglass boat manufacturing materials.	CTG: Control Techniques Guidelines for Fiberglass Boat Manufacturing Materials, EPA–453/R–08–004, September 2008.	8/17/16, 81 FR 54744.
41. Miscellaneous Industrial Adhesives (2008).	SOURCES OF VOC: Section 129.77.—Control of emissions from the use or application of adhesives, sealants, primers and solvents.	CTG: Miscellaneous Industrial Adhesives, EPA–453/R–08–005 September 2008.	6/25/2015, 80 FR 36482.
42. Wood Furniture	WOOD FURNITURE MANUFACTURING OPERATIONS: Sections 129.101–129.107.	CTG: Wood Furniture (CTG–MACT)—draft MACT out 5–94; Final CTG, EPA–453/R–96–007, April 1996; see also 61 FR 25223, and, 61 FR 50823, September 27, 1996.	7/20/01, 66 FR 37908.

The EPA is also proposing to determine that based on its review of PADEP's analysis, the State regulations contained in the May 10, 2023 SIP submission (see table 2 in this document) are sufficient to implement VOC CTG RACT requirements for the 2008 and 2015 Ozone Standards for SOCMI, Shipbuilding and Large Petroleum Dry Cleaning Categories.[31] The rationale is provided in the EPA's TSD and PADEP's analysis is available in the Commonwealth's January 20, 2026 SIP submission. Pennsylvania has no existing Large Petroleum Dry Cleaning facilities and an approved negative declaration.[32] The negative declaration from the EPA's December 14, 2020 approval was retained, not disapproved, in the EPA's August 16, 2024 reconsideration.[33] Pennsylvania is reaffirming in the January 20, 2026 submission that there are no existing sources in this category and that the negative declaration remains. See PADEP's ''2015 RACT Certification Document'' Section 7, in PADEP's January 20, 2026 submission for supporting information.[34]

[28] The CTG regulations for wood furniture coating and ship building are listed in table 1, CTG source category 42 of this document and table 2, CTG source category 46.

[29] The EPA approved PADEP's RACT SIP revision under the 1997 ozone NAAQS, including a negative declaration for this CTG on July 7, 2017 (82 FR 31464). PADEP's SIP revision noted that eight (8) sources previously coded in PADEP's stationary source inventory as flat wood paneling were recoded in the 2005 Air Information Management System (AIMS) to correctly reflect their operations as wood furniture and cabinet manufacturing. Pennsylvania's CTG based rule for flatwood paneling surface coating processes, 25 Pa. Code § 129.52c, was based on the 2006 CTG for Flat Wood Paneling Coating which is more stringent than the 1978 CTG for Surface Coating of Flat Wood Paneling.

[30] These are being approved as SIP strengthening measures, see section B number 21 and 22 of EPA's TSD located in the docket for this action for supporting analysis. Docket Id. EPA–R03–OAR–2026–3764 in *regulations.gov*.

[31] *See* section B of the EPA's TSD located in the docket for this action for supporting analysis. Docket Id. EPA–R03–OAR–2026–3764 in *regulations.gov*.

[32] *See* 85 FR 80616, 80617 (Dec. 14, 2020).

[33] *See* 89 FR 66599, 66600 (Aug. 16, 2024).

[34] *See* section 7 of PADEP's ''2015 RACT SIP Certification Document'' located in the docket for this action. Docket Id. EPA–R03–OAR–2026–3764 in *regulations.gov*.

TABLE 2—NEW VOC CTG RACT REGULATIONS FOR SOCMI, SHIPBUILDING AND LARGE PETROLEUM DRY CLEANERS

CTG source category	Pa. regulation title 25. environmental protection, chapter 129	RACT basis document	SIP revision approved by the EPA (date and citation)
43. SOCMI Distillation and Reactor Processes.	SOURCES OF VOC: Section 129.71—Synthetic organic chemical and polymer manufacturing—fugitive sources. SOURCES OF VOC: Added new section 129.71a—Control of VOC emissions from the synthetic organic chemical manufacturing industry—air oxidation, distillation and reactor processes.	CTG: Control of Volatile Organic Compound Emissions from Reactor Processes and Distillation Operations Processes in the Synthetic Organic Chemical Manufacturing Industry, EPA-450/4-91-031, August 1993.	Submission date: 5/12/23. PADEP is requesting that EPA approves and incorporates amended 25 Pa. Code Chapter 121.1, and newly added 25 Pa. Code 129.71a as part of the Commonwealth's SIP. 25 Pa. Code 129.71 is already approved into the SIP, as noted in Table 1.
44. Large petroleum dry cleaners	SOURCES OF VOC: Pennsylvania added new section 25 Pa. Code Chapter 129.63b.	CTG: Control of VOC emissions from large petroleum dry cleaners EPA–450/3–82–009, September 1982.	Submission date: 5/12/23. PADEP is requesting that EPA approves and incorporates 25 Pa. Code Chapter 129.63b as part of the Commonwealth's SIP.
45. SOCMI Air Oxidation, Processes ...	SOURCES OF VOC: Section 129.71—Synthetic organic chemical and polymer manufacturing—fugitive sources.. SOURCES OF VOC: Section 129.71a—Control of VOC emissions from the synthetic organic chemical manufacturing industry—air oxidation, distillation and reactor processes.	CTG: Control of VOC emissions from the synthetic organic chemical manufacturing industry (SOCMI)—air oxidation, EPA–450/3–84–015, December 1984.	Submission date: 5/12/23. PADEP is requesting that EPA approves and incorporates 25 Pa. Code Chapter 129.71a as part of the Commonwealth's SIP.
46. Shipbuilding and ship repair facilities with surface coating operations.	Pennsylvania amended 25 Pa. Code Chapter 129.52.	CTG: Control of VOC emissions from the shipbuilding and ship repair facilities with surface coating operations, 61 FR–44050, August 1996.	Submission date: 5/12/23. PADEP is requesting that EPA approves and incorporates amendments made to 25 Pa. Code Chapter 129.52 as part of the Commonwealth's SIP.

Pennsylvania conducted its RACT analysis for CTGs by: (1) identifying all applicable categories of CTGs within the Commonwealth; (2) listing the Commonwealth regulation that implements RACT requirements for each CTG; (3) submitting a negative declaration when there are no CTG applicable sources within the Commonwealth; and (4) performing a due diligence analysis on each CTG regulation.

Pennsylvania performed the due diligence analyses in accordance with the EPA's December 19, 2024 ''Due Diligence Review Framework for Air Agencies Developing RACT SIP Revisions,'' to demonstrate that its CTG RACT submittals for the Commonwealth are sufficient to meet VOC CTG RACT requirements under the 2008 and 2015 ozone NAAQS.[35] In Appendix A–2 and B–2 of the January 20, 2026 submission, the Commonwealth details the basis for concluding that its SIP submittals fulfill VOC CTG RACT through comparison with RACT rules developed by other States, CTG documents, results from the review of the RACT/BACT/LAER clearinghouse (RBLC), and other readily available resources. See the EPA's TSD for the EPA's own analysis and summary of PADEP's SIP submission.

B. Certifying Permits for Facilities Covered by the CTG for the Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins as VOC CTG RACT

Pennsylvania does not have regulations for sources covered by the CTG for the Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins [36] located in the Commonwealth. Rather than adopt categorical rules for sources falling into this CTG category, Pennsylvania requested that the EPA approve specific portions of source-specific, federally enforceable permits for the pertinent facilities for incorporation into the Pennsylvania SIP, listed in table 3, in this document. Three of these permits were submitted to the EPA as a SIP revision on February 17, 2026.

[35] *See* Ozone NAAQS Resource Document: Due Diligence Review Framework for Air Agencies Developing RACT SIP Revisions *www.epa.gov/ground-level-ozone-pollution/resource-document-air-agencies-developing-ract-sip-revisions-ozone.*

[36] *See* EPA–450/3–83–008, Nov. 1983 available at *nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=000029VI.txt.*

TABLE 3—PERMITS FOR FACILITIES COVERED BY THE CTG FOR THE MANUFACTURE OF HIGH-DENSITY POLYETHYLENE, POLYPROPYLENE, AND POLYSTYRENE RESINS

[EPA–450/3–83–008]

Facility name	Permit No.
MULTI PLASTICS EXTRUSIONS INC/HAZLETON	40–00083
ROHM & HAAS CO/BRISTOL	09–00015
SHELL CHEMICAL APPALACHIA	04–00740
BASF MONACA *	04–00306

* Previously approved by the EPA as RACT for the 1997 ozone NAAQS (see 66 FR 52705 October 17, 2001).

A fourth facility, BASF Monaca (04–00306), was also determined to have equipment subject to this CTG. CTG Requirements for the affected sources in Permit No 04–00306 were previously approved by the EPA as RACT for the 1997 ozone NAAQS at the BASF Monaca Plant.[37] After reviewing the conditions in this permit, PADEP determined that RACT requirements applicable to subject sources at BASF, that are already approved into the SIP for the 1997 ozone NAAQS, remain adequate to implement VOC CTG RACT for the 2008 and 2015 ozone NAAQS. A Certification SIP was submitted to the EPA on April 10, 2026 and was based on the due diligence analysis outlined in section C of the EPA's TSD.

The EPA is proposing to approve specific portions of the initial three permits listed in Table 3, in this document, (40–0083, 09–00015,04–00740) for incorporation into the SIP to fulfill the Commonwealth's VOC CGT RACT requirements for the category of sources covered by the CTG for the Manufacture of High-Density Polyethylene, Polypropylene, and Polystyrene Resins for the 2008 and 2015 Ozone NAAQS. These redacted permits that the EPA proposes for incorporation by reference were included in the February 17, 2026 SIP submission. Additionally, the EPA is proposing to determine that the controls in the BASF permit (04–00306), that were previously approved into the SIP to fulfill the 1997 ozone RACT requirements for this CTG, remain VOC CTG RACT for the 2008 and 2015 ozone NAAQS.

III. Proposed Action

The EPA's review of these materials indicates that PADEP's submittals are adequate to meet the ozone-specific RACT requirements for VOC CTG sources of CAA sections 172(c)(1), 182(b)(2)(A) and (B) and 184(b)(1)(B) of the CAA, for the 2008 and 2015 8-hour ozone NAAQS and are in accordance with CAA section 110. Therefore, the EPA is proposing to approve the four Pennsylvania SIP revisions relating to VOC CTG RACT for the 2008 and 2015 ozone NAAQS, which were submitted on May 10, 2023, January 20, 2026, February 17, 2026, and April 10, 2026. Consistent with this proposed finding, the EPA also proposes that these materials are sufficient to address the deficiencies outlined in the August 2024 disapproval.

The following bullets were adapted from the August 2024 disapproval final rule publication in 89 FR 66599, August 16, 2024, section IV, labeled ''Final Action.'' Accompanying these bullets are a brief explanation of how the May 10, 2023, January 20, 2026, February 17, 2026, and April 10, 2026, submissions address the deficiencies outlined in that disapproval action.

- In the August 16, 2024 (89 FR 66599) final rule, the EPA disapproved PADEP's certification that their adoption and implementation of regulations to control VOC emissions is consistent with the EPA's CTGs and represents RACT for these covered CTG sources for the 2008 ozone standard. The EPA determined that it erred in previously approving the CTG portion of PADEP's RACT certification SIP, as there was insufficient support in the record that the identified provisions fulfilled the RACT requirements of the 2008 8-hour ozone NAAQS for CTG sources. The January 20, 2026 submission contains extensive technical analysis for all of the PADEP's VOC CTG RACT regulations. In this action, the EPA is proposing that this analysis is sufficient to demonstrate that these provisions meet VOC CTG RACT requirements for the 2008 and 2015 Ozone NAAQS, thus resolving this issue.
- In the August 16, 2024 final rule, the EPA disapproved PADEP's incorporation of specific permit conditions for the purpose of establishing source-specific RACT-level controls for three facilities. Two facilities were subject to the ''Shipbuilding/Repair ACT (EPA 453/R–94–032, April 1994) and the EPA's CTG for Shipbuilding and Ship Repair Operations (Surface Coating) (61 FR 44050, August 27, 1996)'' and one facility was subject to ''Control of Volatile Organic Compound Emissions from Air Oxidation Processes in Synthetic Organic Chemical Manufacturing Industry, EPA–450/3–84–015, December 1984.'' Rather than promulgate a rule to address the RACT requirements of those CTGs for only three affected sources, PADEP incorporated the requirements of the CTGs into Federally enforceable permits and submitted the applicable permit limits for incorporation into the SIP. The EPA determined that the record did not support its conclusion that these permits met VOC CTG RACT requirements and disapproved those components of the submission. The May 12, 2023 submission contains new Rules for the Control of VOC emissions from the synthetic organic chemical manufacturing industry (SOCMI) air oxidation, (EPA–450/3–84–015, December 1984), Control of Volatile Organic Compound Emissions from Reactor Processes and Distillation Operations Processes in the Synthetic Organic Chemical Manufacturing Industry, (EPA 450/4 91 031, August 1993) and Shipbuilding and Ship Repair Facilities with Surface coating operations (See 61 FR–44050 August 1996). The submission also contains extensive technical analysis. The EPA is proposing that these newly adopted regulations and accompanying technical analysis demonstrate that these rules are sufficient to meet VOC CTG RACT for the 2008 and 2015 Ozone Standard, thus resolving this issue.
- In the August 16, 2024 final rule, the EPA disapproved the addition of 25 Pa. Code 129.63a (relating to the control of VOC from industrial cleaning solvents (ICS)) and the amendments to 25 Pa. Code sections 121.1 and 129.51, as PADEP's analysis did not look beyond the CTG requirements. PADEP's January 20, 2026 submission contains extensive technical analysis looking at resources beyond the CTG. This analysis can be reviewed in the attached TSD. The EPA is proposing in this action that this analysis demonstrated that PADEP's

[37] *See* 66 FR 52705, (Oct. 17, 2001).

Industrial Cleaning Solvent CTG is sufficient to meet VOC CTG RACT for the 2008 and 2015 Ozone Standard, thus resolving these issues.

The EPA is soliciting public comments on this proposed approval. These comments will be considered before taking final action.

IV. Incorporation by Reference

In this document, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the amendments to 25 Pa. Code Chapters 121.1, 129.52, and newly added 25 Pa. Code Chapters 129.63b and 129.71a effective January 21, 2023 (see annex A of the May 10, 2023 submission). The EPA is also proposing to incorporate by reference portions of permits described in section II of this document as redacted in Pennsylvania's February 20, 2026 SIP revision. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

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

- Is not a significant regulatory action subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Is not an Executive Order 14192 (90 FR 9065, February 6, 2025) regulatory action because this action is not significant under Executive Order 12866;
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it approves a State program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act.

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

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Amy Van Blarcom-Lackey,

Regional Administrator, Region III.

[FR Doc. 2026–14325 Filed 7–15–26; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R07–OAR–2026–4952; FRL–13457–01–R7]

Approval and Promulgation of State Plan (Negative Declaration) for Designated Facilities and Pollutants; Nebraska; Commercial and Industrial Solid Waste Incineration Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to accept a negative declaration submitted by the Nebraska Department of Water, Energy, and Environment (NDWEE) to satisfy the emission guidelines and associated compliance times requirements for Commercial and Industrial Solid Waste Incineration (CISWI) units for the State of Nebraska. The negative declaration certifies that there are no existing sources within the jurisdiction of Nebraska that must comply with the rule. This action is being taken in accordance with the Clean Air Act (CAA) requirements for emission guidelines and state plans for existing sources. In the ''Rules and Regulations'' section of this **Federal Register**, we are approving the State's negative declaration submission as a direct final rule without a prior proposed rule. If we receive no adverse comment, we will not take further action on this proposed rule.

DATES: Comments must be received by August 17, 2026.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2026–4952, to *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Allyson Prue, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7277; email address: *prue.allyson@epa.gov.*

SUPPLEMENTARY INFORMATION: This document proposes to take action on approving the State of Nebraska's negative declaration, submitted in accordance with 40 CFR 60.23(b) and 62.06, to satisfy requirements in the emission guidelines and compliance times for CISWI units. We have

published a direct final rule approving the State's negative declaration submission in the ''Rules and Regulations'' section of this **Federal Register**, because we view this as a noncontroversial action and anticipate no relevant adverse comment. We have explained our reasons for this action in the preamble to the direct final rule. If we receive no adverse comment, we will not take further action on this proposed rule. If we receive adverse comment, we will withdraw the direct final rule and it will not take effect. We would address all public comments in any subsequent final rule based on this proposed rule. We do not intend to institute a second comment period on this action. Any parties interested in commenting must do so at this time. For further information, please see the information provided in the **ADDRESSES** section of this document.

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Commercial and industrial solid waste incinerators, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: July 6, 2026.

James Macy,

Regional Administrator, Region 7.

[FR Doc. 2026–14329 Filed 7–15–26; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 493

[CMS–3485–NC]

RIN 0938–AW01

Request for Information; Clinical Laboratory Improvement Amendments of 1988 (CLIA) Regulations

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information.

SUMMARY: Clinical laboratory testing technology has advanced significantly since the Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations were implemented in 1992. This request for information (RFI) seeks input from the public regarding various topics related to the CLIA regulations, including: breath testing; laboratory processes and procedures; emergency preparedness, biosafety and biosecurity, and cybersecurity; and specialty testing areas. Responses to this RFI may be used to help inform CMS and the CDC as to what types of action, if any, should be taken to update the existing CLIA regulations through future notice and comment rulemaking.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 14, 2026.

ADDRESSES: In commenting, refer to file code CMS–3485–NC.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation at *https://www.regulations.gov/docket/CMS-2026-2345.* Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3485–NC, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3485–NC, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Penny Keller at *penny.keller@cms.hhs.gov,* 410–786–2035.

Jake D. Bunn at *jbunn@cdc.gov,* 404–498–4493.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov.* Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

On October 31, 1988, Congress enacted the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100–578), which amended section 353 of the Public Health Service Act (PHSA). CLIA requires all facilities that examine materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings to obtain a certificate from HHS. CLIA also requires such facilities to meet certain requirements such as maintaining a quality assurance and quality control program adequate and appropriate for the validity and reliability of the laboratory examinations and other procedures of the laboratory and maintaining laboratory personnel standards. The implementing regulations at 42 CFR part 493 specify, in part, the conditions and standards that a clinical laboratory must meet to achieve and maintain CLIA certification. These conditions and standards strengthen Federal oversight of clinical laboratories and help ensure the accuracy and reliability of patient test results.

II. Solicitation of Public Comments

This RFI seeks public comments on various topics related to the CLIA regulations. CMS and the CDC are issuing this RFI to gather input from the public regarding the following topics related to the CLIA regulations: (A) breath testing; (B) laboratory processes and procedures; (C) emergency preparedness, biosafety and biosecurity, and cybersecurity; and (D) specialty testing areas. CMS, the CDC, interested parties, and State Agency surveyors identified the topics in this RFI as areas in which the CLIA regulations may need to be updated to better reflect current knowledge and advancements in laboratory testing. Commenters are encouraged to identify the specific section and question number(s) (for example, Section A. Breath Testing, Question 1; Section B. Laboratory Processes and Procedures, Subsection 2. Specimen Preparation Activities and Personnel, Question 2) addressed in each portion of their submission and to organize comments consistent with the

structure of this RFI. We encourage input from a wide variety of interested parties on the questions set forth in this RFI.

A. Breath Testing

CMS and the CDC believe that testing using certain newer technologies may fall within the scope of CLIA and its implementing regulations because they may involve examination of ''materials derived from the human body for purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.'' For example, when the CLIA regulations were promulgated in 1992 (57 FR 7002),[1] breath testing had not yet been developed for clinical use and was only utilized for purposes of law enforcement. However, during the SARS-CoV–2 (COVID–19) Public Health Emergency (PHE), researchers and manufacturers developed breath tests for COVID–19, demonstrating an increased interest in expanding its clinical application. As breath testing is not specifically addressed in the current CLIA regulations, CMS has received inquiries regarding whether breath testing for cancer diagnosis, microbial identification, and gastrointestinal disorders is subject to CLIA and its implementing regulations.

CMS and the CDC seek public comments on breath testing used in clinical settings to inform whether updates to the CLIA regulations should be considered. In addition, we seek input on the following specific questions:

1. What breath tests are facilities performing for clinical use?
2. What methodologies and technologies do facilities use in breath testing for clinical use?
3. What type of facilities (such as hospitals, gastrointestinal clinics, and reference laboratories) perform breath testing for clinical use?
4. How do facilities collect, transport, and store clinical breath specimens? What challenges, if any, are encountered?

B. Laboratory Processes and Procedures

1. Pathology Specimen Block Retention

The CLIA regulatory requirement at § 493.1105(a)(7)(ii) currently stipulates that pathology specimen blocks must be retained for a minimum period of 2 years. However, advancements in molecular diagnostics now enable laboratories to perform retrospective testing on tissues more than 2 years old.

CMS and the CDC seek public comments on laboratories' experience with requests for additional testing on pathology specimen blocks beyond the required 2-year retention period. Specifically, we seek input on the following question:

1. What types of requests does the laboratory receive for additional testing on pathology specimen blocks after the required 2-year retention period, and how frequently does the laboratory receive them?

2. Specimen Preparation Activities and Personnel

The preanalytic phase of laboratory testing encompasses all processes that occur before the analytical testing, including specimen collection, preparation, and handling. The scope of specimen preparation activities is broad, encompassing processes such as centrifuging, aliquoting, tissue processing, slide staining, inoculating culture plates, and extracting ribonucleic acid (RNA) and deoxyribonucleic acid (DNA). At § 493.2, the definition of ''laboratory'' provides that facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories for CLIA certification purposes. Given the critical role that preanalytic processes play in ensuring accurate and reliable test results, and the potential impact of preanalytic errors on patient care, CMS and the CDC are soliciting public comment on the preanalytic practices currently employed by clinical laboratories, as well as the qualifications, education, and experience of personnel responsible for performing these activities. In addition, we seek input on the following specific questions:

1. What activities does the laboratory consider to be part of specimen preparation (for example, centrifuging, aliquoting, loading on analyzers, adding chemicals for preparation, tissue processing, slide staining, inoculating culture plates, DNA/RNA extraction)?
2. What is the education and experience of the personnel who perform specimen preparation activities for your laboratory?
3. What types of training does the laboratory provide for the personnel who perform specimen preparation activities?
4. How does the laboratory ensure that personnel who perform specimen preparation activities remain competent?

3. Suboptimal Specimens

Section 493.1242(a) of the CLIA regulations requires laboratories to establish and follow written policies and procedures for specimen acceptability and rejection. Clinical laboratories sometimes receive specimens in suboptimal conditions that do not meet their specimen acceptability policies and procedures and are asked by providers to perform testing. CMS has received inquiries regarding the handling of suboptimal specimens.

CMS and the CDC seek public comments on how laboratories address suboptimal specimens. In addition, we seek input on the following specific questions:

1. What are the circumstances under which the laboratory tests suboptimal specimens?
2. How often does your laboratory test suboptimal specimens annually?
3. How does the laboratory document and report results from suboptimal specimens?
4. How does the laboratory communicate with ordering providers regarding suboptimal specimens?
5. What quality assurance measures does the laboratory apply to the testing of suboptimal specimens?
6. What challenges does the laboratory face in managing suboptimal specimens while ensuring test result quality?

4. Establishment and Verification of Performance Specifications

The CLIA regulatory requirement at § 493.1253 requires laboratories to verify performance specifications when introducing any unmodified Food and Drug Administration (FDA)-cleared or approved test system, and to establish performance specifications when introducing any test system that is not FDA-cleared or approved, or that is a modification to an FDA-cleared or approved test system. The performance specifications required to be established at § 493.1253(b)(2) include accuracy, precision, analytical sensitivity, analytical specificity to include interfering substances, reportable range of test results for the test system, reference intervals (normal values), and any other performance characteristics required for test performance. CMS has received inquiries regarding the performance specifications of tests that are not FDA-cleared or approved, including modifications to FDA-cleared or approved tests.

[1] *Medicare, Medicaid and CLIA Programs; Regulations Implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA) Final Rule with Comment Period* (57 FR 7002, February 28, 1992), available at *https://tile.loc.gov/storage-services/service/ll/fedreg/fr057/fr057040/fr057040.pdf.*

CMS and the CDC seek public comments on how laboratories establish performance specifications for tests that are not FDA-cleared or approved, including modifications of FDA-cleared or approved tests. In addition, we seek input on the following specific questions:

1. For tests that are not FDA-cleared or approved, including modifications of FDA-cleared or approved tests, what challenges does the laboratory encounter when establishing adequate performance specifications and appropriate acceptance criteria? Specify the relevant test or procedure associated with such challenges.

2.a. What testing methods (for example, toxicology and next-generation sequencing (NGS)), and/or specific applications of those methods (for example, use of NGS to test for somatic or germline variants, minimal residual disease, methylation, bacterial resistance mutations, viral identification, or HLA matching), have unique performance characteristics that need to be established and are not already addressed in the CLIA regulations or guidance?

2.b. What are those performance characteristics (for example, stability studies, carry-over, internal standards, ionization, and clinical validity)?

3. How does the laboratory currently design, develop, and prepare reagents for tests developed in-house?

4. What types of modifications does the laboratory commonly make to FDA-cleared or approved test systems?

5. Calibration Verification

Calibration verification procedures are critical to ensuring the accuracy and reliability of clinical laboratory test systems. Section 493.1255 requires laboratories performing nonwaived testing to substantiate the continued accuracy of their test systems throughout the laboratory's reportable range of results. Specifically, § 493.1255(b)(1) requires laboratories to follow the manufacturer's calibration verification instructions.

Manufacturers design factory-calibrated, non-adjustable instruments, including closed systems and cartridge-based analyzers such as point-of-care test systems, with embedded reagents and calibration parameters that are locked at the time of manufacture. CMS has received inquiries regarding calibration verification for test systems that manufacturers entirely calibrate, and that end users cannot adjust.

CMS and the CDC seek public comments on calibration verification practices for factory-calibrated, non-adjustable instruments. In addition, we seek input on the following specific question:

1. What technical and operational challenges does the laboratory face when performing calibration verification on FDA-cleared or approved manufacturer-calibrated devices?

6. Postanalytic Interpretation and Use of Artificial Intelligence (AI)

CMS has received multiple inquiries regarding which postanalytic activities CMS considers part of the testing process. Test systems are becoming increasingly complex and integrated with advanced technology and AI systems. Certain software and software functions are subject to regulation as medical devices under the Federal Food, Drug, and Cosmetic Act.

As test systems become increasingly complex, CMS and the CDC seek public comments on the use of advanced technology or AI-assisted interpretation in clinical laboratories and the testing process. In addition, we seek input on the following specific questions:

1. How does the laboratory use software algorithms or AI tools in the postanalytic process?

2. Under what circumstances are software functions, including certain AI tools, used for the interpretation of the results of a test? For example, NGS, histocompatibility, and pharmacogenomics testing.

3. What roles do software functions, including certain AI tools, currently play in the interpretation of histopathology slides or results?

4. What methods do laboratories use to verify the performance of the software functions (including image resolution accuracy and quality, and AI tools as well as the performance of computers and monitors) used with a test system?

5. Are there additional technology considerations for high complexity tests, including but not limited to laboratory use of automation, laboratory use of cloud analytics, and laboratory use of artificial intelligence, that CMS and the CDC should consider incorporating into the CLIA regulations?

7. Data-Only Facilities

Section 493.2 of the CLIA regulations defines a ''laboratory'' as a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. In addition, § 493.2 defines ''distributive testing'' as laboratory testing performed on the same specimen, or an aliquot of it, that requires sharing it between two or more laboratories to obtain all data required to complete an interpretation or calculation necessary to provide a final reportable result for the originally ordered test. When such testing occurs at multiple locations with different CLIA certificates, CMS considers it distributive testing.

Facilities that only process analytical data or provide specialized data interpretation, some of which may be manufacturers of medical device software, have emerged. CMS has received inquiries on whether these types of data-only facilities require a CLIA certificate. These inquiries have in part focused on facilities that review and interpret genetic data, digital images, and perform calculations of risk factors.

CMS and the CDC seek public comments on data-only facilities. In addition, we seek input on the following question:

- What activities do data-only facilities perform to generate, or help to generate, test results and interpretations?

8. Remote Direct Observation Competency Assessment

Sections 493.1413(b)(8)(i) and (iv) and 493.1451(b)(8)(i) and (iv) of the CLIA regulations include direct observation of routine patient test performance and instrument maintenance and function checks as part of the evaluation of testing personnel competency by the technical consultant or technical supervisor. CMS has received requests from laboratories to include remote technology solutions in their competency assessment processes. Interested parties have advocated for the use of virtual competency assessments, particularly noting that facilities in rural areas would benefit from such remote assessment capabilities. At its November 2024 meeting, the Clinical Laboratory Improvement Advisory Committee (CLIAC) recommended that CMS allow remote assessment to be used for the direct observation component of competency assessment.[2] This recommendation included using both on-site and virtual access technology to assess laboratory personnel competency, especially in remote or rural areas where in-person assessments are difficult or expensive.

CMS and the CDC seek public comments, including evidence,

[2] CLIAC November 2024 Meeting Summary, *https://www.cdc.gov/cliac/php/meetings/index.html#cc-widget-e3e3.*

research, and trends on the use of remote technology to conduct the direct observation component of competency assessments for laboratory personnel. In addition, we seek input on the following specific questions:

1. How does the laboratory currently use remote direct observation for competency assessment?

2. What types of devices (for example, smartphones, tablets, virtual reality devices/glasses, and dedicated video systems) does the laboratory currently use for remote direct observation for competency assessment?

3. What challenges or limitations does the laboratory encounter with remote direct observation for competency assessment?

C. Emergency Preparedness, Biosafety and Biosecurity, and Cybersecurity

1. Emergency Preparedness

In 2016, CMS issued the Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers final rule,[3] which established national emergency preparedness requirements for certain healthcare provider types to ensure adequate planning for natural disasters, human-caused disasters, facility emergencies, and emerging infectious diseases. However, this rule did not include CLIA-certified independent laboratories in its scope.

A 2025 Office of Inspector General (OIG) Report recommended that CMS consider requiring independent laboratories that participate in Medicare to have emergency preparedness plans to better ensure that Medicare enrollees have access to diagnostic testing related to an emerging infectious disease or a biological toxin in the event of a future PHE.[4] CLIA and its implementing regulations encompass a broad spectrum of laboratories, ranging from physician offices to large reference laboratories. CLIA regulations apply to laboratories, as defined at § 493.2, regardless of their Medicare participation.

CMS and the CDC seek public comments on how laboratories prepare for emergencies and any associated operational challenges. In addition, we seek input on the following specific questions:

1. What are the best practices for laboratory emergency preparedness? Indicate the type of laboratory, for example, hospital-based or independent laboratory.

2. What challenges does the laboratory face in maintaining operations during emergencies such as natural and human-caused disasters, facility emergencies, and emerging infectious diseases?

3. What elements does the laboratory include in its current emergency preparedness plans and protocols?

4. What lessons has the laboratory learned from recent emergency situations (for example, natural disasters, pandemics, and power outages)?

2. Biosafety and Biosecurity

The CLIA regulatory requirement at § 493.1101 requires laboratories to, among other things, establish appropriate safety procedures and comply with applicable Federal, State, and local requirements. Sections 493.1407(e)(2) and 493.1445(e)(2) assign laboratory directors the responsibility for ensuring that physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards.

During the COVID–19 PHE, the CDC provided comprehensive guidance on biosafety and biosecurity protocols, risk assessments, and safety practices for laboratory personnel handling infectious materials.[5] This guidance highlighted the essential role of proper biosafety and biosecurity training in ensuring that laboratory personnel could safely conduct testing procedures while minimizing risks to themselves, their colleagues, and the broader community. This training was essential at the beginning of the COVID–19 PHE, when patient testing volumes and operational demands increased, along with exposure risks for personnel. Throughout the COVID–19 PHE, the CDC received numerous inquiries from laboratories regarding biosafety and biosecurity knowledge and training.

CMS and the CDC seek public comments on biosafety and biosecurity protocols, risk assessments, and safety practices for laboratory personnel handling infectious materials. Respondents should not include any information that might be considered proprietary or confidential. In addition, we seek input on the following specific questions:

1. What challenges does the laboratory face in biosafety and biosecurity?

2. What elements or best practices does the laboratory include in its current biosafety and biosecurity plans and protocols?

3. How does the laboratory train personnel on biosafety and biosecurity plans and protocols?

3. Cybersecurity

Cybersecurity threats across the healthcare sector have expanded in both scope and severity.[6] As clinical laboratories increasingly rely on digital systems and connected technologies—such as Laboratory Information System (LIS), Electronic Health Record (EHR) integration, automated diagnostic devices, and virtual or remote access to laboratory and patient data—new cybersecurity risks have emerged. Various HHS agencies have a role in cybersecurity.

CMS and the CDC seek public comments on laboratory cybersecurity practices and experiences. Respondents should not include any information that might be considered proprietary or confidential. In addition, we seek input on the following specific questions:

1. What cybersecurity protocols/policies does the laboratory have in place to protect patient data and laboratory operations?

1.a. What is the frequency and process you follow to verify new or existing user identity and access requirements?

1.b. Are individuals, entities, or both outside the U.S. and its Territories ever allowed to access your lab systems that contain personal information? If so, when and under what conditions?

1.c. How does your laboratory system(s) restrict ports and/or internet protocol (IP) addresses used to access the environment?

1.d. What elements are included in your cybersecurity incident response plan?

2. What challenges or experiences has the laboratory faced in maintaining cybersecurity?

[3] *Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers Final Rule,* 81 FR 63860 (September 16, 2016), available at *https://www.federalregister.gov/documents/2016/09/16/2016-21404/medicare-and-medicaid-programs-emergency-preparedness-requirements-for-medicare-and-medicaid.*

[4] U.S. Department of Health and Human Services, Office of Inspector General. *By Requiring Emergency Preparedness Plans for Independent Labs, CMS Could Better Ensure That Medicare Enrollees Have Access to Infectious-Disease Diagnostic Testing During a Public Health Emergency,* OIG Report. 2025, available at *https://oig.hhs.gov/reports/all/2025/by-requiring-emergency-preparedness-plans-for-independent-labs-cms-could-better-ensure-that-medicare-enrollees-have-access-toinfectious-disease-diagnostic-testing-during-a-public-health-emergency/.*

[5] Centers for Disease Control and Prevention (CDC), Laboratory Biosafety Guidelines for *Working* with SARS–CoV–2. *U.S. Department of Health and Human Services, https://www.cdc.gov/covid/php/lab/index.html*

[6] U.S. Department of Health and Human Services, Office for Civil Rights (OCR), *Breach Portal: Notice to the Secretary of HHS—Breach of Unsecured Protected Health Information. https://ocrportal.hhs.gov/ocr/breach/breach_report.jsf.*

3. Which laboratory job position(s) is responsible for cybersecurity in the laboratory?

4. How does the laboratory train personnel on cybersecurity?

D. Specialty Testing Areas

1. General

CMS has received inquiries about adding additional specialties to the CLIA regulations, including, but not limited to, Mohs testing, andrology, and molecular testing.

Given the rapid advancements in laboratory medicine, diagnostic technologies, and clinical practice patterns, CMS and the CDC are seeking public comments on operational challenges that laboratories encounter with specialties or subspecialties that are governed by the current CLIA regulations. In addition, we seek input on the following specific questions:

1. What specific challenges or limitations, if any, does your laboratory currently experience with the test specialty and subspecialty categories in the CLIA regulations? For example, are there areas where existing CLIA test specialty and subspecialty categories could be revised to better reflect current laboratory testing practices?

2. Are there additional specialties or subspecialties that CMS and the CDC should consider incorporating into the CLIA regulations to ensure comprehensive oversight of laboratory testing as specialties evolve? Provide evidence-based rationale supporting their inclusion, including considerations related to patient safety, testing complexity, and public health impact.

2. Clinical Cytogenetics

If a laboratory provides services in the specialty of clinical cytogenetics, in addition to requirements in other subparts of Part 493, the laboratory must meet the requirements set forth in §§ 493.1225, 493.1230 through 493.1256, 493.1276, and 493.1281 through 493.1299 of the CLIA regulations.

Clinical cytogenetics provides genetic testing for chromosome abnormalities associated with congenital disorders and cancer. Laboratories employ both conventional cytogenetic and molecular cytogenomic approaches, including fluorescence in situ hybridization (FISH), to analyze genomic abnormalities at chromosomal and subchromosomal levels. Cytogenetic test results are important in managing patients with constitutional genetic conditions and cancer, as well as providing risk assessments for genetic counseling.[7] Over the last 30 years, the field of clinical cytogenetics has seen significant technological advances, including molecular testing.[8]

CMS and the CDC seek public comments on technical advancements in clinical cytogenetic testing. In addition, we seek input on the following specific questions:

1. What clinical cytogenetics test procedures and technologies does the laboratory currently use?

2. What, if any, challenges does the laboratory face with existing CLIA regulations applicable to clinical cytogenetics?

3. Immunohematology

Immunohematology is an area of laboratory medicine that involves the selection and preparation of blood and blood components for transfusion as well as the monitoring of those components following transfusion.[9] Electronic crossmatching systems use computer algorithms to compare patient blood type information and antibody screening results with donor blood characteristics stored in Blood Establishment Computer Systems (BECS). The distinction between traditional serologic crossmatching and electronic crossmatching represents a fundamental shift in laboratory methodology. Serologic crossmatching involves the physical mixing of a patient specimen with donor red blood cells to directly test for compatibility reactions. Electronic crossmatching, by contrast, relies on validated computer systems that must receive FDA clearance, for which laboratories must verify performance specifications, with qualified technologists reviewing and approving all results despite the automated nature of the compatibility determination.[10] Since the CLIA regulations were promulgated, the field of immunohematology testing has seen significant medical and technological advancements.[11]

CMS and the CDC seek public comments on technical advancements in immunohematology. In addition, we seek input on the following specific questions:

1. What immunohematology practices and technologies does the laboratory currently use?

2. What, if any, challenges does the laboratory face with existing CLIA regulations for immunohematology?

3. What operational challenges does the laboratory face with electronic crossmatches?

4. What type of quality assurance issues does the laboratory encounter in electronic crossmatch compared to the traditional serologic crossmatch?

4. Microbiology

Blood culture contamination (BCC) represents a significant quality concern within microbiology specialty testing that directly impacts patient care outcomes, healthcare costs, and antimicrobial stewardship efforts. Contaminated blood cultures can lead to false-positive results, resulting in unnecessary antimicrobial therapy, extended hospital stays, additional diagnostic procedures, and increased healthcare expenditures. Furthermore, high contamination rates may mask true bacteremia cases and compromise the laboratory's ability to provide accurate diagnostic information to clinicians.

There are no specific CLIA regulations governing BCC rates or mandating systematic monitoring and corrective action protocols. At its November 2023 meeting, CLIAC recommended updating the CLIA regulations to include BCC rate monitoring within the laboratory quality management system.[12]

Considering the critical nature of blood culture testing in diagnosing life-threatening infections, CMS and the CDC seek public comments on how laboratories monitor BCC rates. In addition, we seek input on the following specific questions:

1. What best practices has the laboratory implemented to reduce and monitor BCC?

2. What challenges does the laboratory face in maintaining low blood culture contamination rates?

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[7] National Institute of Health (NIH), National Library of Medicine, Muhammad Zubair, et.al., *Genetics, Cytogenetic Testing and Conventional Karyotype, https://www.ncbi.nlm.nih.gov/books/NBK563293/.*

[8] Anniker Biliard, *Advances in Cytogenetic Technologies, types and their Applications*, Perspective, J Clin Exp Oncol, Vol: 13 Issue:2; *https://www.scitechnol.com/peer-review/advances-in-cytogenetic-technologies-types-and-their-applications-uNFB.php?article_id=26372#:~:text=Fluorescence%20In%20Situ%20Hybridization%20(FISH,and%20studying%20complex%20genomic%20rearrangements.*

[9] National Institute of Health (NIH), National Library of Medicine, Edward C C Wong, *Blood banking/immunohematology: special relevance to pediatric patients,* Pediatr Clin North Am, 2013 Dec;60(6):1541–68; *https://pubmed.ncbi.nlm.nih.gov/24237987/.*

[10] Food and Drug Administration (FDA), ''Computer Crossmatch'' (Computerized Analysis of the Compatibility between the Donor's Cell Type and the Recipient's Serum or Plasma Type); FDA, *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/computer-crossmatch-computerized-analysis-compatibility-between-donors-cell-type-and-recipients.*

[11] National Institute of Health (NIH), National Library of Medicine, Fernanda Morelati, et.al., *New technologies in immunohaematology; https://pmc.ncbi.nlm.nih.gov/articles/PMC2535883/#sec8.*

[12] CLIAC November 2023 Meeting Summary, *https://www.cdc.gov/cliac/php/meetings/index.html#cc-widget-e3e3.*

III. Collection of Information Requirements

This is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, we are not seeking proposals through this RFI and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFI; all costs associated with responding to this RFI will be solely at the interested party's expense. We note that not responding to this RFI does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor this RFI announcement for additional information pertaining to this request. In addition, we note that CMS will not respond to questions about the policy issues raised in this RFI.

We will actively consider all input as we develop future regulatory proposals or future subregulatory policy guidance. We may or may not choose to contact individual responders. Such communications would be for the sole purpose of clarifying statements in the responders' written responses. Contractor support personnel may be used to review responses to this RFI. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of this RFI may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. In addition, we may publicly post the public comments received, or a summary of those public comments.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 8, 2026.

Jay Bhattacharya, MD, Ph.D., Senior Official Carrying out the Delegable Duties of the Centers for Disease Control and Prevention Director, approved this document on July 13, 2026.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

[FR Doc. 2026–14358 Filed 7–15–26; 8:45 am]

BILLING CODE 4169–69–P

Notices

Federal Register
Vol. 91, No. 135
Thursday, July 16, 2026

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[Doc. No. AMS–FGIS–26–1123]

Grain Inspection Advisory Committee Meeting

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act, this notice announces an upcoming meeting of the Grain Inspection Advisory Committee (Committee). The Committee meets no less than once annually to advise the Secretary of Agriculture on the programs and services delivered by the Agricultural Marketing Service (AMS) under the U.S. Grain Standards Act. Recommendations by the Committee help AMS meet the needs of its customers, who operate in a dynamic and changing marketplace.

DATES: The meeting will be held on August 25, from 1:00 p.m. to 5:30 p.m. Central and on August 26, 2026, from 8:00 a.m. to 12:00 p.m. Central.

Written Comments: Any member of the public may file written comments with the Committee before or within 15 days after the date on which the meeting concludes. Comments should be submitted via email to *Anthony.T.Goodeman@usda.gov.* The Committee will consider comments submitted on or before 11:59 p.m. ET on August 10, 2026, prior to the meeting. Comments submitted after this date will be provided to the Committee, but the Committee may not have adequate time to consider those comments prior to the meeting. Comments submitted after the conclusion of the meeting will be posted on the public website.

Oral Comments: The Committee is providing the public an opportunity to present oral comments and will accommodate as many individuals and organizations as time permits. Persons or organizations wishing to make oral comments must pre-register by 11:59 p.m. ET, August 20, 2026, and may only register for one speaking slot. Instructions for registering and participating in the meeting can be obtained by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section by or before the deadline.

ADDRESSES: *Meeting Location:* The Committee meeting will take place at the AMS National Grain Center, 10383 N. Ambassador Drive, Kansas City, Missouri 64153. Further meeting details can be found at the Advisory Committee website at *https://www.ams.usda.gov/about-ams/facas-advisory-councils/giac.*

FOR FURTHER INFORMATION CONTACT: Anthony Goodeman by phone at (202) 720–0291 or by email at *Anthony.T.Goodeman@usda.gov.*

SUPPLEMENTARY INFORMATION: The purpose of the Committee is to provide advice to AMS with respect to the implementation of the U.S. Grain Standards Act (7 U.S.C. 71–87k). Information about the Committee is available on the AMS website at *https://www.ams.usda.gov/about-ams/facas-advisory-councils/giac.*

The agenda for the upcoming meeting will focus on grain inspection matters including, but not limited to, regulatory updates; technology modernization initiatives; inspection policies; and operational updates.

The meeting will be open to the public. Public participation will be limited to written statements and interested parties who have registered to present comments orally to the Committee.

Equal opportunity practices, in accordance with USDA policies, will be followed in all membership appointments to the Committee.

In accordance with Federal civil rights law and USDA civil rights regulations and policies, the USDA, its Agencies, offices, and employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Persons with disabilities who require alternative means of communication for program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the State or local Agency that administers the program or contact USDA through the Telecommunications Relay Service at 711 (voice and TTY). Additionally, program information may be made available in languages other than English.

Dated: July 13, 2026.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2026–14253 Filed 7–15–26; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 17, 2026 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day

Review—Open for Public Comments'' or by using the search function. An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Research Service

Title: Evaluation of User Satisfaction with NAL Internet Sites.

OMB Control Number: 0518–0040.

Summary of Collection: This is a reinstatement without change of a currently approved information collection request. The National Agricultural Library (NAL) measures user satisfaction with internet sites in order for NAL to comply with Executive Order 12862, which directs federal agencies that provide significant services directly to the public to survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services. NAL internet sites are a vast collection of web pages created and maintained by component organizations of NAL.

Need and Use of the Information: The purpose of the research is to ensure that intended audiences find the information provided on the internet sites easy to access, clear, informative, and useful. The research will provide a means by which to classify visitors to the NAL internet sites, to better understand how to serve them. The information generated from this research will enable NAL to evaluate the success of its web presence in support of its mission to facilitate the creation of agricultural knowledge through the acquisition, curation, and dissemination of the information needed to solve agricultural challenges today and in the future. If the information is not collected, NAL will be limited in its ability to provide accurate, timely information to its user community.

Description of Respondents: Individuals or households; business or other for-profit; not-for-profit institutions; farms; State, local or Tribal government.

Number of Respondents: 3,410.

Frequency of Responses: Reporting: annually.

Total Burden Hours: 419.

Rachelle Ragland-Greene,

Departmental Information Collection Clearance Officer.

[FR Doc. 2026–14297 Filed 7–15–26; 8:45 am]

BILLING CODE 3410–03–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and approval under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 17, 2026 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food Safety and Inspection Service

Title: Procedures for the Notification of New Technology.

OMB Control Number: 0583–0127.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18 and 2.53), as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, and properly labeled.

FSIS established flexible procedures to actively encourage the development and use of new technologies in meat and poultry establishments and egg products plants. These procedures facilitate notification to the Agency of any new technology that is intended for use in meat and poultry establishments and egg products plants so that the Agency can decide whether the new technology requires a pre-use review. A pre-use review often includes an in-plant trial.

Need and Use of the Information: FSIS will collect information to determine if a pre-use review is needed. If an in-plant trial is necessary, FSIS will request that the firm submit a protocol that is designed to collect relevant data to support the use of the new technology. To not collect this information would reduce the effectiveness of the meat, poultry, and egg products inspection program.

Description of Respondents: Business or other for-profit.

Number of Respondents: 210.

Frequency of Responses: Recordkeeping; Reporting: on occasion.

Total Burden Hours: 12,800.

Food Safety and Inspection Service

Title: Nutrition Labeling of Major Cuts of Single-Ingredient Raw Meat or Poultry Products and Ground or Chopped Meat and Poultry Products.

OMB Control Number: 0583–0148.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U. S.C. 601 *et. seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*) These statutes mandate that FSIS protect the public by verifying that meat and poultry products are safe, wholesome, and properly labeled. FSIS requires nutrition labeling of the major cuts of single-ingredients, raw meat and poultry products, unless an exemption applies. FSIS also requires nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. Further, the nutrition labeling requirements for all ground or chopped

meat and poultry products are consistent with the nutrition labeling requirements for multi-ingredient and heat processed products (9 CFR 381.400(a), 9 CFR 317.300(a), 9 CFR 317.301(a), 9 CFR 381.401(a)).

Need and Use of the Information: FSIS requires nutrition labeling of major cuts of single-ingredient, raw meat and poultry products, all ground or chopped meat and poultry products to ensure that consumers will use this information to make better informed nutrition choices when purchasing these meat and poultry products.

Description of Respondents: Business or other for-profit.

Number of Respondents: 76,439.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 67,861.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2026–14382 Filed 7–15–26; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding; whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments regarding this information collection received by August 17, 2026 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Animal and Plant Health Inspection Service

Title: Control of Chronic Wasting Disease.

OMB Control Number: 0579–0189.

Summary of Collection: The Animal Health Protection Act (AHPA) of 2002 is the primary Federal law governing the protection of animal health. The law gives the Secretary of Agriculture broad authority to detect, control, and eradicate pests or diseases of livestock or poultry, and to pay claims arising from destruction of animals. Disease prevention is the most effective method for maintaining a healthy animal population and enhancing the Animal and Plant Health Inspection Service (APHIS) ability to complete in exporting animals and animal products. Chronic wasting disease (CWD) is a transmissible spongiform encephalopathy (TSE) of elk, deer and moose typified by chronic weight loss leading to death. The presence of CWD disease in cervids causes significant economic and market losses to U.S. producers. To accelerate the control and limit the spread of this disease in the United States, APHIS created a cooperative, voluntary Federal-State-private sector CWD Herd Certification Program. The program is designed to identify farmed or captive herds infected with CWD and provided for the management of these herds in a way that reduces the risk of spreading CWD.

Need and Use of the Information: APHIS will collect information from owners of elk, deer, and moose herds who choose to participate in the CWD Herd Certification program. They would need to follow program requirements for animal identification, testing, herd management, and movement of animals into and from herds. APHIS also established requirements for the interstate movement of cervids to prevent movement of elk, deer, and moose that pose a risk of spreading CWD. Carrying out this program will entail the use of several information collection activities and three APHIS forms. Failing to collect it would make it impossible for APHIS to maintain its CWD Herd Certification Program, thereby hindering APHIS' ability to prevent and control the spread of CWD in the United States.

Description of Respondents: Business or other for-profit and not-for-profit; State, Local or Tribal Government.

Number of Respondents: 1,588.

Frequency of Responses: Reporting and Recordkeeping: On occasion.

Total Burden Hours: 162,510.

Rachelle Ragland-Greene,

Departmental Information Collection Clearance Officer.

[FR Doc. 2026–14258 Filed 7–15–26; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2026–0433]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Horse Protection Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with the Horse Protection Program and enforcement of the Horse Protection Act.

DATES: We will consider all comments that we receive on or before September 14, 2026.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2026–0433 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2026–0433, Regulatory Analysis and Development, PPD, APHIS, Regulatory Analysis and Development, PPD, APHIS, 5601 Sunnyside Ave., #AP760, Beltsville, MD 20705.

Supporting documents and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30

p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the Horse Protection Act Regulations, contact Ms. SaMonia Ford, APHIS, Animal Care, 2150 Centre Avenue, Building B, 3W11, Fort Collins, CO 80526; 970–494–7478; *AC.PublicComment@usda.gov.* For more information on the information collection reporting process, contact Ms. Sheniqua Harris, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2528 or email *APHIS.PRA@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Horse Protection Regulations.

OMB Control Number: 0579–0056.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Horse Protection Act (HPA) of 1970 (Pub. L. 91–540), as amended July 13, 1976 (Pub. L. 94–360), was enacted to prevent showing, exhibiting, selling, or auctioning of ''sore'' horses, and certain transportation of sore horses in connection therewith, at horse shows, horse exhibitions, horse sales, and horse auctions. ''Soring'' is a process whereby chemical or mechanical agents, or a combination thereof, are applied to the limbs(s) of a horse in order to exaggerate its gait(s). A ''sore'' horse is one that has been subjected to prohibited practices and, as a result, suffers, or can reasonably be expected to suffer, physical pain or distress, inflammation, or lameness when walking, trotting or otherwise moving. A horse that is ''sore'' is prohibited from entering or participating in HPA-regulated events because exhibitors, owners, and trainers of such horse may obtain unfair advantage over individuals exhibiting horses that are not ''sore.''

Section 1828 of the HPA authorizes the promulgation of regulations to implement the provisions of the Act. Those regulations are found in Title 9, Chapter I, Part 11, of the Code of Federal Regulations. The regulations delineate procedures relative to three processes:

(1) Certification of licensing programs for Designated Qualified Persons (DQPs) that are operated by Horse Industry Organizations (HIOs). Managers and operators of HPA-regulated events may appoint and retain the services of DQPs to inspect and detect a horse that is sore or otherwise noncompliant with the HPA (Section 1823(c) of the Act), (2) Responsibilities and liabilities of management (Section 1823(d) of the Act), and (3) Prohibitions and requirements concerning persons involved in transportation of certain horses (Section 1824, paragraph (1) of the Act).

An HIO wishing to certify a program to license DQPs to inspect horses for compliance under the HPA must satisfy and abide by the requirements of the HPA and regulations. After requesting and receiving United States Department of Agriculture (USDA) certification from the Animal and Plant Health Inspection Service (APHIS), HIOs must maintain an acceptable DQP program and recordkeeping systems. The responsibilities of HIOs, DQPs, event management, and horse transporters are outlined in the regulations.

APHIS works with HIOs on an ongoing basis to oversee their performance under the HPA. Throughout the year, APHIS uses training sessions, conference calls, and open letters to HIOs, event managers, exhibitors, owners, trainers, custodians, and farriers involved in HPA-covered activities to provide communication and feedback to address issues and strengthen enforcement under the Act. Data collected throughout the year from within APHIS and from the HIOs and event management provide an account of the HIOs' performance and progress toward eliminating the soring of horses and promoting fair competition. HIOs, through their certified licensing programs for DQPs, provide the primary means of detecting sored horses.

Title 9, Chapter I, Part 12, of the Code of Federal Regulations provides the Rules of Practice applicable to adjudicatory, administrative proceedings under Sections 1825(a), (b) and (c) of the HPA. Subpart A incorporates the Uniform Rules of Practice for the Department of Agriculture promulgated in subpart H of Part 1, subtitle A, title 7, Code of Federal Regulations. Subpart B sets forth Supplemental Rules of Practice allowing stipulations in settlement of particular matters if specified procedures are followed.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities for 3 years. APHIS has amended this information collection by decreasing the number of Respondents resulting in a decrease in Responses and Total Burden Hours being reported for the collection.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 1.235 hours per response.

Estimated annual number of respondents: 380.

Estimated annual number of responses per respondent: 6.

Estimated annual number of responses: 1,934.

Estimated total annual burden on respondents: 2,389 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 13th day of July 2026.

Kelly Moore,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2026–14321 Filed 7–15–26; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2026–0826]

Notice of Request for Revision to and Extension of Approval of an Information Collection; Citrus Canker, Citrus Greening, and Asian Citrus Psyllid; Quarantine and Interstate Movement Regulations

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to

request a revision to and extension of approval of an information collection associated with the regulations to prevent the spread of citrus canker, citrus greening, and citrus greening's vector, the Asian citrus psyllid, to noninfested areas of the United States.

DATES: We will consider all comments that we receive on or before September 14, 2026.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2026–0826 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2026–0826, Regulatory Analysis and Development, PPD, APHIS, 5601 Sunnyside Ave., #AP760, Beltsville, MD 20705.

Supporting documents and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: For information on the regulations for the interstate movement of regulated articles to prevent the spread of citrus canker, citrus greening, and citrus greening's vector, the Asian citrus psyllid, contact Dr. Abby Stilwell, National Policy Manager for Citrus Health Response Program, EDP, PPQ, APHIS, 920 Main Campus Drive, Suite 200, Raleigh, NC 27606; (919)–323–6296. For information on the information collection reporting process, contact Ms. Sheniqua Harris, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2528 or email *APHIS.PRA@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: Citrus Canker, Citrus Greening, and Asian Citrus Psyllid; Quarantine and Interstate Movement Regulations.

OMB Control Number: 0579–0363.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: The Plant Protection Act (PPA, 7 U.S.C. 7701 *et seq.*) authorizes the Secretary of the U.S. Department of Agriculture (USDA), either independently or in cooperation with States, to carry out operations or measures to detect, eradicate, suppress, control, prevent, or retard the spread of plant pests and diseases that are new to or not widely distributed within the United States. Under the Act, the Secretary may also issue regulations requiring plants and plant products moved in interstate commerce to be subject to remedial measures determined necessary to prevent the spread of the pest or disease, or requiring the objects to be accompanied by a permit issued by the Secretary prior to movement. The USDA's Animal and Plant Health Inspection Service (APHIS) administers the regulations to implement the PPA.

Citrus canker is a plant disease that is caused by the bacterium *Xanthomonas citri* subsp. *citri* that affects plants and plant parts of citrus and citrus relatives of the Rutaceae family. Citrus canker can cause defoliation and other serious damage to the leaves and twigs of susceptible plants. It can also cause lesions on the fruit of infected plants and cause infected fruit to drop from trees before reaching maturity. The aggressive A (Asiatic) strain of citrus canker can infect susceptible plants rapidly and lead to extensive economic losses in commercial citrus-producing areas. Citrus greening, also known as Huanglongbing, is considered to be one of the most serious citrus diseases in the world. Citrus greening is a bacterial disease that attacks the vascular system of host plants. This bacterial pathogen can be transmitted by grafting and, under laboratory conditions, by parasitic plants. The pathogen can also be transmitted by two insect vectors, one of which is *Diaphorina citri* Kuwayama, the Asian citrus psyllid (ACP). ACP can also cause economic damage to citrus in groves and nurseries by direct feeding. Both adults and nymphs feed on young foliage, depleting the sap and causing galling or curling of leaves. High populations feeding on a citrus shoot can kill the growing tip.

Under the regulations in ''Subpart M-Citrus Canker'' (7 CFR 301.75–1 through 301.75–17) and ''Subpart N-Citrus Greening and Asian Citrus Psyllid'' (7 CFR 301.76 through 301.76–11), APHIS restricts the interstate movement of regulated articles from quarantined areas to control the artificial spread of citrus canker and citrus greening and its vector, ACP, to noninfested areas of the United States. The regulations contain requirements that involve information collection activities, including labeling; recordkeeping; and appealing the cancellation of a certificate, permit, or compliance agreement.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years. APHIS has amended this information collection by removing PPQ Form 519 (Compliance Agreement), PPQ Form 530 (Limited Permit), PPQ Form 540 (Federal Certificate) and PPQ Form 523 (Emergency Action Notification) and moving these activities to a new PPQ Permit information collection. In addition, the total annual respondents has decreased.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate whether the collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.398 hours per response.

Respondents: Commercial nurseries/operations in U.S. States or U.S. Territories quarantined for citrus canker, citrus greening, or ACP.

Estimated annual number of respondents: 593.

Estimated annual number of responses per respondent: 16,609.

Estimated annual number of responses: 9,849,138.

Estimated total annual burden on respondents: 325,201 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 9th day of July 2026.

Kelly Moore,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2026–14323 Filed 7–15–26; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Administration

National School Lunch, Special Milk, and School Breakfast Programs, National Average Payments/Maximum Reimbursement Rate

AGENCY: Food and Nutrition Administration (FNA), USDA

ACTION: Notice.

SUMMARY: This Notice announces the annual adjustments to the national average payments, the amount of money the Federal Government provides States for lunches, afterschool snacks, and breakfasts served to children participating in the National School Lunch and School Breakfast Programs; to the maximum reimbursement rates, the maximum per lunch rate from Federal funds that a State can provide a school food authority for lunches served to children participating in the National School Lunch Program; and to the rate of reimbursement for a half-pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. The annual payments and rates adjustments for the National School Lunch and School Breakfast Programs reflect changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers. The annual rate adjustment for the Special Milk Program reflects changes in the Producer Price Index for Fluid Milk Products. Further adjustments are made to these rates to reflect higher costs of providing meals in Alaska, Guam, Hawaii, Puerto Rico, and Virgin Islands. The payments and rates are prescribed on an annual basis each July.

DATES: These rates are in effect from July 1, 2026, through June 30, 2027.

FOR FURTHER INFORMATION CONTACT: Penny Burke, Branch Chief, Program Monitoring and Operational Support Division, Child Nutrition Programs, FNA USDA, 1400 Independence Avenue SW, Washington, DC 20250, 720–822–8597.

SUPPLEMENTARY INFORMATION:

Background

Special Milk Program for Children—Pursuant to section 3 of the Child Nutrition Act of 1966, as amended (42 U.S.C. 1772), the Department announces the rate of reimbursement for a half pint of milk served to non-needy children in a school or institution that participates in the Special Milk Program for Children. This rate is adjusted annually to reflect changes in the Producer Price Index for Fluid Milk Products, published by the Bureau of Labor Statistics of the Department of Labor.

National School Lunch and School Breakfast Programs—Pursuant to sections 11 and 17A of the Richard B. Russell National School Lunch Act, (42 U.S.C. 1759a and 1766a), and section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773), the Department annually announces the adjustments to the National Average Payment Factors and to the maximum Federal reimbursement rates for lunches and afterschool snacks served to children participating in the National School Lunch Program and breakfasts served to children participating in the School Breakfast Program. Adjustments are prescribed each July 1, based on changes in the Food Away From Home series of the Consumer Price Index for All Urban Consumers, published by the Bureau of Labor Statistics of the Department of Labor.

Lunch Payment Levels—Section 4 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1753) provides general cash for food assistance payments to States to assist schools in purchasing food. The Richard B. Russell National School Lunch Act provides two different section 4 payment levels for lunches served under the National School Lunch Program. The lower payment level applies to lunches served by school food authorities in which less than 60 percent of the lunches served in the school lunch program during the second preceding school year were served free or at a reduced price. The higher payment level applies to lunches served by school food authorities in which 60 percent or more of the lunches served during the second preceding school year were served free or at a reduced price.

To supplement these section 4 payments, section 11 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1759a) provides special cash assistance payments to aid schools in providing free and reduced-price lunches. The section 11 National Average Payment Factor for each reduced-price lunch served is set at 40 cents less than the factor for each free lunch.

As authorized under sections 8 and 11 of the Richard B. Russell National School Lunch Act (42 U.S.C. 1757 and 1759a), maximum reimbursement rates for each type of lunch are prescribed by the Department in this Notice. These maximum rates are to ensure equitable disbursement of Federal funds to school food authorities.

Performance-based Reimbursement—In addition to the funding mentioned above, school food authorities certified as meeting the meal pattern and nutrition standard requirements set forth in 7 CFR parts 210 and 220 are eligible to receive performance-based cash assistance for each reimbursable lunch served.

Afterschool Snack Payments in Afterschool Care Programs—Section 17A of the Richard B. Russell National School Lunch Act (42 U.S.C. 1766a) establishes National Average Payments for free, reduced-price, and paid afterschool snacks as part of the National School Lunch Program.

Breakfast Payment Factors—Section 4 of the Child Nutrition Act of 1966 (42 U.S.C. 1773) establishes National Average Payment Factors for free, reduced-price, and paid breakfasts served under the School Breakfast Program and additional payments for free and reduced-price breakfasts served in schools determined to be in ''severe need'' because they serve a high percentage of free and reduced eligible children.

Adjusted Payments

The following specific section 4, section 11, and section 17A National Average Payment Factors and maximum reimbursement rates for lunch, the afterschool snack rates, and the breakfast rates are in effect from July 1, 2026, through June 30, 2027. Due to a higher cost of living, the average payments and maximum reimbursements for Alaska, Guam, Hawaii, Puerto Rico, and Virgin Islands are higher than those for all other States. The District of Columbia uses figures specified for the contiguous States. These rates do not include the value of USDA Foods or cash-in-lieu of USDA Foods, which schools receive as additional assistance for each meal served to participants under the Program. A notice announcing the value of USDA Foods and cash-in-lieu of USDA Foods is published separately in the **Federal Register**.

Adjustments to the national average payment rates for all lunches served under the National School Lunch Program, breakfasts served under the School Breakfast Program, and afterschool snacks served under the National School Lunch Program are rounded down to the nearest whole cent.

Special Milk Program Payments

For the period July 1, 2026, through June 30, 2027, the rate of reimbursement for a half pint of milk served to a non-needy child in a school or institution that participates in the Special Milk Program is 28.00 cents. This change is

based on the 4.18 percent increase in the Producer Price Index for Fluid Milk Products from May 2025 to May 2026.

As a reminder, schools or institutions with pricing programs that elect to serve milk free to eligible children continue to receive the average cost of a half pint of milk (the total cost of all milk purchased during the claim period divided by the total number of purchased half pints) for each half pint served to an eligible child.

National School Lunch Program Payments

Overall, payments for the National School Lunch Program and the Afterschool Snack Program reflect 3.54 percent increase in the national average payment rates for schools and residential child care institutions for the period July 1, 2026, through June 30, 2027 in the Consumer Price Index for All Urban Consumers for the Food Away From Home series during the 12-month period May 2025 to May 2026 (from a level of 381.228 in May 2025, as previously published in the **Federal Register** to 394.728 in May 2026)

These changes are reflected below.

Section 4 National Average Payment Factors– In school food authorities that served less than 60 percent free and reduced-price lunches in School Year (SY) 2024–2025, the payments for meals served are: *Contiguous States*—paid rate—45 cents (1 cent increase from the 2025–2026 rate); free and reduced-price rate—45 cents (1 cent increase); maximum rate—53 cents (1 cent increase); Alaska—paid rate—74 cents (3 cent increase); free and reduced-price rate—74 cents (3 cent increase); maximum rate—84 cents (1 cent increase); *Guam, Hawaii, Puerto Rico, and Virgin Islands*—paid rate—59 cents (2 cents increase); free and reduced-price rate—59 cents (2 cent increase); maximum rate 68 cents (1 cent increase).

In school food authorities that served 60 percent or more free and reduced-price lunches in SY 2024–2025, payments are: *Contiguous States*—paid rate—47 cents (1 cent increase); free and reduced-price rate—47 cents (1 cent increase); maximum rate—53 cents (1 cent increase); *Alaska*—paid rate—76 cents (3 cents increase, free and reduced-price rate—76 cents (3 cent increase), maximum rate—84 cents (1 cent increase); *Guam, Hawaii, Puerto Rico, and Virgin Islands*—paid rate—61 cents (2 cents increase); free and reduced-price rate—61 cents (2 cent increase); maximum rate 68 cents (1 cent increase).

School food authorities certified to receive the performance-based cash assistance will receive an additional 9 cents (adjusted annually) added to the above amounts as part of their section 4 payments.

Section 11 National Average Payment Factors—Contiguous States– free lunch—4 dollars and 31 cents (15 cents increase from the SY 2025–2026 rate); reduced-price lunch—3 dollars and 91 cents (15 cents increase); *Alaska*—free lunch—6 dollars and 98 cents (24 cents increase), reduced-price lunch—6 dollars and 58 cents (24 cents increase); *Guam, Hawaii, Puerto Rico, and Virgin Islands*—free lunch—5 dollars and 60 cents (19 cents increase), reduced-price lunch—5 dollars and 20 cent (19 cents increase).

Afterschool Snacks in Afterschool Care Programs—The payments are: *Contiguous States*—free snack—1 dollar and 30 cents (4 cents increase from the SY 2025–2026), reduced-price snack—65 cents (2 cents increase), paid snack—12 cents (1 cents increase); *Alaska*—free snack—2 dollars and 12 cents (8 cents increase), reduced-price snack—1 dollar and 6 cents (4 cents increase), paid snack—19 cents (1 cent increase); *Guam, Hawaii, Puerto Rico, and Virgin Islands*—free snack—1 dollar and 70 cents (6 cents increase), reduced-price snack—85 cents (3 cents increase), paid snack—15 cents (no change).

School Breakfast Program Payments

Overall, payments for the School Breakfast Program reflect a 3.54 percent increase in the national average payment rates for schools and residential child care institutions for the period July 1, 2026, through June 30, 2027 in the Consumer Price Index for All Urban Consumers in the Food Away From Home series during the 12-month period May 2025 to May 2026 (from a level of 381.228 in May 2025, as previously published in the **Federal Register** to 394.728 in May 2026).

These changes are reflected below.

For schools ''not in severe need'' the payments are: *Contiguous States*—free breakfast—2 dollars and 54 cents (8 cents increase from the SY 2025–2026 rate), reduced-price breakfast—2 dollars and 24 cents (8 cents increase), paid breakfast—42 cents (2 cent increase); *Alaska* free breakfast—4 dollars and 9 cents (14 cents increase), reduced-price breakfast—3 dollars and 79 cents (14 cents increase), paid breakfast—64 cents (2 cents increase); *Guam, Hawaii, Puerto Rico, and Virgin Islands*—free breakfast—3 dollars and 29 cents (11 cents increase), reduced-price breakfast—2 dollars and 99 cents (11 cents increase), paid breakfast—52 cents (1 cent increase).

For schools in ''severe need'' the payments are: *Contiguous States*—free breakfast—3 dollars and 5 cents (11 cents increase from the SY 2025–2026), reduced-price breakfast—2 dollars and 75 cents (11 cents increase), paid breakfast—42 cents (2 cent increase); *Alaska*—free breakfast—4 dollars and 90 cents (17 cents increase), reduced-price breakfast—4 dollars and 60 cents (17 cents increase), paid breakfast—64 cents (2 cents increase); *Guam, Hawaii, Puerto Rico, and Virgin Islands*—free breakfast—3 dollars and 94 cents (13 cents increase), reduced-price breakfast—3 dollars and 64 cents (13 cents increase), paid breakfast—52 cents (1 cent increase).

Payment Chart

The following chart illustrates the lunch National Average Payment Factors with the sections 4 and 11 already combined to indicate the per lunch amount; the maximum lunch reimbursement rates; the reimbursement rates for afterschool snacks served in afterschool care programs; the breakfast National Average Payment Factors including severe need schools; and the milk reimbursement rate. All amounts are expressed in dollars or fractions thereof. The payment factors and reimbursement rates used for the District of Columbia are those specified for the contiguous States.

BILLING CODE 3410–02–P

SCHOOL PROGRAMS *MEAL, SNACK, AND MILK PAYMENTS TO STATES AND SCHOOL FOOD AUTHORITIES* *Expressed in Dollars or Fractions Thereof* Effective from: July 1, 2026 to June 30, 2027							
NATIONAL SCHOOL LUNCH PROGRAM[1]		**LESS THAN 60%**	**LESS THAN 60% + 9 cents[2]**	**60% OR MORE**	**60% or MORE + 9 cents[2]**	**MAXIMUM RATE**	**MAXIMUM RATE + 9 cents[2]**
CONTIGUOUS STATES	PAID	0.45	0.54	0.47	0.56	0.53	0.62
	REDUCED-PRICE	4.36	4.45	4.38	4.47	4.53	4.62
	FREE	4.76	4.85	4.78	4.87	4.93	5.02
ALASKA	PAID	0.74	0.83	0.76	0.85	0.84	0.93
	REDUCED-PRICE	7.32	7.41	7.34	7.43	7.57	7.66
	FREE	7.72	7.81	7.74	7.83	7.97	8.06
GUAM, HAWAII, PUERTO RICO, and VIRGIN ISLANDS	PAID	0.59	0.68	0.61	0.70	0.68	0.77
	REDUCED-PRICE	5.79	5.88	5.81	5.90	6.00	6.09
	FREE	6.19	6.28	6.21	6.30	6.40	6.49

SCHOOL BREAKFAST PROGRAM		**NON-SEVERE NEED**	**SEVERE NEED**
CONTIGUOUS STATES	PAID	0.42	0.42
	REDUCED-PRICE	2.24	2.75
	FREE	2.54	3.05
ALASKA	PAID	0.64	0.64
	REDUCED-PRICE	3.79	4.60
	FREE	4.09	4.90
GUAM, HAWAII, PUERTO RICO, and VIRGIN ISLANDS	PAID	0.52	0.52
	REDUCED-PRICE	2.99	3.64
	FREE	3.29	3.94

SPECIAL MILK PROGRAM	**ALL MILK**	**PAID MILK**	**FREE MILK**
PRICING PROGRAMS WITHOUT FREE OPTION	0.28	N/A	N/A
PRICING PROGRAMS WITH FREE OPTION	N/A	0.28	Average Cost Per 1/2 Pint of Milk
NONPRICING PROGRAMS	0.28	N/A	N/A

AFTERSCHOOL SNACKS SERVED IN AFTERSCHOOL CARE PROGRAMS		
CONTIGUOUS STATES	PAID	0.12
	REDUCED-PRICE	0.65
	FREE	1.30
ALASKA	PAID	0.19
	REDUCED-PRICE	1.06
	FREE	2.12
GUAM, HAWAII, PUERTO RICO, and VIRGIN ISLANDS	PAID	0.15
	REDUCED-PRICE	0.85
	FREE	1.70

[1] Payment listed for Free and Reduced-Price Lunches include both section 4 and section 11 funds

[2] Performance-based cash reimbursement (adjusted annually for inflation)

BILLING CODE 3410–02–C

This action is not a rule as defined by the Regulatory Flexibility Act (5 U.S.C. 601–612) and thus is exempt from the provisions of that Act. This notice has

been determined to be exempt under Executive Order 12866.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507), no new recordkeeping or reporting requirements have been included that are subject to approval from the Office of Management and Budget.

National School Lunch, School Breakfast, and Special Milk Programs are listed in the Catalog of Federal Domestic Assistance under No. 10.555, No. 10.553, and No. 10.556, respectively, and are subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials (See 2 CFR 415.3–415.6).

Authority: Sections 4, 8, 11, and 17A of the Richard B. Russell National School Lunch Act, as amended, (42 U.S.C. 1753, 1757, 1759a, 1766a) and sections 3 and 4(b) of the Child Nutrition Act, as amended, (42 U.S.C. 1772 and 42 U.S.C. 1773b).

Shiela Corley,

Acting Administrator, Food and Nutrition Administration, USDA.

[FR Doc. 2026–14252 Filed 7–15–26; 8:45 am]

BILLING CODE 3410–30–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meetings of the Montana Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: Commission on Civil Rights.

ACTION: Announcement of public briefings.

SUMMARY: Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act, that the Montana Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a public briefing every second Thursday of the month (September 2026 through December 2026) via Zoom at 3:00 p.m. MT. The purpose of these briefings is to hear testimony concerning potential civil rights violations resulting from Diversity, Equity, and Inclusion Policies at Montana Public Universities.

DATES:

- Thursday, September 10, 2026, from 3:00 p.m.–4:00 p.m. Mountain Time
- Thursday, October 8, 2026, from 3:00 p.m.–4:00 p.m. Mountain Time
- Thursday, November 12, 2026, from 3:00 p.m.–4:00 p.m. Mountain Time
- Thursday, December 10, 2026, from 3:00 p.m.–4:00 p.m. Mountain Time

ADDRESSES: The briefings will be held via Zoom Webinar. Members of the public only need to register once.

Registration Link (Audio/Visual) for All Meetings: https://www.zoomgov.com/webinar/register/WN_al1uOdtmQfWayWGrd3rJ7g.

Join by Phone (Audio Only) for All meetings: (833) 435–1820 USA Toll-Free; Meeting ID: 165 131 9571.

Agendas (Note: final briefing agendas will be available prior to each meeting date).

FOR FURTHER INFORMATION CONTACT: Ana Victoria Fortes, Designated Federal Officer, at *afortes@usccr.gov* or (202) 681–0857.

SUPPLEMENTARY INFORMATION: These virtual committee meetings are available to the public through the registration links above. Any interested member of the public may join at the links to listen to this meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Pursuant to the Federal Advisory Committee Act, public minutes of the meetings will include a list of persons who are present at the meetings. If joining via phone, callers can expect to incur regular charges for calls they initiate over wireless lines, according to their wireless plan. The Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. Closed captioning is available by selecting ''CC'' in the Zoom meeting platform. To request additional accommodations, please email Support Services Specialist, Angelica Trevino at *atrevino@usccr.gov* at least 10 business days prior to each meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the scheduled meeting. Written comments may be emailed to Ana Fortes at *afortes@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at (202) 681–0857.

Records generated from these meetings may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meetings. Records of the meetings will be available via the file sharing website: *https://usccr.app.box.com/folder/314981673190?s=mw9mbsf7b9dy00grnfelpzs0tykg6isr.*

as well as at: *www.facadatabase.gov* under the Commission on Civil Rights, selecting the Advisory Committee of interest. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov*, or may contact the Regional Programs Coordination Unit at the phone number listed above.

Dated: July 13, 2026.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2026–14296 Filed 7–15–26; 8:45 am]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Order No. 2184]

Approval of Subzone Status; Webco Industries, Inc.; Kellyville, Oklahoma

Pursuant to its authority under the Foreign-Trade Zones Act of June 18, 1934, as amended (19 U.S.C. 81a-81u), the Foreign-Trade Zones Board (the Board) adopts the following Order:

Whereas, the Foreign-Trade Zones (FTZ) Act provides for ''. . . the establishment . . . of foreign-trade zones in ports of entry of the United States, to expedite and encourage foreign commerce, and for other purposes,'' and authorizes the Foreign-Trade Zones Board to grant to qualified corporations the privilege of establishing foreign-trade zones in or adjacent to U.S. Customs and Border Protection ports of entry;

Whereas, the Board's regulations (15 CFR part 400) provide for the establishment of subzones for specific uses;

Whereas, the Muskogee City-County Port Authority, grantee of Foreign-Trade Zone 164, has made application to the Board for the establishment of a subzone at the facility of Webco Industries, Inc., located in Kellyville, Oklahoma (FTZ Docket B–47–2026, docketed May 13, 2026);

Whereas, notice inviting public comment has been given in the **Federal Register** (91 FR 28554, May 18, 2026) and the application has been processed pursuant to the FTZ Act and the Board's regulations; and,

Whereas, the Board adopts the findings and recommendations of the examiners' memorandum, and finds that the requirements of the FTZ Act and the Board's regulations are satisfied;

Now, Therefore, the Board hereby approves subzone status at the facility of Webco Industries, Inc., located in Kellyville, Oklahoma (Subzone 164B), as described in the application and **Federal Register** notice, subject to the

FTZ Act and the Board's regulations, including section 400.13.

Dated: July 3, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance. Alternate Chairman, Foreign-Trade Zones Board.

[FR Doc. 2026–14295 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–139]

Certain Mobile Access Equipment and Subassemblies Thereof From the People's Republic of China: Preliminary Results, Preliminary Determination of No Shipments, and Partial Rescission of Antidumping Duty Administrative Review; 2024–2025

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that certain exporters made sales of subject merchandise at less than normal value (NV) during the period of review (POR), April 1, 2024, through March 31, 2025, and that these companies qualify for separate rates. We also preliminarily find that one additional exporter is no longer eligible for a separate rate and that one exporter made no shipments during the POR. Finally, we are rescinding this review with respect to four companies with existing separate rates who had no entries of subject merchandise during the POR. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable July 16, 2026.

FOR FURTHER INFORMATION CONTACT: Javier Barrientos, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2243.

SUPPLEMENTARY INFORMATION:

Background

On May 20, 2025, based on timely requests for review, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the antidumping duty (AD) order on mobile access equipment and subassemblies thereof (MAE) from the People's Republic of China (China).[1] On July 8, 2025, Commerce selected Zhejiang Dingli Machinery Co., Ltd. (Dingli) as the sole mandatory respondent in this review.[2]

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.[3] Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.[4] On February 27, 2026, we extended the deadline for the preliminary results of this review to June 30, 2026.[5] On June 30, 2026, we further extended the deadline for the preliminary results of this review to July 7, 2026.[6]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[7] A list of the topics discussed in the Preliminary Decision Memorandum is attached as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via ACCESS, which is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

Scope of the Order

The merchandise covered by the scope of the *Order* is MAE from China. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of an AD order where it concludes that there were no suspended entries of subject merchandise during the POR.[8] Normally, upon completion of an administrative review, the suspended entries are liquidated at the AD assessment rate for the review period.[9] Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that Commerce can instruct U.S. Customs and Border Protection (CBP) to liquidate at the calculated AD assessment rate for the review period.[10] Commerce notified all interested parties of its intent to rescind the instant review regarding the following four companies because there were no reviewable, suspended entries of subject merchandise from these companies during the POR: (1) Lingong Group Jinan Heavy Machinery Co., Ltd.; (2) Mantall Heavy Industry Co., Ltd.; (3) Noblelift Intelligent Equipment Co., Ltd.; and (4) Sany Marine Heavy Industry Co., Ltd.[11] Although we invited interested parties to comment,[12] we received no comments from any interested party.

In the absence of any suspended entries of subject merchandise from these companies during the POR, we are rescinding this administrative review

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 90 FR 21459 (May 20, 2025) (*Initiation Notice*); *see also Certain Mobile Access Equipment and Subassemblies Thereof from the People's Republic of China: Antidumping Duty Order,* 87 FR 22190 (April 14, 2022) (*Order*).

[2] *See* Memorandum, ''Respondent Selection,'' dated July 8, 2025.

[3] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' dated November 14, 2025.

[4] *See* Memorandum, ''Tolling of all Case Deadlines,'' dated November 24, 2025.

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated February 27, 2026.

[6] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review,'' dated June 30, 2026.

[7] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review Order of Certain Mobile Access Equipment and Subassemblies Thereof from the People's Republic of China; 2024–2025,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[8] *See, e.g., Certain Carbon and Alloy Steel Cut-to Length Plate from the Federal Republic of Germany: Recission of Antidumping Administrative Review; 2020–2021,* 88 FR 4154 (January 24, 2023).

[9] *See* 19 CFR 351.212(b)(1).

[10] *See, e.g., Shanghai Sunbeauty Trading Co.* v. *United States,* 380 F.Supp.3d 1328, 1337 (CIT 2019), at 12 (referring to section 751(a) of the Act, the U.S. Court of International Trade held that ''{w}hile the statute does not explicitly require that an entry be suspended as a prerequisite for establishing entitlement to a review, it does explicitly state the determined rate will be used as the liquidation rate for the reviewed entries. This result can only obtain if the liquidation of entries has been suspended''; *see also Certain Frozen Fish Fillets from the Socialist Republic of Vietnam: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2018–2019,* 86 FR 36102 (July 8, 2021), and accompanying Issues and Decision Memorandum at Comment 4; and *Solid Fertilizer Grade Ammonium Nitrate from the Russian Federation: Notice of Rescission of Antidumping Duty Administrative Review,* 77 FR 65532 (October 29, 2012) (noting that ''for an administrative review to be conducted, there must be a reviewable, suspended entry to be liquidated at the newly calculated assessment rate'').

[11] *See* Memorandum, ''Notice of Intent to Rescind Review, In Part,'' dated March 13, 2026.

[12] *Id.*

for the above-referenced companies, in accordance with 19 CFR 351.213(d)(3).

Preliminary Determination of No Shipments

One exporter in this review, Oshkosh JLG (Tianjin) Equipment Technology Co., Ltd. (JLG Tianjin) certified that it had no shipments of subject merchandise to the United States during the POR. At our request, JLG Tianjin submitted documentation supporting its claim. As a result, and based on the record evidence submitted by JLG Tianjin, we preliminarily find that the company did not have shipments of subject merchandise during the POR. Consistent with Commerce's assessment practice, we are completing the review with respect to JLG Tianjin and intend to issue appropriate instructions to CBP based on the final results of review.[13]

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act). Because China is a non-market economy country within the meaning of section 771(18) of the Act, we calculated NV in accordance with section 773(c) of the Act. For a full description of the methodology underlying our preliminary results, *see* the Preliminary Decision Memorandum.

Separate Rates

We preliminarily determine that, in addition to Dingli, two companies not individually examined are eligible for separate rates in this administrative review, Hunan Sinoboom Intelligent Equipment Co., Ltd. (Sinoboom) and Terex (Changzhou) Machinery Co., Ltd. (Terex), while one exporter, Xuzhou Construction Machinery Group Imp. & Exp. Co., Ltd., is not.[14]

The Act and Commerce's regulations do not address the establishment of a separate rate to be applied to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, Commerce looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for separate-rate respondents which Commerce did not examine individually in an administrative review.

Dumping Margin for Non-Selected Separate Rate Companies

The Act does not address the establishment of a rate to apply to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce's regulation at 19 CFR 351.109(g) states that Commerce will determine the rate for non-selected companies by following the process set forth in 19 CFR 351.109(f)(1)–(2), which generally parallels the process for determining the all-others rate in an investigation under section 735(c)(5) of the Act.

Section 735(c)(5)(A) of the Act and 19 CFR 351.109(f) state that, for companies not investigated, in general, we will determine an all-others rate by weight averaging the estimated weighted-average dumping margins established for the individually investigated exporters, excluding zero and *de minimis* rates or any rates based entirely on facts available.

Commerce calculated an individual estimated weighted-average dumping margin for Dingli that is not zero, *de minimis,* or based entirely on facts otherwise available. Dingli is the sole mandatory respondent in this review. Thus, the weighted-average dumping margin calculated for Dingli is the preliminary dumping margin assigned to Sinoboom and Terex in this administrative review.[15]

China-Wide Entity

Commerce's policy regarding conditional review of the China-wide entity applies to this administrative review.[16] Under this policy, the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity, the entity is not under review, and the entity's rate (*i.e.,* 165.14 percent)[17] is not subject to change.

Preliminary Results of Review

Commerce preliminarily determines that the following weighted-average dumping margins exist for the period April 1, 2024, through March 31, 2025:

Exporter	Weighted-average dumping margin (percent)
Zhejiang Dingli Machinery Co., Ltd	35.79
Non-Individually Examined Companies Receiving a Separate Rate	
Hunan Sinoboom Intelligent Equipment Co., Ltd	35.79
Terex (Changzhou) Machinery Co., Ltd.	35.79

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties for these preliminary results within 10 days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

Commerce received a timely request from the petitioner[18] to verify the information submitted in this administrative review, pursuant to 19 CFR 351.307(b)(1).[19] As provided in section 782(i)(3) of the Act, Commerce intends to verify the information reported by Dingli prior to issuing its final results.

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance no later than seven days after the date on which the last verification report is issued in this review. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[20] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[21]

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public executive summary for each issue raised

[13] *See* Preliminary Decision Memorandum at ''Preliminary Determination of No Shipments'' for further discussion.

[14] *See* Preliminary Decision Memorandum at ''Separate Rate Determinations'' for further discussion.

[15] *Id.*

[16] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[17] *See Order,* 87 FR at 22191.

[18] The petitioner in this proceeding is the Coalition of American Manufacturers of Mobile Access Equipment.

[19] *See* Petitioner's Letter, ''Request for Administrative Review,'' dated April 30, 2025. Additionally, Commerce conducted no verification in the prior two segments.

[20] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[21] *See* 19 CFR 351.309(c)(2) and (d)(2).

in their briefs.[22] Further, we request that interested parties limit their public, executive summary of each issue to no more than 450 words, not including citations. We intend to use the public, executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public, executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[23]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants, and whether any participant is a foreign national; and (3) a list of issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing.[24]

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

If Dingli's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.50 percent) in the final results of this review, Commerce intends to calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those sales. Where we do not have entered values for all U.S. sales to a particular importer, we will calculate an importer-specific, per-unit assessment rate on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total quantity of those sales.[25] To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values. If Dingli's weighted-average dumping margin is zero or *de minimis* or where an importer-specific *ad valorem* assessment rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[26]

For entries that were not reported in the U.S. sales database submitted by Dingli during this review, Commerce will instruct CBP to liquidate such entries at the China-wide rate.

For the companies that were not selected for individual examination in this administrative review but which qualified for a separate rate, we will instruct CBP to assess antidumping duties on all appropriate entries at a rate equal to the weighted-average dumping margin determined in the final results of this review, unless that rate is zero or *de minimis,* in which case we intend to instruct CBP to liquidate relevant entries without regards to antidumping duties.

With respect to JLG Tianjin, we have preliminarily found no shipments and intend to issue appropriate instructions to CBP based on the final results of the review.

Similarly, for the final results, if we continue to treat the companies identified in Appendix II as part of the China-wide entity, we will instruct CBP to apply an *ad valorem* assessment rate of 165.14 percent to all entries of subject merchandise during the POR which were exported by those companies.

For the companies for which the review is being rescinded with these preliminary results, we will instruct CBP to assess antidumping duties on all appropriate entries rates equal to the cash deposit rate for estimated antidumping duties required at the time of entry, or withdrawal from warehouse, for consumption during the period April 1, 2024, through March 31, 2025, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue assessment instructions to CBP for the rescinded companies no earlier than 35 days after the date of publication of this notice in the **Federal Register**.

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from China entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by sections 751(a)(2)(C) of the Act: (1) for the companies listed above which have a separate rate, the cash deposit rate will be that established in the final results of this review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed China and non-China exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the existing rate for the China-wide entity of 165.14 percent; and (4) for all non-China exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-China exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in case and rebuttal briefs, within 120 days of publication of these preliminary results of review in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping and/or countervailing duties prior to liquidation of the

[22] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[23] *See APO and Service Procedures.*

[24] *See* 19 CFR 351.310(d).

[25] *See* 19 CFR 351.212(b)(1).

[26] *See* 19 CFR 351.106(c)(2); *see also Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping and/or countervailing duties occurred and the subsequent assessment of double antidumping duties, and/or an increase in the amount of antidumping duties by the amount of countervailing duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: July 7, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Rescission of Administrative Review, In Part
V. Preliminary Determination of No Shipments
VI. Discussion of the Methodology
VII. Adjustment Under Section 777A(f) of the Act
VIII. Currency Conversion
IX. Recommendation

Appendix II

Companies Determined To Be Part of the China-Wide Entity

1. Anhui Heli Industrial Vehicle Imp. & Exp. Co., Ltd
2. Changzhou Hengxuan Logistics Co., Ltd.
3. Crown Equipment (Suzhou) Co., Ltd.
4. Deqing Liguan Machinery Trading Co. Ltd.
5. Dongguan Tinbo Packing Industrial Co., Ltd.
6. Everocean International Forwarding Co., Ltd.
7. Fujiang Jingong Machinery Co., Ltd.
8. Gmg Outdoor Products Co., Ltd
9. Guangdong Machinery Imp. & Exp. Co., Ltd.
10. Guangxi LiuGong Machinery Co., Ltd.
11. Guangzhou Eounice Machinery Co., Ltd.
12. Hangzhou Hengli Metal Processing Co., Ltd.
13. Henan Global Heavy Industry Technology Co., Ltd.
14. Jiaxing Xinfeng Zhong Wang Hydrualic Pressure Accessory Factory
15. Jinan Zhongtang Mechanical Equipment
16. Jinan Zhongtian International Trading
17. Leader Technology Co., Ltd
18. Lingong Heavy Machinery Co., Ltd.
19. Shandong Huifeng Auto Fittings
20. Shandong Lede Machinery
21. Shandong Tavol Machinery Co., Ltd.
22. Shanghai Full Trans Global Forwarding Co., Ltd.
23. Shanghai Inter Cooperation Co., Ltd.
24. Shanghai Xiangcheng Trading Co., Ltd.
25. Shanghai Xindun Trade Co., Ltd.
26. Shenzhen Shining Ocean International Logistics Co., Ltd
27. Skyjack Inc
28. Sunward Intelligent Equipment Co., Ltd.
29. Wuhai Huadong Heavy Industry Foundry Co., Ltd.
30. Xuzhou Construction Machinery Group Fire-Fighting Safety Equipment Co., Ltd.
31. Xuzhou Construction Machinery Group Imp. & Exp. Co., Ltd. (XCMG I&E)
32. Yantai Carhart Manufacturing Co., Ltd.
33. Yantai Empire Industry and Trade
34. Zhejiang Smile Tools Co., Ltd.
35. Zhongshan Shiliwang Machinery Co., LTD
36. Zoomlion Heavy Industry Science & Technology Co., Ltd.

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–054]

Certain Aluminum Foil From the People's Republic of China: Preliminary Results and Rescission, in Part, of Countervailing Duty Administrative Review; 2024

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that countervailable subsidies were provided to producers and exporters of certain aluminum foil (aluminum foil) from the People's Republic of China (China). The period of review (POR) is January 1, 2024, through December 31, 2024. In addition, Commerce is rescinding this review, in part, with respect to five companies. Interested parties are invited to comment on these preliminary results.

DATES: Applicable July 16, 2026.

FOR FURTHER INFORMATION CONTACT: Harrison Tanchuck or Madeline Robinson, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–7421 or (202) 482–0585, respectively.

SUPPLEMENTARY INFORMATION:

Background

On May 20, 2025, based on timely requests for review, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the countervailing duty order on aluminum foil from China.[1] On August 1, 2025, Commerce selected Dingheng New Materials Co., Ltd. (Dingheng) and Jiangsu Zhongji Lamination Materials Co., Ltd. (Zhongji) as the mandatory respondents in this administrative review.[2] On August 14, 2025, Zhongji notified Commerce that it would not participate in this review.[3] On August 18, 2025, the petitioners[4] withdrew their request for review with respect to five entities, listed in Appendix II.[5]

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.[6] Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.[7] Between February and June 2026, we extended the

[1] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 90 FR 21459, 21467 (May 20, 2025); *see also Certain Aluminum Foil from the People's Republic of China: Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 83 FR 17360 (April 19, 2018); *see also Certain Aluminum Foil from the People's Republic of China: Notice of Court Decision Not in Harmony With the Amended Final Determination in the Countervailing Duty Investigation, and Notice of Amended Final Determination and Amended Countervailing Duty Order,* 85 FR 47730 (August 6, 2020) (*Amended Order*) (collectively, *Order*).

[2] *See* Memorandum, ''Respondent Selection,'' dated August 1, 2025.

[3] *See* Zhongji's Letter, ''Notice of Intent Not to Participate,'' dated August 14, 2025 (Zhongji Non-Participation Letter). Zhongji's letter was filed on behalf of the following companies: Jiangsu Zhongji Lamination Materials Co., Ltd. (f/k/a Jiangsu Zhongji Lamination Materials Stock Co., Ltd.), Jiangsu Huafeng Aluminium Industry Co., Ltd., Jiangsu Zhongji Lamination Materials Co., (HK) Limited, Anhui Zhongji Battery Foil Science & Technology Co., Ltd. (f/k/a Anhui Maximum Aluminium Industries Company Ltd.), Anhui Maximum Aluminum Co., Ltd., Shantou Wanshun New Material Group Co., Ltd. (f/k/a Shantou Wanshun Package Material Stock Co., Ltd) and Sichuan Wanshun Zhongji Aluminium Industry Co., Ltd., (collectively, Zhongji).

[4] The petitioners are the Aluminum Association Trade Enforcement Working Group and its individual members: JW Aluminum Company, Novelis Corporation, and Reynolds Consumer Products LLC.

[5] *See* Petitioners' Letter, ''Petitioners' Partial Withdrawal of Requests for Administrative Reviews,'' dated August 18, 2025 (Petitioners' Partial Withdrawal Request).

[6] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' dated November 14, 2025.

[7] *See* Memorandum, ''Tolling of all Case Deadlines,'' dated November 24, 2025.

deadline for the preliminary results of this review until July 7, 2026.[8]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[9] A list of topics discussed in the Preliminary Decision Memorandum is included as Appendix I to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via ACCESS. ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

Scope of the Order

The product covered by the *Order* is aluminum foil from China. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if all parties that requested the review withdraw their requests within 90 days of publication of the notice of initiation. As noted above, Commerce received timely filed withdrawal requests with respect to the companies listed in Appendix II, and no other parties requested a review of these companies. Therefore, we are rescinding this administrative review with respect to these companies, pursuant to 19 CFR 351.213(d)(1).

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(l)(A) of the Tariff Act of 1930, as amended (Act). For each of the subsidy programs found countervailable, Commerce preliminarily determines that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[10] For a full description of the methodology underlying our conclusions, including our reliance, in part, on facts otherwise available with adverse inferences pursuant to sections 776(a) and (b) of the Act, *see* the Preliminary Decision Memorandum.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following net countervailable subsidy rates exist for the POR, January 1, 2024, through December 31, 2024:

Company	Subsidy rate (percent *ad valorem*)
Dingheng New Materials Co., Ltd.[11]	21.62
Jiangsu Zhongji Lamination Materials Co., Ltd.[12]	149.69

Disclosure

Commerce intends to disclose the calculations and analysis performed to interested parties for these preliminary results within 10 days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Verification

Commerce received a timely request from the petitioners to verify the information submitted in this administrative review, pursuant to 19 CFR 351.307(b)(1)(iv).[13]

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance.[14] Pursuant to 19 CFR 351.309(c)(1)(ii), we have modified the deadline for interested parties to submit case briefs to Commerce no later than 21 days after the date of the publication of this notice.[15] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[16] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[17] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public executive summary for each issue raised in their briefs.[18] Further, we request that interested parties limit their executive summary of each issue to no more than 450 words, not including citations. We intend to use the executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the executive summary of each issue. Note that Commerce has amended certain of its requirements

[8] *See* Memoranda, ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,'' dated February 12, 2026; ''Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review,'' dated June 30, 2026.

[9] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Administrative Review of Countervailing Duty Order on Certain Aluminum Foil from the People's Republic of China; 2024,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[10] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[11] As discussed in the Preliminary Decision Memorandum, Commerce has found the following companies to be cross-owned with Dingheng: Jiangsu Dingsheng New Materials Joint-Stock Co., Ltd.; Dingsheng Aluminum Industries (Hong Kong) Trading Co., Ltd. or Dingsheng Aluminium Industries (Hong Kong) Trading Co., Limited or Dingsheng Aluminium Industries (Hong Kong) Trading Co., Ltd; Hangzhou Dingsheng Import & Export Co., Ltd. or Hangzhou Dingsheng Import and Export Co., Ltd. or Hangzhou Dingsheng Import&Export Co., Ltd.; Hangzhou Teemful Aluminium Co., Ltd.; Inner Mongolia Liansheng New Energy Material Co., Ltd. (or Inner Mongolia Liansheng New Energy Material Joint-Stock Co., Ltd.); Inner Mongolia Xinxing New Energy Material Co., Ltd. (or Inner Mongolia Xinxing New Material Co., Ltd.); Hangzhou Dingsheng Industrial Group Co., Ltd.; Hangzhou DingCheng Aluminium Co., Ltd. or Hangzhou DingCheng Aluminum Co., Ltd; Luoyang Longding Aluminum Co., Ltd.; Walson (HK) Trading Co., Limited; Hangzhou Five Star Aluminium Co., Ltd.; and Thai Ding Li New Materials Co., Ltd. (collectively, Dingsheng Respondents).

[12] Commerce has previously found the following companies to be to be cross-owned with Jiangsu Zhongji Lamination Materials Co., Ltd. (Zhongji): (1) Jiangsu Huafeng Aluminium Industry Co., Ltd. (Jiangsu Huafeng), (2) Shantou Wanshun New Material Group Co., Ltd. (f/k/a Shantou Wanshun Package Material Stock Co., Ltd.), (3) Anhui Zhongji Battery Foil Sci&Tech Co., Ltd. (AKA Anhui Zhongii Battery Foil Science & Technology Co., Ltd.) (f/k/a Anhui Maximum Aluminium Industries Company Limited), (4) Sichuan Wanshun Zhongji Aluminium Industry Co., Ltd., and (5) Anhui Maximum Aluminum Co., Ltd. Furthermore, Commerce has also previously found that Zhongji wholly owns trading company Jiangsu Zhongji Lamination Materials Co., (HK) Limited. *See Certain Aluminum Foil from the People's Republic of China: Final Results of Countervailing Duty Administrative Review; 2023,* 91 FR 7438 (February 18, 2026).

[13] *See* Petitioners' Letter, ''Petitioners' Request for Verification,'' dated August 22, 2025.

[14] *See* 19 CFR 351.309(c)(1)(ii); *see also* 19 CFR 351.303 (for general filing requirements).

[15] *See* 19 CFR 351.309.

[16] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[17] *See* 19 CFR 351.309(c)(2) and (d)(2).

[18] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

pertaining to the service of documents in 19 CFR 351.303(f).[19]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, filed electronically via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants and whether any participant is a foreign national; and (3) a list of issues to be discussed. Oral presentations at the hearing will be limited to those raised in the briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing.[20]

Assessment Rates

Consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), upon issuance of the final results, Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, countervailing duties on all appropriate entries covered by this review.

For the companies listed in Appendix II for which the review is being rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated CVDs required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2024, through December 31, 2024, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue rescission instructions to CBP no earlier than 35 days after the date of publication of this notice in the **Federal Register**.

Commerce intends to issue assessment instructions to CBP regarding Dingheng and Zhongji no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.107(e), Commerce intends to instruct CBP to collect cash deposits of estimated countervailing duties with regard to shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review, as follows: (1) the cash deposit rate for the companies listed above will be equal to the company-specific estimated individual countervailable subsidy rates determined in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) if both the producer and exporter of the subject merchandise have company-specific estimated subsidy rates assigned, and their rates differ, then the applicable cash deposit rate will be the higher of these two rates; (3) if either the producer or the exporter, but not both, of the subject merchandise has a company-specific estimated subsidy rate assigned, the applicable cash deposit rate will be that company's company-specific rate; and (4) the cash deposit rate for all other producers and exporters will be continue to be 13.28 percent, the all-others subsidy rate established in the investigation.[21] These cash deposit instructions, when imposed, shall remain in effect until further notice.

Final Results of Review

Unless the deadline is extended, Commerce intends to issue the final results of this administrative review, which will include the results of Commerce's analysis of the issues raised in the case briefs, within 120 days of publication of these preliminary results in the **Federal Register**, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.221(b)(4).

Dated: July 7, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Diversification of China's Economy
V. Subsidies Valuation
VI. Interest Rate Benchmarks, Discount Rates, and Benchmarks for Measuring the Adequacy of Remuneration
VII. Use of Facts Otherwise Available and Adverse Inferences
VIII. Analysis of Programs
IX. Recommendation

Appendix II

Companies for Which the Review Is Rescinded

1. Alcha International Holdings Limited
2. Baotou Alcha Aluminum Co., Ltd.
3. Gränges Aluminum (Shanghai) Co., Ltd.
4. Shanghai Shenyan Packaging Materials Co., Ltd.
5. Yinbang Clad Material Co., Ltd.

[FR Doc. 2026–14294 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–DS–P

[19] *See APO and Service Procedures.*

[20] *See* 19 CFR 351.310(d).

[21] *See Amended Order,* 85 FR 47730.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–570–231]

Tris(hydroxymethyl)aminomethane From the People's Republic of China: Postponement of Preliminary Determination in the Countervailing Duty Investigation

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

DATES: Applicable July 16, 2026.

FOR FURTHER INFORMATION CONTACT: Shane Subler at (202) 482–6241 or Katerina Katsiadas at (202) 482–4929, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On May 11, 2026, the U.S. Department of Commerce (Commerce) initiated a countervailing duty (CVD) investigation of imports of Tris(hydroxymethyl)aminomethane (Tris) from the People's Republic of China (China).[1] Currently, the preliminary determination is due no later than July 15, 2026.

Postponement of Preliminary Determination

Section 703(b)(1) of the Tariff Act of 1930, as amended (the Act), requires Commerce to issue the preliminary determination in a countervailing duty investigation within 65 days after the date on which Commerce initiated the investigation. However, section 703(c)(1) of the Act permits Commerce

[1] *See Tris(hydroxymethyl)aminomethane from the People's Republic of China: Initiation of Countervailing Duty Investigation,* 91 FR 28559 (May 18, 2026) (*Initiation Notice*).

to postpone the preliminary determination until no later than 130 days after the date on which Commerce initiated the investigation if: (A) the petitioner makes a timely request for a postponement; [2] or (B) Commerce concludes that the parties concerned are cooperating, that the investigation is extraordinarily complicated, and that additional time is necessary to make a preliminary determination.

Commerce has determined that parties involved in these proceedings are cooperating because parties have requested extensions of time to respond to questionnaires,[3] and/or submitted portions of questionnaire responses.[4] In addition, we find that this investigation is extraordinarily complicated within the meaning of section 703(c)(1)(B)(i) of the Act and that Commerce requires additional time to reach its preliminary determination.

Section 703(c)(1)(B)(i)(I) of the Act provides that ''the number and complexity of the alleged countervailable subsidy practices'' is a consideration in determining whether a case is extraordinarily complicated. In these cases, Commerce is investigating an unusually high number of alleged subsidy programs and will require additional time to analyze the questionnaire responses and issue appropriate requests for clarification and additional information, particularly regarding questions of affiliation and cross-ownership and program use by the respondents.

In accordance with 19 CFR 351.205(e), the petitioner has stated the reasons for requesting a postponement of the preliminary determination, and Commerce finds no compelling reason to deny the request. Therefore, in accordance with section 703(c)(1)(B) of the Act, Commerce is postponing the deadline for the preliminary determination to no later than 130 days after the date on which this investigation was initiated, *i.e.,* September 18, 2026. Pursuant to section 705(a)(1) of the Act and 19 CFR 351.210(b)(1), the deadline for the final determination of this investigation will continue to be 75 days after the date of the preliminary determination.

Notification to Interested Parties

This notice is issued and published pursuant to section 703(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: July 10, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2026–14290 Filed 7–15–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[C–557–822]

Utility Scale Wind Towers From Malaysia: Rescission of Countervailing Duty Administrative Review; 2024

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) is rescinding the administrative review of the countervailing duty (CVD) order on utility scale wind towers (wind towers) from Malaysia for the period of review (POR) January 1, 2024, through December 31, 2024.

DATES: Applicable July 16, 2026.

FOR FURTHER INFORMATION CONTACT: Kelsie Hohenberger AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2517.

SUPPLEMENTARY INFORMATION:

Background

On August 4, 2021, Commerce published in the **Federal Register** the CVD order on wind towers from Malaysia.[1] On August 1, 2025, Commerce published a notice of opportunity to request an administrative review of the *Order*.[2] On September 2, 2025, the Wind Tower Trade Coalition (the petitioner) submitted a timely request that Commerce conduct an administrative review.[3] On September 25, 2025, Commerce initiated an administrative review with respect to five companies.[4]

Due to the lapse in appropriations and Federal Government Shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days.[5] Additionally, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.[6] Accordingly the deadline for the preliminary results of this review is now July 10, 2026.

On November 18, 2025, Commerce placed on the record U.S. Customs and Border Protection (CBP) entry data for the companies subject to the review, showing no reviewable POR entries, and invited interested parties to comment.[7] No party filed comments with respect to the CBP data. On March 13, 2026, Commerce issued a notice of intent to rescind the 2024 administrative review and invited interested parties to comment.[8] No party filed comments with respect to the Notice of Intent to Rescind.

Rescission of Review

Pursuant to 19 CFR 351.213(d)(3), it is Commerce's practice to rescind an administrative review of a CVD order where it concludes that there were no entries of subject merchandise during the POR.[9] Normally, upon completion of an administrative review, the

[2] The petitioner in this proceeding is Advancion Corporation (the petitioner). *See* Petitioner's Letter, ''Petitioner's Request for Postponement of Preliminary Determination,'' dated July 2, 2026. In its letter, the petitioner requested that Commerce postpone the preliminary determination because interested parties are cooperating and Commerce required additional time to collect and analyze responses from the Government of the People's Republic of China (GOC) and the mandatory respondents.

[3] *See* Suzhou Yacoo Science Co., Ltd. (Yacoo)'s Letter, ''Yacoo's Affiliated Companies Response Extension Request,'' dated June 17, 2026; *see also* Yacoo's Letter, ''Extension Request for Suzhou Yacoo's Initial Questionnaire Response,'' dated June 30, 2026.

[4] *See* Yacoo's Letter, ''Suzhou Yacoo's Response to the Affiliated Companies Section of the Initial Questionnaire,'' dated July 1, 2026.

[1] *See Utility Scale Wind Towers from Malaysia: Countervailing Duty Order,* 86 FR 41950 (August 4, 2021) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 90 FR 36141 (August 1, 2025).

[3] *See* Petitioner's Letter, ''Request for Administrative Review,'' dated September 2, 2025.

[4] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 90 FR 46173 (September 25, 2025) (*Initiation Notice*).

[5] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' dated November 14, 2025.

[6] *See* Memorandum, ''Tolling of all Case Deadlines,'' dated November 24, 2025.

[7] *See* Memorandum, ''Release of Customs and Border Protection Data,'' dated November 18, 2025.

[8] *See* Memorandum, ''Notice of Intent to Rescind Review,'' dated March 13, 2026 (Notice of Intent to Rescind).

[9] *See, e.g., Welded Line Pipe from the Republic of Turkey: Rescission of the Antidumping Duty Administrative Review; 2019–2020,* 87 FR 27988 (May 10, 2022); *see also, e.g., Certain Softwood Lumber Products from Canada: Final Results and Final Rescission, in Part, of the Countervailing Duty Administrative Review, 2020,* 87 FR 48455 (August 9, 2022); and *Certain Non-Refillable Steel Cylinders from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2020–2021,* 87 FR 64008 (October 21, 2022).

suspended entries are liquidated at the CVD assessment rate(s) calculated for the review period.[10] Therefore, for an administrative review to be conducted, there must be a reviewable, suspended entry that Commerce can instruct CBP to liquidate at the calculated CVD assessment rates for the review period.[11] As noted above, there were no suspended entries of subject merchandise for any companies subject to this review during the POR. Accordingly, in the absence of reviewable, suspended entries of subject merchandise during the POR, we are hereby rescinding this administrative review in its entirety, in accordance with 19 CFR 351.213(d)(3).

Cash Deposit Requirements

As Commerce has proceeded to a final rescission of this administrative review, no cash deposit rates will change. Accordingly, the current cash deposit requirements shall remain in effect until further notice.

Assessment Rates

Commerce will instruct CBP to assess countervailing duties on all appropriate entries of wind towers from Malaysia. Countervailing duties shall be assessed at rates equal to the cash deposit rate of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, in accordance with 19 CFR 351.212(c)(1)(i). Commerce intends to issue appropriate assessment instructions to CBP no earlier than 35 days after publication of this notice in the **Federal Register**.

Notification Regarding Administrative Protective Order

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a sanctionable violation.

Notification to Interested Parties

This notice is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(d)(4).

[10] *See* 19 CFR 351.212(b)(2).

[11] *See* 19 CFR 351.212(d)(3).

Dated: July 10, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2026–14289 Filed 7–15–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–016, C–570–017]

Certain Passenger Vehicle and Light Truck Tires From the People's Republic of China: Continuation of Antidumping Duty Order and Countervailing Duty Order

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determinations by the U.S. Department of Commerce (Commerce) and the U.S. International Trade Commission (ITC) that revocation of the antidumping duty (AD) order and countervailing duty (CVD) order on certain passenger vehicle and light truck tires (passenger tires) from the People's Republic of China (China) would likely lead to the continuation or recurrence of dumping, and countervailable subsidies, and material injury to an industry in the United States, Commerce is publishing a notice of continuation of these AD and CVD orders.

DATES: Applicable July 7, 2026.

FOR FURTHER INFORMATION CONTACT: Eric Chen, AD/CVD Operations, Office IX, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2860.

SUPPLEMENTARY INFORMATION:

Background

On August 10, 2015, Commerce published in the **Federal Register** the AD and CVD orders on passenger tires from China.[1] On January 2, 2026, the ITC instituted,[2] and Commerce initiated,[3] the second sunset review of the *Orders,* pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act). As a result of its reviews, Commerce determined that revocation of the *Orders* would likely lead to the continuation or recurrence of dumping and countervailable subsidies, and therefore, notified the ITC of the magnitude of the margins of dumping and subsidy rates likely to prevail should the *Orders* be revoked.[4]

On July 7, 2026, the ITC published its determination, pursuant to sections 751(c) and 752(a) of the Act, that revocation of the *Orders* would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[5]

Scope of the Orders

The scope of the *Orders* is passenger vehicle and light truck tires. Passenger vehicle and light truck tires are new pneumatic tires, of rubber, with a passenger vehicle or light truck size designation. Tires covered by these *Orders* may be tube-type, tubeless, radial, or non-radial, and they may be intended for sale to original equipment manufacturers or the replacement markets.

Subject tires have, at the time of importation, the symbol ''DOT'' on the sidewall, verifying that the tires conforms to applicable motor vehicle safety standards. Subject tires may also have the following prefixes or suffix in their tire size designation, which also appears on the sidewall of the tire:

Prefix designations:

P—Identifies a tire intended primarily for service on passenger cars.

LT—Identifies a tire intended primarily for service on light trucks.

Suffix letter designations:

LT—Identifies light truck tires for service on trucks, buses, trailers, and multipurpose passenger vehicles used in nominal highway service.

All tired with a ''P'' or ''LT'' prefix, and all tires with an ''LT'' suffix in their sidewall markings are covered by these *Orders* regardless of their intended use. In addition, all tires that lack a ''P'' or ''LT'' prefix or suffix in their sidewall markings, as well as tires that include

[1] *See Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Amended Final Affirmative Antidumping Duty Determination and Antidumping Duty Order; and Amended Final Affirmative Countervailing Duty Determination and Countervailing Duty Order,* 80 FR 47902 (August 10, 2015).

[2] *See Passenger Vehicle and Light Truck Tires from China; Institution of a Five-Year Reviews,* 91 FR 159 (January 2, 2026).

[3] *See Initiation of Five-Year (Sunset) Reviews,* 91 FR 125 (January 2, 2026).

[4] *See Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Final Results of the Expedited Second Sunset Review of the Antidumping Duty Orders,* 91 FR 23955 (May 4, 2026), and accompanying Issues and Decision Memorandum (IDM); and *Certain Passenger Vehicle and Light Truck Tires from the People's Republic of China: Final Results of the Expedited Second Sunset Review of the Countervailing Duty Order,* 91 FR 23966 (May 4, 2026), and accompanying IDM.

[5] *See Passenger Vehicle and Light Truck Tires from China,* 91 FR 41661 (July 7, 2026) (*ITC Final Determination*).

any other prefix or suffix in their sidewall marking, are included in the scope, regardless of their intended use, as long at the tire is of a size that is among the numerical size designations listing in the passenger car section or light truck section of the Tire and Rime Association Year Book (TRA Year Book), as updated annually, unless the tire falls within one of the specific exclusions set out below.

Passenger vehicle and light truck tires, whether or not attached to wheel or rims, are included in the scope. However, if a subject tire is imported attached to a wheel or rim, only the tire is covered by the scope.

Specifically excluded from the scope are the following types of tires:

(1) Racing car tires; such tires do not bear the symbol ''DOT'' on the sidewall and may be marked with ''ZR'' in size designation;

(2) New pneumatic tires, of rubber, of a size that is not listed in the passenger car section or light truck section of the TRA Year Book;

(3) Pneumatic tires, of rubber, that are not new, including recycled and retreaded tires;

(4) Non-pneumatic tires, such as solid rubber tires;

(5) Tires designed and marked exclusively as temporary use spare tires for passenger vehicles which, in addition, exhibit each of the following characteristics:

a. The size designation and load index combination molded on the tire's sidewall are listed in Table PCT–1B (''T'' Type Spare Tires for Temporary Use on Passenger Vehicles) of the TRA Year Book,

b. The designation ''T'' is molded into the tire's sidewall as part of the size designation, and,

c. The tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by TRA Year Book, and the rated speed is 81 MPH or a ''M'' rating;

(6) Tired designed and marketed exclusively for specialty tires (ST) use which, in addition, exhibit each of the following conditions:

a. The size designation molded on the tire's sidewall is listed in the ST sections of the TRA Year Book,

b. The designation ''ST'' is molded into the tire's sidewall as part of the size designation,

c. The tire incorporates a warning, prominently molded on the sidewall, that the tire is ''For Trailer Service Only'' or ''For Trailer Use Only'',

d. The load index molded on the tire's sidewall meets or exceeds those load indexes listed in the TRA Year Book for the relevant ST tire size, and

e. Either

i. The tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by the TRA Year Book, and the rated speed does not exceed 81 MPH or an ''M'' rating; or

ii. The tire's speed rating molded on the sidewall is 87 MPH or an ''N'' rating, and in either case the tire's maximum pressure and maximum load limit are molded on the sidewall and either

1. Both exceed the maximum pressure and maximum load limit for any tire of the same size designation in either the passenger car or light truck section of the TRA Year Book; or

2. If the maximum cold inflation pressure molded on the tire is less than any cold inflation pressure listed for that size designation in either the passenger car or light truck section of the TRA Year Book, the maximum load limit molded on the tire is higher than the maximum load limit listed at that cold inflation pressure for that size designation in either the passenger car or light truck section of the TRA Year Book.

(7) Tires designed and marketed exclusively for off-road use and which, in addition, exhibit each of the following characteristics:

a. The size designation and load index combination molded on the tire's sidewall are listed in the off-the-road, agricultural, industrial, or ATV section of the TRA Year Book,

b. In addition to any size designation markings, the tire incorporates a warning, prominently molded on the sidewall, that the tire is ''Not for Highway Service'' or ''Not for Highway Use'',

c. The tire's speed rating is molded on the sidewall, indicating the rated speed in MPH or a letter rating as listed by the TRA Year Book, and the rated speed does not exceed 55 MPH or a ''G'' rating, and

d. The tire features a recognizable off-road tread design.

The products covered by the *Orders* are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4011.10.10.10, 4011.10.10.20, 4011.10.10.30, 4011.10.10.40, 4011.10.10.50, 4011.10.10.60, 4011.10.10.70, 4011.10.50.00, 4011.20.10.05, and 4011.20.50.10. Tires meeting the scope description may also enter under the following HTSUS subheadings: 4011.90.2050, 4011.99.45.10, 4011.99.45.50, 4011.99.85.10, 4011.99.85.50, 8708.70.45.30, 8708.70.45.45, 8708.70.45.46, 8708.70.45.48, 8708.70.45.60, 8708.70.60.30, 8708.70.60.45, and 8708.70.60.60. While HTSUS subheadings are provided for convenience and for customs purposes, the written description of the subject merchandise is dispositive.

Continuation of the Orders

As a result of the determinations by Commerce and the ITC that revocation of the *Orders* would likely lead to continuation or recurrence of dumping, countervailable subsidies, and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, Commerce hereby orders the continuation of the *Orders.* U.S. Customs and Border Protection will continue to collect AD and CVD cash deposits at the rates in effect at the time of entry for all imports of subject merchandise.

The effective date of the continuation of the *Orders* will be July 7, 2026.[6] Pursuant to section 751(c)(2) of the Act and 19 CFR 351.218(c)(2), Commerce intends to initiate the next five-year reviews of the *Orders* not later than 30 days prior to the fifth anniversary of the date of the last determination by the ITC.

Administrative Protective Order (APO)

This notice also serves as a final reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

Notification to Interested Parties

These five-year (sunset) reviews and this notice are in accordance with sections 751(c) and 751(d)(2) of the Act and published in accordance with section 777(i) of the Act, and 19 CFR 351.218(f)(4).

Dated: July 13, 2026.

Scot Fullerton,

Acting Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2026–14293 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See ITC Final Determination.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–985]

Xanthan Gum From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Determination of No Shipments; 2023–2024

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that Neimenggu Fufeng Biotechnologies Co., Ltd. (aka Inner Mongolia Fufeng Biotechnologies Co., Ltd.), Shandong Fufeng Fermentation Co., Ltd., and Xinjiang Fufeng Biotechnologies Co., Ltd. (collectively, Fufeng) and Deosen Biochemical (Ordos) Ltd. (Deosen) sold xanthan gum from the People's Republic of China (China) at less than normal value during the period of review (POR), July 1, 2023, through June 30, 2024. Additionally, we find that Jianlong Biotechnology Co., Ltd. (Jianlong), Jilin Meihua Amino Acid Co., Ltd (Jilin Meihua), Meihua Group International Trading (Hong Kong) Limited/Langfang Meihua Biotechnology Co., Ltd.,/ Xinjiang Meihua Amino Acid Co., Ltd (Meihua), and Ningxia Top Hydrocolloids Co., Ltd.(Ningxia) are eligible for a separate rate. Commerce also determines that Deosen Biochemical Ltd., had no shipments during the POR.

DATES: Applicable July 16, 2026.

FOR FURTHER INFORMATION CONTACT: Joseph Molokwu or Paul Kebker, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–8043 or (202) 482–2254, respectively.

SUPPLEMENTARY INFORMATION:

Background

On January 9, 2026, Commerce published the *Preliminary Results* in the **Federal Register** and invited interested parties to comment.[1] Commerce extended the deadline for the final results by 60 days until July 8, 2026.[2] On June 11, 2026, Commerce issued a post-preliminary analysis memorandum and invited interested parties to comment on those results.[3] On July 8, 2026, Commerce placed U.S. Customs and Border (CBP)'s *de novo* review of Enforce and Protect Act (EAPA) 8144 on the record of the review.[4] For further details regarding the events that occurred subsequent to the *Preliminary Results, see* the Issues and Decision Memorandum.[5] Commerce conducted this administrative review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [6]

The product covered by scope of the *Order* is xanthan gum from China. For a full description of the scope of the *Order, see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues parties raised and to which we responded in the Issues and Decision Memorandum is provided in the appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), which is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

Final Determination of No Shipments

In the *Preliminary Results,* Commerce determined that Deosen Biochemical Ltd. did not have shipments of subject merchandise during the POR.[7] As we received no information to contradict our preliminary determination with respect to Deosen Biochemical Ltd, we continue to find that it made no shipments of subject merchandise to the United States during the POR.

Changes Since the Preliminary Results

Based on a review of the record, and comments received from interested parties regarding our *Preliminary Results* and Post-Preliminary Analysis, we made certain changes to the weighted-average dumping margin calculations for both Fufeng and Deosen. For further discussion of these changes, *see* the Issues and Decision Memorandum.

Separate Rates

In the *Preliminary Results,* we determined that Fufeng, Deosen, and four other companies demonstrated their eligibility for a separate rate.[8] For these final results, we continue to determine that the Fufeng, Deosen, and the four non-examined companies are eligible for a separate rate. We received comments on our calculation of a separate rate in the Post-Preliminary Analysis. Commerce has made no changes to our methodology for calculating a separate rate from the *Preliminary Results.*

China-Wide Entity

Under Commerce's policy regarding the conditional review of the China-wide entity,[9] the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because no party requested a review of the China-wide entity in this review, the entity is not under review, and the entity's rate (*i.e.,* 154.07 percent) is not subject to change.[10]

Aside from Deosen Biochemical Ltd., for which we continune to find no shipments, and CP Kelco (Shandong) Biological Company Limited, for which this review was rescinded at the *Preliminary Results,* Commerce considers all other companies for which a review was requested and did not demonstrate separate rate eligibility to be part of the China-wide entity. For these final results, we continue to consider Shanghai Smart Chemicals Co. Ltd. to be part of the China-wide entity because it did not file a separate rate application or certification.

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[1] *See Xanthan Gum From the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review, Rescission, in Part, and Preliminary Determination of No Shipments; 2023–2024,* 91 FR 959 (January 9, 2026) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated April 15, 2026; *see also* Memorandum, ''Second Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated June 25, 2026.

[3] *See* Memorandum, ''Post-Preliminary Analysis Memorandum Regarding CBP's EAPA Report,'' dated June 11, 2026 (Post-Preliminary Analysis).

[4] *See* Memorandum, ''Placing TRLED New Factual Information on the Record,'' dated July 8, 2026, which contains CBP's July 8, 2026, *De Novo* Administrative Review.

[5] *See* Memorandum, '' Issues and Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Xanthan Gum From the People's Republic of China; 2023–2024, dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[6] *See Xanthan Gum from the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 78 FR 43143 (July 19, 2013) (*Order*).

[7] *See Preliminary Results,* 91 FR 959.

[8] *Id.*

[9] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[10] *See Order,* 78 FR at 43144.

Final Results of Review

We determine that the following weighted average dumping margins exist for the period July 1, 2023, through June 30, 2024:

Exporter	Weighted-average dumping margin (percent)
Deosen Biochemical (Ordos) Ltd	22.57
Neimenggu Fufeng Biotechnologies Co., Ltd. (aka Inner Mongolia Fufeng Biotechnologies Co., Ltd.)/Shandong Fufeng Fermentation Co., Ltd./Xinjiang Fufeng Biotechnologies Co., Ltd.[11]	38.62
Non-Individually Examined Companies Receiving a Separate Rate:	
Jianlong Biotechnology Co., Ltd. (formerly, Inner Mongolia Jianlong Biochemical Co., Ltd.)	35.61
Jilin Meihua Amino Acid Co., Ltd	35.61
Meihua Group International Trading (Hong Kong) Limited/Langfang Meihua Biotechnology Co., Ltd.,/Xinjiang Meihua Amino Acid Co., Ltd	35.61
Ningxia Top Hydrocolloids Co., Ltd	35.61

Disclosure

Commerce intends to disclose its calculations and analysis performed for these final results of review to interested parties within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries of subject merchandise covered by the final results of this review. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the publication date of these final results in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

For Fufeng and Deosen, Commerce will calculate importer-specific assessment rates for antidumping duties, in accordance with 19 CFR 351.212(b)(1). Where the respondent reported reliable entered values, Commerce intends to calculate importer-specific *ad valorem* assessment rates by aggregating the amount of dumping calculated for all U.S. sales to the importer and dividing this amount by the total entered value of the merchandise sold to the importer.[12] Where the respondent did not report entered values, Commerce will calculate importer-specific assessment rates by dividing the amount of dumping for reviewed sales to the importer by the total quantity of those sales. Commerce will calculate an estimated *ad valorem* importer-specific assessment rate to determine whether the per-unit assessment rate is *de minimis* (*i.e.,* 0.50 percent or below); however, Commerce will use the per-unit assessment rate where entered values were not reported.[13] Where an importer-specific *ad valorem* assessment rate is not zero or *de minimis,* Commerce will instruct CBP to collect the appropriate duties at the time of liquidation. Where either the respondent's weighted average dumping margin is zero or *de minimis,* or an importer-specific *ad valorem* assessment rate is zero or *de minimis,* Commerce will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[14]

For entries submitted by an exporter individually examined during this review that were not reported in the U.S. sales database, but that entered under the case number of that exporter (*i.e.,* at the individually-examined exporter's cash deposit rate), Commerce will instruct CBP to liquidate such entries at the China-wide entity rate (*i.e.,* 154.07 percent).[15]

For respondents not individually examined in this administrative review that qualified for a separate rate (*i.e.,* Jianlong, Jilin Meihua, Meihua, and Ningxia), the assessment rate will be the weighted average of the dumping margin assigned to the mandatory respondents (*i.e.,* Fufeng and Deosen) in these final results of this review.[16]

For the respondents not eligible for a separate rate, that are part of the China-wide entity, we intend to instruct CBP to apply an *ad valorem* assessment rate of 154.07 percent (*i.e.,* the China-wide entity rate) to all entries of subject merchandise exported by these companies during the POR.

Additionally, for the above companies for which we made final no shipment determinations, any suspended entries that entered under that exporter's case number will be liquidated at the China-wide entity rate.

Cash Deposit Requirements

Pursuant to section 751(a)(2)(C) of the Act, the cash deposit requirements effective for shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of review will be as follows: (1) for the exporters listed in the table above, the cash deposit rate will be the rate indicated; (2) for previously investigated or reviewed exporters of subject merchandise not listed in the table above that have separate rates, the cash deposit rate will continue to be the

[11] Commerce continues to find that Neimenggu Fufeng Biotechnologies Co., Ltd. (aka Inner Mongolia Fufeng Biotechnologies Co., Ltd.), Shandong Fufeng Fermentation Co., Ltd., and Xinjiang Fufeng Biotechnologies Co., Ltd. are a single entity. *See Xanthan Gum from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2013–2014,* 80 FR 47464 (August 7, 2015), and accompanying PDM at 6, unchanged in *Xanthan Gum from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2013–2014,* 82 FR 11428 (February 23, 2017).

[12] *See* 19 CFR 351.212(b)(1).

[13] *Id.*

[14] *See* 19 CFR 351.106(c)(2).

[15] *See Order,* 78 FR at 43144.

[16] *See Drawn Stainless Steel Sinks from the People's Republic of China: Preliminary Results of the Antidumping Duty Administrative Review and Preliminary Determination of No Shipments: 2014–2015,* 81 FR 29528 (May 12, 2016), and accompanying PDM at 10–11, unchanged in *Drawn Stainless Steel Sinks from the People's Republic of China: Final Results of Antidumping Duty Administrative Review; Final Determination of No Shipments; 2014–2015,* 81 FR 54042 (August 15, 2016).

most recently published exporter-specific rate; (3) for all China exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the rate previously established for the China-wide entity (*i.e.,* 154.07 percent); and (4) for all non-China exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the China exporter that supplied that non-China exporter. The cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification of Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during the POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order (APO)

This notice also serves as a reminder to parties subject to an APO of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the terms of an APO is a sanctionable violation.

Notification to Interested Parties

Commerce is issuing and publishing the final results of this review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: July 8, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Changes Since the *Preliminary Results* and Post Preliminary Analysis
V. Discussion of the Issues
Comment 1: Whether the New Price Difference Test was Unlawfully Implemented
Comment 2: Whether to Deduct Certain Expenses from Fufeng's U.S. Price
Comment 3: Whether to Deduct Section 301 Duties from Fufeng's U.S. Price
Comment 4: Whether to Adjust the Surrogate Value (SV) for Labor
Comment 5: Whether to Adjust the SV for Marine Insurance Involving Fufeng's Air Shipments
Comment 6: Whether to Select Türkiye as the Surrogate Country
Comment 7: Whether Malaysia has the Best Available SV Information
Comment 8: Whether to Directly Value Energy Factor of Production (FOP) Inputs
Comment 9: Whether to Allow Byproduct Offsets for Certain By-products
Comment 10: Whether the Application of Adverse Facts Available (AFA) was Appropriate
Comment 11: Whether to Defer the Final Results
Comment 12: Whether an Insufficient Comment Period was Provided
Comment 13: Whether the Weighted-Average Dumping Margin for Non-Selected Respondents was Appropriately Calculated
VI. Recommendation

[FR Doc. 2026–14288 Filed 7–15–26; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–549–833]

Citric Acid and Certain Citrate Salts From Thailand: Preliminary Results of Antidumping Duty Administrative Review; 2024–2025

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) preliminarily determines that producers/exporters subject to this review did not make sales of subject merchandise at less than normal value (NV) during the period of review (POR), July 01, 2024, through June 30, 2025. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable July 16, 2026.

FOR FURTHER INFORMATION CONTACT: Anjali Mehindiratta, and Joy Zhang, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–9127.

SUPPLEMENTARY INFORMATION:

Background

On June 30, 2025, based on timely requests for review, in accordance with 19 CFR 351.221(c)(1)(i), we initiated an administrative review of the antidumping duty order on citric acid and certain citrate salts (citric acid) from Thailand.[1] On September 10, 2025, we selected COFCO and Sunshine as the mandatory respondents in this antidumping administrative review.[2]

Due to the lapse in appropriations and Federal Government shutdown, on November 14, 2025, Commerce tolled all deadlines in administrative proceedings by 47 days,[3] and, due to a backlog of documents that were electronically filed via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) during the Federal Government shutdown, on November 24, 2025, Commerce tolled all deadlines in administrative proceedings by an additional 21 days.[4] Finally, on June 3, 2026, Commerce extended the preliminary results of this review by 30 days, to no later than July 9, 2026.[5]

For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[6] A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via ACCESS. ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *https://access.trade.gov/frnotices.*

Scope of the Order

The merchandise subject to the *Order* is citric acid from Thailand. For a

[1] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity to Request Administrative Review and Join Annual Inquiry Service List,* 90 FR 27841 (June 30, 2025); and *Citric Acid and Certain Citrate Salts from Belgium, Colombia, and Thailand: Antidumping Duty Orders,* 83 FR 35214 (July 25, 2018) (*Order*).

[2] *See* Memorandum ''Respondent Selection,'' dated September 10, 2025.

[3] *See* Memorandum, ''Deadlines Affected by the Shutdown of the Federal Government,'' dated November 14, 2025.

[4] *See* Memorandum, ''Tolling of all Case Deadlines,'' dated November 24, 2025.

[5] *See* Memorandum, ''Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review: 2024–2025,'' dated June 3, 2026.

[6] *See* Memorandum, ''Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Citric Acid and Certain Citrate Salts from Thailand; 2024–2025, dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.

Methodology

Commerce is conducting this review in accordance with section 751(a) of the Tariff Act of 1930, as amended (the Act). Export price and constructed export price are calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

Rate for Non-Individually Examined Companies

The Act does not address the establishment of a rate to apply to companies not selected for individual examination when Commerce limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. However, Commerce's regulation at 19 CFR 351.109(g) sets forth the process for determining the rate for non-individually examined companies. This regulation explains that Commerce generally will follow the process for calculating the all-others rate under 19 CFR 351.109(f) and section 735(c)(5) of the Act.

Under section 735(c)(5)(A) of the Act, the all-others rate is normally an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any rates that are zero, *de minimis* (*i.e.,* less than 0.5 percent), or determined entirely on the basis of facts available. Where the weighted-average dumping margin for each of the individually examined companies is zero, *de minimis,* or based entirely on facts available, section 735(c)(5)(B) of the Act provides that Commerce may use ''any reasonable method to establish the estimated all-others rate for exporters and producers not individually investigated, including averaging the estimated weighted-average dumping margins determined for the exporters and producers individually investigated.'' [7]

In this review, we preliminarily calculated dumping margins of zero percent for both COFCO and Sunshine. Consistent with 19 CFR 351.109(f)(2)(iii), the U.S. Court of Appeals for the Federal Circuit's Decision in *Albermarle,*[8] and Commerce's practice in this proceeding,[9] we preliminarily assigned the non-selected company a zero percent rate, based on the rates calculated for the two mandatory respondents.

Preliminary Results of Review

As a result of this review, we preliminarily determine the following estimated weighted-average dumping margin exists for the period July 01, 2024, though June 30, 2025:

Producer or exporter	Weighted-average dumping margin (percent)
COFCO Biochemical (Thailand) Co., Ltd	0.00
Sunshine Biotech International Co. Ltd	0.00
Xitrical Group Co. LTD	0.00

Disclosure

Commerce intends to disclose its calculations and analysis performed to interested parties for these preliminary results within 10 days of any public announcement or, if there is no public announcement, within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b).

Public Comment

Case briefs or other written comments may be submitted to the Assistant Secretary for Enforcement and Compliance. Pursuant to 19 CFR 351.309(c)(1)(ii), we have modified the deadline for interested parties to submit case briefs to Commerce to no later than 21 days after the date of the publication of this notice.[10] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.[11] Interested parties who submit case briefs or rebuttal briefs in this proceeding must submit: (1) a table of contents listing each issue; and (2) a table of authorities.[12] All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety in ACCESS by 5:00 p.m. Eastern Time on the established deadline.

As provided under 19 CFR 351.309(c)(2)(iii) and (d)(2)(iii), we request that interested parties provide at the beginning of their briefs a public executive summary for each issue raised in their briefs.[13] Further, we request that interested parties limit their public executive summary of each issue to no more than 450 words, not including citations. We intend to use the public executive summaries as the basis of the comment summaries included in the issues and decision memorandum that will accompany the final results in this administrative review. We request that interested parties include footnotes for relevant citations in the public executive summary of each issue. Note that Commerce has amended certain of its requirements pertaining to the service of documents in 19 CFR 351.303(f).[14]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) the party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Oral presentations at the hearing will be limited to issues raised in the briefs. If a request for a hearing is made, Commerce will inform parties of the scheduled date for the hearing.[15]

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review.

If the weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.50 percent) for COFCO or Sunshine in the final results of this review, Commerce intends to calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those sales. Where we do not have entered values for all U.S. sales to a particular importer, we will

[7] *See* 19 CFR 351.109(f)(2)(iii).

[8] *See Albemarle Corp.* v. *United States,* 821 F.3d 1345 (Fed. Cir. 2016) (*Albemarle*).

[9] *See Citric Acid and Certain Citrate Salts from Thailand: Final Results of Antidumping Duty Administrative Review; 2023–2024,* 91 FR 8417 (February 23, 2026); *see also Citric Acid and Certain Citrate Salts from Thailand: Final Results of Antidumping Duty Administrative Review; 2022–2023,* 89 FR 94706 (November 29, 2024).

[10] *See* 19 CFR 351.309.

[11] *See* 19 CFR 351.309(d); *see also Administrative Protective Order, Service, and Other Procedures in Antidumping and Countervailing Duty Proceedings,* 88 FR 67069, 67077 (September 29, 2023) (*APO and Service Procedures*).

[12] *See* 19 CFR 351.309(c)(2) and (d)(2).

[13] We use the term ''issue'' here to describe an argument that Commerce would normally address in a comment of the Issues and Decision Memorandum.

[14] *See APO and Service Procedures.*

[15] *See* 19 CFR 351.310(d).

calculate an importer-specific, per-unit assessment rate on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total quantity of those sales.[16] To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values. If COFCO's or Sunshine's weighted-average dumping margin is zero or *de minimis* or where an importer-specific *ad valorem* assessment rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[17]

In accordance with Commerce's ''automatic assessment'' practice, for entries of subject merchandise during the POR produced by COFCO and Sunshine for which they did not know that the merchandise was destined for the United States, we intend to instruct CBP to liquidate those entries at the all-others rate calculated in the less-than-fair-value (LTFV) investigation if there is no rate for the intermediate company(ies) involved in the transaction.[18]

For the company which was not selected for individual examination, Xitrical Group Co. LTD, we will instruct CBP to assess antidumping duties at an *ad valorem* assessment rate equal to the company-specific weighted-average dumping margin determined in the final results.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for the companies listed above will be that established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously investigated or reviewed companies not covered by this review, the cash deposit rate will continue to be the company-specific cash deposit rate published for the most recently completed segment of this proceeding in which the company participated; (3) if the exporter is not a firm covered in this review, or the LTFV investigation, but the manufacturer is, then the cash deposit rate will be the rate established for the most recent segment for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 11.25 percent, the all-others rate established in the LTFV investigation.[19] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results of review in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(2) and 351.221(b)(4).

Dated: July 9, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the *Order*
IV. Discussion of the Methodology
V. Currency Conversion
VI. Recommendation

[FR Doc. 2026–14292 Filed 7–15–26; 8:45 am]

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[16] *See* 19 CFR 351.212(b)(1).

[17] *See* 19 CFR 351.106(c)(2); *see also Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[18] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[19] *See Order.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–557–816]

Certain Steel Nails From Malaysia: Final Results of Antidumping Duty Administrative Review; 2023–2024; Correction

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

ACTION: Notice; correction.

SUMMARY: The U.S. Department of Commerce (Commerce) published notice in the **Federal Register** of May 14, 2026, in which Commerce published the final results of the 2023–2024 administrative review of the antidumping duty (AD) order on certain steel nails from Malaysia. This notice inadvertently included the company Foison Hardware Inc. as a company subject to the review.

FOR FURTHER INFORMATION CONTACT: Tyler Weinhold, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1121.

SUPPLEMENTARY INFORMATION:

Background

On May 14, 2026, Commerce published in the **Federal Register** the final results of the 2023–2024 AD administrative review of certain steel nails from Malaysia.[1] In the *Final Results,* we inadvertently included the company Foison Hardware Inc. as a company subject to the review.

Correction

In the **Federal Register** of May 14, 2026, in FR Doc 2026–09709, on page 27250, in the second column, under ''Appendix II,'' correct the ''Non-Selected Companies for Individual Review'' section by removing ''1. Foison Hardware Inc.''

Notification to Interested Parties

This notice is issued and published in accordance with section 751(a)(1) and 777(i) of the Tariff Act of 1930, as amended, and 19 CFR 351.221(b)(5).

[1] *See Certain Steel Nails from Malaysia: Final Results of Antidumping Duty Administrative Review; 2023–2024,* 91 FR 27248 (May 14, 2026) (*Final Results*).

Dated: July 9, 2026.

Christopher Abbott,

Deputy Assistant Secretary for Policy and Negotiations, performing the non-exclusive functions and duties of the Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2026–14291 Filed 7–15–26; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF749]

Request for Information on Ropeless Fishing; Fisheries of the Northeastern United States and Atlantic Coastal Fisheries Cooperative Management

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

ACTION: Notice; request for information.

SUMMARY: NMFS is requesting information from fishery participants and others with specialized knowledge on the potential use of ropeless fishing gear, which includes on-demand fishing gear and other fixed gear that does not use persistent buoy lines. This information will inform any potential future use, development, and management of these systems in fisheries in the Greater Atlantic Region. NMFS intends to summarize the responses to this request for information and share that summary publicly.

DATES: Responses are due on or before October 14, 2026.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2026–2080, by the following method:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Visit *https://www.regulations.gov* and type NOAA–NMFS–2026–2080 in the Search box. Click on the ''Comment'' icon, complete the required fields, and enter or attach your comments.

Instructions: When responding to this request for information, please label your response with the corresponding question number to which your input is directed. Comments sent by any other method than the one listed above, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *https://www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address, *etc.*), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Copies of supporting documentation to this request for information are available online. The technical report *Evaluation of On-Demand Gear Acoustic Interoperability Approaches in the Northeast U.S.* by the MITRE Corporation, is available at *https://library.oarcloud.noaa.gov/noaa_documents.lib/NMFS/On-Demand_Gear_Interoperability_Report.pdf.* The Northeast Fisheries Science Center report *A Proposal for Functional Data Specifications of On-Demand Fishing Gear, Version 2* (Galvez, 2026) is available at *https://repository.library.noaa.gov/view/noaa/73583/noaa_73583_DS1.pdf.*

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SUPPLEMENTARY INFORMATION:

I. Introduction

Under the Consolidated Appropriations Act, 2023, NMFS is required to, ''in consultation with affected States and fishing industry participants, promote the innovation and adoption of gear technologies'' (Division JJ, Title I, Section 101(a)(1)). The Act mandates this effort to implement ''new regulations for the American lobster and Jonah crab fisheries consistent with the [Marine Mammal Protection Act (MMPA) and Endangered Species Act] that take effect by December 31, 2028, utilizing existing and innovative gear technologies, as appropriate'' (Division JJ, Title I, Section 101(a)(2)).

Accordingly, NMFS is providing resources to support the development of ropeless fishing gear as a potential voluntary alternative for fixed-gear fishermen to operate in areas with persistent buoy line restrictions while minimizing risks to large marine mammals. NMFS continues to collaborate with fishermen, technology manufacturers, state agencies, fishery management organizations, and other partners to explore the benefits and limitations of these technologies. This request for information (RFI) is a key step of this ongoing effort to comply with the mandates of the Consolidated Appropriations Act, 2023. This RFI does not limit NMFS' ability to consider other innovative gear or management activities and various management options are being considered.

Buoy lines connecting physical surface markers with fixed fishing gear—such as traps, pots, and gillnets—can become entangled with large whales, leading to the serious injury or death of the whale. Restricting the use of persistent buoy lines is one way to reduce the risk of entanglement for protected species, including North Atlantic right whales. Ropeless fishing gear substantially reduces entanglement risk and, if approved, could be used in areas with persistent buoy line restrictions.

In 2021, to comply with the requirements of the MMPA and respond to high rates of incidental deaths and serious injuries exceeding allowable limits, NMFS amended the Atlantic Large Whale Take Reduction Plan (86 FR 51970, September 17, 2021). This rule restricted the use of persistent buoy lines in particularly high-risk entanglement hotspot areas during times of the year when North Atlantic right whales and persistent buoy lines are most likely to co-occur.

The Consolidated Appropriations Act, 2023, requires NMFS to implement ''additional whale protection measures by December 31, 2028,'' (Division JJ, Title I, Section 101(a)(1)). If the best available scientific data shows that U.S. commercial fixed-gear fisheries continue to exceed the MMPA's legal thresholds, new or modified times and areas where persistent buoy lines are restricted may be considered, including during right whale aggregations. However, if authorized by NMFS, fixed-gear fishermen could use ropeless gear to continue fishing in new or modified areas, as well as the previously restricted areas.

Currently, the regulations governing the operation of federal waters fisheries in the Greater Atlantic Region require all fixed fishing gear to have physical surface markers (buoy/high flyer with radar reflector/pennant) (*e.g.,* 50 CFR 648 for Council-managed fisheries and part 697 for the lobster/Jonah crab fisheries). As a result of these gear marking requirements, any area that prohibits persistent buoy lines, but would otherwise allow fishing without those buoy lines, remains an area closed to fixed-gear fishing.

In 2025, the New England and Mid-Atlantic Fishery Management Councils initiated the Joint Omnibus Alternative Gear-Marking Framework Adjustment to consider whether to recommend that NMFS allow the use of fixed gear without physical surface markers in Council-managed fisheries if an equivalent alternative marking method

is used. NMFS is also considering whether to similarly modify the Federal American lobster/Jonah crab gear-marking regulations. If NMFS authorizes the use of gear-marking alternatives, such as digital gear markings, lobstermen could regain fishing access to current and any potential future restricted areas by using authorized ropeless fishing gear. Similarly, with these alternatives, fishermen could respond to sudden aggregations of large whales in an area by removing one or both endline(s), thereby reducing the likelihood of entanglement for the period of time the whales remain in an area. However, the Councils' action was postponed, pending additional input from stakeholders including the fishing industry. NMFS has, likewise, postponed action with respect to the lobster and Jonah crab fisheries to gather additional input and ensure consistency among the actions.

This RFI requests information specific to the program design, utility, limitations, and technical capability of ropeless fishing. It contains questions and associated context that were developed with a focus on Greater Atlantic Region operational and management considerations. However, NMFS also welcomes feedback informed by experiences where these gear alternatives are being used outside the Greater Atlantic Region. This RFI does not request comment on the number, size, location, or seasonality of any existing or future whale protection areas. The public will be notified if and when NMFS requests comment on those topics, which will occur through a different process and at a later time.

Description of Ropeless Fishing Gear

In this RFI, the term ''ropeless'' is used to describe all types of fixed-gear fishing that does not use persistent buoy lines. Therefore, ropeless fishing gear includes fixed gear rigged with an on-demand device or timed-retrieval device that triggers a retrieval mechanism. While gear rigged with these devices can still have ropes that are used to retrieve the gear, any buoy lines are only intended to remain in the water column for a short time during gear retrieval. Because ropeless gear refers to all fixed gear without any persistent buoy lines, it also encompasses fixed gear without one of these devices that can be retrieved by grappling. A string or trawl of fixed gear that uses a traditional, persistent buoy line on only one end is referred to as ''one-end ropeless.'' The end without the persistent buoy line may or may not be rigged with an on-demand or timed-retrieval device and retrieval mechanism.

Both trap/pot and gillnet gear, as well as other fixed gear types, can be fished in a ropeless configuration. For on-demand and timed-retrieval devices, the line can be stowed on the ocean floor rather than vertically in the water column between the bottom gear and the surface marker. An on-demand device uses acoustic communication to activate a retrieval mechanism such as a pop-up buoy, inflatable lift bag, or buoyant-rope spool. Timed-retrieval devices are designed to function similarly, except they use a timer or galvanic link to activate a retrieval mechanism. All of these types of ropeless fishing gear can be marked using alternative gear-markings such as digital markings.

Section III of this RFI provides definitions of the terms used in this RFI.

Ropeless Fishing Gear's Functional Equivalence to Traditional Gear

Ropeless fishing gear that does not use persistent buoy lines and surface markers should reproduce the functions served by surface markers. Such functions may include, but are not limited to: Allowing ocean users to visually detect the location of the gear; conveying set direction; allowing the gear to be retrieved; conveying identifying information that is required by the relevant fishery (*e.g.,* permit number); and allowing law enforcement to locate, retrieve, and redeploy the gear. Reproducing these functions allows fishermen and other ocean users to continue to operate in close proximity to the fixed gear while minimizing gear conflict. To achieve these functions, in part, ropeless fishing gear can be marked and visualized digitally. This RFI requests comment on how this should most effectively be accomplished.

II. Topics for Comment

1.0 Authorization of Ropeless Fishing Gear

Context

Through the Alternative Gear-Marking Framework Adjustment action, the New England and Mid-Atlantic Councils are considering when and where digitally marked gear could be allowed in its fixed gear fisheries. NMFS is concurrently considering whether to modify Federal lobster gear-marking regulations to relieve surface marking restrictions. During this process, the Councils received feedback highlighting the diversity of the fixed-gear industry, suggesting that regulatory changes must account for regional differences in fishing practices. In addition, other solutions such as grappling or removing one endline have been suggested as potential solutions to reduce large whale entanglement risk. Therefore, NMFS requests comments on information that will help inform decision making.

Questions

1. What experience do you have with ropeless fishing gear?

2. Ropeless fishing gear: Under what specific environmental, seasonal, or operational circumstances should NMFS authorize the use of ropeless fishing gear? Conversely, under what circumstances should its use be denied?

3. One-end ropeless gear: Under what specific circumstances should NMFS authorize the use of one-end ropeless gear? When should it be explicitly denied?

4. Do you support the use of grappling-only ropeless fishing gear? What limitations or guidelines should accompany its use?

2.0 Safety and Performance of On-Demand and Timed-Retrieval Fishing Gear

Context

NMFS is working to develop standards that ropeless systems would need to meet to be approved for use in regular commercial fishing operations in the Greater Atlantic Region. Establishing these standards will help ensure that fishermen have a range of safe, reliable, and effective system options from which to choose.

Safety

Ensuring that ropeless systems are safe to use is of paramount importance. Ropeless fishing gear eliminates the persistent endlines that could otherwise entangle a crewmember during deployment. However, because there is no persistent buoy line immediately available, recovering a crewmember who becomes entangled in a groundline could be more difficult. Thus, while some note that ropeless gear reduces the initial risk of crewmember entanglement by eliminating the endline that can entangle the crew, others caution that it could decrease the chances of a successful recovery if a ''man overboard'' incident occurs from groundline entanglement.

Stakeholders have also raised operational safety concerns regarding the gear itself. These include the physical weight of the systems, the use of compressed air tanks, the hauling process, mechanical or digital failures, and premature releases. Additionally, safety concerns related to potential gear conflicts have been noted.

While there have been no documented safety incidents during on-demand research and trials conducted by the Northeast Fisheries Science Center, developers are actively working on a ''man overboard'' feature that would immediately trigger the gear's retrieval mechanism. One developer has implemented this feature with its on-demand gear. However, gear rigged with a timed-retrieval device or gear that requires grappling would not necessarily support this function, potentially limiting this safety option for those gear types. Concerns have also been raised about the safety of grappling for ropeless gear.

Questions

5. What are the human safety-related concerns with and benefits of on-demand fishing? How do these concerns and benefits compare with traditional fishing gear?

6. What safety requirements or standards should be considered as part of approving a ropeless system for use?

7. Is ''man overboard'' functionality helpful for improving safety? If so, should it be a mandatory requirement for some or all types of ropeless gear? Are there other features that could increase safety of ropeless gear?

8. How could timed-retrieval devices or grappling methods be modified to increase safety?

Successful Retrievals

Ensuring that on-demand or timed-retrieval devices function as intended is necessary for the safe and continued operation of the gear. When retrieving on-demand fishing gear, ''success'' is measured by the ability to acoustically communicate with the device on the seafloor, trigger the release mechanism, and retrieve the gear at the surface. The overall success rate is over 91 percent for trials conducted under an EFP by the Northeast Fisheries Science Center. Nearly every unsuccessful haul was retrieved by other means, such as grappling. Based on anecdotes from fishermen using traditional fixed gear—which is subject to loss from storms, vessel traffic, gear conflict, and other losses—this 91-percent retrieval rate of on-demand gear is at least as good as, if not better than, fishing with traditional fixed gear. For the EFP trials from summer 2020 to early 2026, fewer than 1 in 600 hauls have led to the loss of an on-demand device, a recovery rate of 99.8 percent. While the Northeast Fisheries Science Center is not currently testing timed-retrieval devices, a similar measure of success, such as retrieval rate, could be developed for that gear type. However, determining the reliability of grappling may prove more difficult.

Questions

9. Should individual makes and models of ropeless fishing gear be subject to minimum reliability standards prior to approval for use? If so, how would you approach implementing this? Specifically, which components of a ropeless system (*e.g.,* the release mechanism, the on-demand/timed-retrieval device, other) should be subject to minimum reliability standards? What success criteria and testing parameters (*e.g.,* duration of deployment, depth, specific fishery conditions) should be used to evaluate reliability?

10. If a ropeless system no longer meets a reliability standard, what should the process be for re-approval?

11. Should fishermen be allowed to design and use their own rope containment systems to pair with approved on-demand or timed-retrieval release mechanisms or should complete-only designs be approved (with all or some modifications prohibited)?

12. Should there be a periodic inspection requirement to ensure gear safety or viability?

Premature Releases

On-demand or timed-retrieval systems have the potential to prematurely release. Tracking and reporting these premature releases is critical for at least two reasons: (1) It is important to know when and where buoy lines are present in the water column, especially if the area prohibits persistent vertical buoy lines; and (2) if a particular make and model of on-demand or timed-retrieval gear repeatedly releases prematurely, that information would be important for decision making, including device approval by NMFS.

Questions

13. Should fishermen be required to report premature releases of on-demand or timed-retrieval fishing gear?

14. Should premature release notifications be automatically sent to the gear owner and/or NMFS? Currently, this requires an additional device and increases the price of each ropeless system.

3.0 Alternative Gear Marking

Context

Currently, most vessel operators testing ropeless systems manually mark the gear's location by a button-push using a gear manufacturer-provided digital application using a tablet or smartphone. This creates a digital mark of the gear's position. However manual entry is prone to error; an operator may forget to mark gear during deployment, resulting in missing or inaccurate location data. Additionally, an operator could intentionally log a digital marker without actually deploying gear, creating a false mark. Both of these scenarios decrease the reliability of data that other ocean users would rely on to operate near ropeless fishing gear and avoid gear conflicts.

Ropeless gear can be marked automatically. For example, surface markings can be automatically created when the gear is deployed into the water. In addition, some on-demand systems automatically mark the gear's location on the seafloor via acoustic localization if the vessel is equipped with a through-hull transducer (although there may be other methods by which this functionality could be achieved). However, most systems do not currently have this capability and might only adopt it if it becomes a regulatory requirement. Furthermore, for fixed gear with physical surface markers, fishermen must estimate the location of gear on the seafloor based on the location of the buoys at the surface. Alternatively, acoustic communication can detect and mark the gear's position on the seafloor. This method may provide more accurate and precise gear location markings than using a global positioning system (GPS) to mark the gear's deployment location at the surface; however, it increases cost and technological complexity. Because gear density and the potential for gear conflict vary by region, it may be necessary to require the use of more precise location marking technology in certain areas. NMFS sponsored the technical report *Evaluation of On-Demand Gear Acoustic Interoperability Approaches in the Northeast U.S.* by the MITRE Corporation (see **ADDRESSES**), which, in part, examines localization accuracy requirements of ropeless gear.

Questions

15. How precisely do you need to know the geographic location of ropeless fishing gear to ensure safe operations and prevent gear conflicts (*e.g.,* within 25 feet of the true location)? In what specific areas, depths, or fishery conditions do you need to have this level of location precision? Are there other areas, depths, or fishery conditions where you would need more or less precision?

16. Should ropeless systems be required to automatically mark their deployment locations to eliminate human error, or is manual input (*e.g.,* via a mobile app or chartplotter) sufficient?

17. If manual marking is permitted, what measures or penalties should be considered to deter the creation of false marks or the failure to mark deployed gear?

18. How should NMFS balance the high cost and complexity of reliance on through-hull transducers for automatic acoustic marking against the need for highly reliable spatial data?

19. How desirable is it to be able to mark ropeless gear and trigger release mechanisms with a chartplotter as opposed to using a manufacturer's mobile application?

4.0 Gear Viewing

Context

Ocean users (*e.g.,* mobile fishing vessels, other fixed-gear vessels, vessels transiting nearby) must be able to detect ropeless fishing gear. This is a fundamental element of functional equivalence to physical surface markers (discussed in Section I. Introduction). Currently, in the Greater Atlantic Region, other ocean users can access location information from every ropeless system, regardless of manufacturer, on a unified platform that alleviates the potential need to monitor multiple applications or devices. This is accomplished through a data aggregator that compiles the location information for ropeless gear (generated by individual fixed-gear fishing vessels and ropeless gear manufacturers) and disseminates the information to other user groups. NMFS has developed partnerships and prototype data aggregation systems with independent organizations to facilitate the exchange of ropeless gear location information. For more discussion about data aggregators, see Section 9.0.

Option for Sharing Ropeless Gear Location Data

Decision-makers should establish rules regarding what information a data aggregator shares and with whom. For example, in an extreme case, a data aggregator could allow the precise location and identification information of digitally marked gear to be viewable to anyone and from shore. Alternatively, shoreside viewing could be restricted to displaying only areas of high gear density (without identifying information). As another option, viewing could be restricted to users within a specific physical distance from the gear comparable to visual sighting of traditional gear.

Determining how digital gear-marking data are shared requires balancing three key factors: Data transmission costs; the privacy of a vessel's location; and the privacy of the fishing gear's location. It should also be noted that sending and receiving ropeless gear information to and from a data aggregator in near real-time would require access to the internet or cellular data. However, there may be specific circumstances where information is not needed in near-real time, such as in areas with low fishing effort.

There are at least four possible options for sharing gear location information with vessels at sea:

Option 1: Curated by a Data Aggregator

- *Process:* A vessel actively shares its current location with a data aggregator. The data aggregator transmits location data of ropeless gear within a pre-specified radius of the vessel.
- *Priorities/trade offs:* This prioritizes ropeless gear location privacy and lower data transmission costs, but it requires vessels to anonymously provide their physical location to the aggregator.

Option 2: GPS Filtered on Vessel

- *Process:* A data aggregator sends all ropeless gear location data to a vessel (or all locations within a certain range of where the vessel is taking its trip). The vessel's integrated GPS technology then filters the information locally, displaying only the gear within a specified radius.
- *Priorities/trade offs:* Compared to option 1, this would increase vessel location privacy, but could increase data transmission costs and may create data security vulnerabilities that could expose ropeless gear information beyond the specified radius if the GPS-filtering technology was hacked.

Option 3: Criteria-Based Access

- *Process:* This refines Options 1 or 2 by restricting the aggregator to only send data to vessels that meet specific criteria (*e.g.,* vessels actively permitted to fish in certain areas or fisheries).
- *Priorities/trade offs:* This alleviates some data security concerns, but significantly increases management and administrative complexity.

Option 4: Fully Public

- *Process:* The data aggregator publicly shares all ropeless gear location data.
- *Priorities/trade offs:* This places the highest priority on vessel location privacy. However, it essentially eliminates on-demand gear location privacy and has a comparatively high data transmission cost.

Some of these options require a data aggregator to temporarily know the location of the vessels to which it is sharing gear location data. This is similar to how you need to allow a mapping/navigational app to know your location while traveling for it to provide directions, traffic, or road conditions in real-time. A data governance plan (discussed in Section 9) could specify how long a data aggregator may retain vessel location data.

While NMFS has implemented location data collection programs, such as vessel monitoring systems, and states have implemented electronic tracking of Federal lobster vessels, these programs were created for specific purposes and mandate specifically what information must be shared when and with whom. Moreover, these programs do not include all vessels that operate near fixed gear. Thus, these programs, and similar state programs, are not sufficient as a comprehensive solution if vessel location needs to be shared with a data aggregator for the purposes of disseminating ropeless gear location information.

Questions

20. Which of the four data-sharing options (or combination thereof) is preferable, and why? How should data transmission costs, privacy of a vessel's location, and privacy of the fishing gear's location be prioritized against each other?

21. Under what circumstances is it necessary or desirable that ropeless fishing gear markings be viewable and updated in near real-time? Under what circumstances is it unnecessary?

22. At what specific distance from deployed ropeless gear should its location become visible on a vessel's display? Should this distance vary for specific fisheries, users, or circumstances?

23. Should digitally marked gear be viewable from shore? If so, which specific user groups (*e.g.,* law enforcement, researchers, the general public) should have shoreside access? Would you support shoreside viewability if it only provided aggregated and anonymized information (*e.g.,* a heat map)?

24. Should there be a tiered-distance threshold where *only* the gear's location is viewable from a certain distance away, but detailed identifying information (*e.g.,* permit or ownership details, as appropriate) becomes visible only when the vessel is in very-close proximity?

25. Should vessel location data be shared with a data aggregator so it may curate and provide only the gear data within a specific radius (Option 1; akin to sharing your location with a mapping application for driving directions)? If

not, what are your concerns regarding this option?

5.0 Gear Conflict

Context

Gear conflict avoidance relies on vessel operators adequately marking their gear, maintaining a vigilant watch, and taking necessary steps to avoid marked gear. Generally, all fishermen have equal access to fish in Federal waters in the manner specified by law. Fishermen are prohibited from causing a gear conflict by negligently and without authorization removing, damaging, or tampering with another person's fishing gear. These obligations and requirements apply whether the fisherman is utilizing traditional or ropeless fishing gear and whether they operate with fixed or mobile gear.

Many stakeholders express concern that eliminating or reducing the number of physical surface markers with ropeless gear will increase the incidence of gear conflict. Conversely, others suggest that digitally marked gear may actually reduce conflicts due to the distinct advantages of digital marks. Environmental factors—such as nighttime operations, fog, and heavy seas—severely limit the visibility of traditional surface markers. Digital marking provides reliable, long-range viewability of fixed gear under both normal and adverse conditions that may be superior to visual sightings of surface markers.

Furthermore, because ropeless gear could be less susceptible to displacement by heavy weather, and some systems can be acoustically detected even if displaced, its adoption could result in less ''ghost'' gear, further reducing the potential for conflict. Additionally, removing physical buoy lines from the water column allows vessels to safely transit directly over fixed gear without causing a conflict.

Stakeholders have also pointed out that digital marks could significantly assist in the enforcement and resolution of gear conflict incidents. If law enforcement agencies are authorized to access digital gear-marking data, combining near real-time ropeless gear locations with existing vessel tracking systems (such as vessel monitoring systems or automatic identification systems) could provide useful data to support investigations into gear conflicts.

In 1996, at the recommendation of the New England Council in coordination with the Mid-Atlantic Council and the Atlantic States Marine Fisheries Commission, NMFS implemented a process for resolving gear conflicts in fixed and mobile gear fishery management plans through a framework adjustment. NMFS or the Councils could initiate a new framework adjustment that specifically considers and delineates the operational obligations and responsibilities for fishing with, and around, ropeless fishing gear in Federal waters.

Questions

26. What are the gear conflict-related benefits and concerns of ropeless fishing? How are those benefits or concerns different for one-end ropeless?

27. Are specific steps or regulatory measures necessary to proactively decrease gear conflicts related to ropeless fishing? If so, what are they?

28. Is it necessary for fishing vessels operating around ropeless gear to view digital gear markings in near real-time? Does this depend on the fishery or location?

29. Should fishing vessels operating near ropeless gear be required by regulation to carry the technology necessary (*e.g.,* internet and a visualization tool, such as a chartplotter) to view digital gear markings in near real-time? Or, are the consequences of causing a gear conflict enough deterrence that such regulatory requirements are not necessary?

30. Should fishermen be required to report gear conflicts?

31. Does the digitization of fishing gear locations improve situational awareness of gear locations at sea?

6.0 Equity

Context

Currently, the Greater Atlantic Region fixed-gear fishery regulations require various physical surface markers, prohibiting the use of ropeless gear. Research and testing of ropeless fishing gear is being conducted through exempted fishing permits (EFP), which allow approved vessels to engage in otherwise prohibited activities. While some view EFPs as a viable pathway for permitting ropeless fishing to advance our knowledge and experience, others argue they are inequitable because they grant fishing privileges to a limited number of select permit holders. NMFS, in general, supports permanently relieving the restrictions on gear-marking requirements, in part, to minimize the burden on the industry to apply for and report on EFPs, as well as to minimize governmental resource burdens. Furthermore, long-term reliance on EFPs to authorize ropeless fishing could lead to unequal access and opportunities among fishermen.

Some forms of ropeless fishing—such as on-demand gear—require different technology compared to traditional fixed-gear fishing. For fishermen who choose to adopt ropeless gear, their operational methods could change in ways that some allege would potentially alter the character of the fishery. Some have voiced concerns that the technological and financial requirements of on-demand gear could shift the balance of competitive success, which could ultimately lead to the consolidation of some fixed-gear fisheries. Others note that industries regularly adapt to emerging technologies while maintaining the character of the industry.

Questions

32. What specific equity concerns do you have regarding the authorization and use of ropeless fishing gear?

33. What measures could NMFS implement to address equity concerns?

34. How does the current reliance on EFPs impact the development, fairness, and opportunity within the fishery?

35. How can ropeless fishing programs be designed and managed to ensure fair access and equitable outcomes for all willing participants and affected parties?

7.0 Potential Training Requirements To Use Ropeless Fishing Gear

Context

As with any technology, it is assumed that experience with a new gear will foster proficiency with its use. To establish a baseline of proficiency, a knowledge demonstration or training requirement could be required before fishermen are authorized to use ropeless systems. This requirement could be structured in various ways, ranging from an on-the-water practical test to simply reviewing educational materials (such as ''how-to'' videos for a manufacturer's mobile application) followed by a brief knowledge assessment. If a training requirement is deemed necessary, decisions on which entities should develop and provide this training, and exactly how fishermen should be expected to demonstrate their competency with ropeless systems, will need to be made.

Questions

36. Should ropeless users be required to demonstrate that they know how to properly deploy, retrieve, and/or mark ropeless fishing gear before being authorized to use it?

37. If a knowledge demonstration or training requirement is implemented, what specific elements or milestones should be required of the operator? Who should be responsible for developing

and administering this training (*e.g.,* NMFS, gear manufacturers, other)?

38. Should other ocean users (*e.g.,* mobile gear fishermen) be required to demonstrate proficiency in using the visualization technology necessary to detect digitally marked gear?

39. How should NMFS handle repeated instances of operator error? How would NMFS distinguish between an operator error and an equipment malfunction?

8.0 Law Enforcement

Context

Ropeless systems present both challenges and practical utility for law enforcement. For example, on-demand gear manufacturers currently use proprietary acoustic communication protocols, requiring law enforcement vessels to carry multiple, manufacturer-specific deck boxes and transducers to retrieve and inspect different ropeless gear systems. While efforts are underway to develop and test a universal deck box capable of communicating with all on-demand gear, this remains a technological hurdle. If manufacturers adopted a common acoustic-signaling standard, a universal deck box would be unnecessary; however, there is currently no industry-wide initiative or regulatory requirement to pursue a standardized acoustic protocol. The MITRE Corporation's technical report *Evaluation of On-Demand Gear Acoustic Interoperability Approaches in the Northeast U.S.* (see **ADDRESSES**) examines whether a common acoustic signaling approach is needed.

In addition to the challenge of triggering on-demand devices, enforcement personnel must be trained to safely operate various proprietary release mechanisms to retrieve and properly redeploy gear during at-sea inspections. Furthermore, it may be impractical for law enforcement to inspect timed-retrieval devices. Safety and logistical concerns also exist for grappling ropeless gear. Covert inspections may also be logistically challenging.

Despite these physical challenges, digitally marked gear offers practical utility for enforcement operations. If law enforcement personnel are authorized to access digital gear location data from shore, or from an expanded radius at-sea, it could streamline patrol trip planning and help agencies allocate their on-water resources more efficiently. Likewise, digital markers and associated data records could provide law enforcement with useful information to support investigations—information that is simply not available with traditional fixed gear.

Questions

40. What concerns or suggestions do you have regarding enforcing ropeless fishing?

41. How should law enforcement address the inspection of ropeless gear that is rigged with timed-retrieval devices or that is grapple-only?

9.0 Data Governance and Management

Context

Data Standard

For digital gear markings to successfully reproduce the functions of physical surface markers, a robust data-governance framework must be developed to ensure that essential information flows efficiently among data users. NMFS is currently working to identify the specific information that should be aggregated from ropeless fishing systems and disseminated to end users. Standardizing the data associated with digitally marked gear (as is done for other U.S. fisheries programs) can support software development, efficiency in information management and dissemination, and generally increase the quality and accuracy of data. A potential list of data elements and user groups is provided in a Northeast Fisheries Science Center report (Galvez, 2026, see **ADDRESSES**).

Data Aggregator(s)

As described in Section 5.0, an entity must act as a data aggregator that collects and disseminates the location information of ropeless fishing gear. Currently, two organizations act as data aggregators in the Greater Atlantic Region. NMFS has conducted an initial evaluation regarding the role of the Federal government in providing these data services, as well as the additional legal requirements that would apply. Federal management of ropeless gear location information would likely require complex procedures to comply with multiple Federal statutes. Given that certain Federal statutory requirements would not necessarily apply to private or independent entities, a non-Federal third party could aggregate this data more efficiently than NMFS, potentially providing more effective data services for ocean users.

Currently, data from each on-demand system is transmitted to the manufacturer's database, transmitted to one data aggregator, shared with the other data aggregator, and finally distributed back out to visualization platforms. Having a single data aggregator and fewer points of transmission would reduce errors and latency and increase reliability and efficiency. It would be helpful to determine if multiple organizations should be allowed to coordinate with each other and each act as a data aggregator or if only one organization should act as a data aggregator. In addition, NMFS is seeking stakeholder input on what requirements there should be for digitally marked gear databases to protect fishermen's proprietary data.

Questions

42. How should data for ropeless fishing be governed and managed?

43. Do you have any additional feedback or recommendations regarding the list of data elements in the report *A Proposal for Functional Data Specifications of On-Demand Fishing Gear* (Galvez, 2026, see **ADDRESSES**)? Are there any missing data elements, or elements that should be modified or removed?

44. What specific security and operational requirements should be considered for independent third parties managing digitally marked gear locations and other associated data?

10.0 Additional Considerations

Questions

45. Is there any other information that you would like to share in response to this request for information or regarding ropeless fishing more generally?

46. NMFS has heard concerns regarding the cost of systems. For fishermen who choose to fish with ropeless fishing gear, there could be several ways to reduce the cost of acquiring ropeless systems, such as by leasing gear from gear libraries or utilizing grant or loan programs. How should NMFS balance the potential regulatory requirements for technologically complex features (*e.g.,* automated acoustic marking, real-time data transmission, *etc.*) against the potential cost of these features?

47. Beyond the direct cost of purchasing ropeless gear, what are the other economic costs of ropeless fishing? What are the economic benefits?

48. Should NMFS require a common acoustic protocol or signaling standard for all approved on-demand systems to ensure interoperability across the industry, or should manufacturers be permitted to maintain proprietary acoustic approaches? This topic is discussed in the MITRE technical report *Evaluation of On-Demand Gear Acoustic Interoperability Approaches in the Northeast U.S.* (see **ADDRESSES**).

49. If NMFS allows the use of ropeless fishing gear, should the option to use it be phased in (*e.g.,* by specific geographic regions, by fishery, or through pilot programs)?

50. How can NMFS design ropeless fishing regulations to be flexible enough to accommodate future technological advancements?

51. What are the potential environmental benefits or consequences of fishing with ropeless gear? What are the potential benefits or consequences of ropeless fishing on fisheries operations?

52. Ropeless fishing gear is currently being used in fisheries outside of the Greater Atlantic Region. Do you have examples of its use or management outside the Greater Atlantic Region that should be emulated or avoided within the Greater Atlantic Region?

III. Definitions

Grappling: Method of retrieving fishing gear from the ocean floor by dragging a weighted hook along the bottom to snag rope (such as a groundline or bridle) that is connected to traps, pots, or nets.

Interoperability: Capability of different technologies, systems, devices, models, or brands to communicate, share information, and function with each other.

Retrieval mechanism: Apparatus designed to surface a retrieval line to allow for the hauling of fixed gear. For example, a buoyant spool, inflatable lift bag, and pop-up buoy.

On-demand device: Equipment that uses acoustic release technology to trigger a retrieval mechanism.

On-demand fishing gear: Fixed gear equipped with at least one on-demand device.

On-demand system: Combination of technologies and devices, including an on-demand device, that allow for the deployment, retrieval, and marking of fixed gear positions without persistent buoy lines. This definition excludes the technology needed to share and display digital gear marks. An on-demand system is a type of ropeless system.

One-end ropeless: String or trawl of fixed gear that uses a traditional, persistent buoy line on only one end. The end without the persistent buoy line may or may not be rigged with an on-demand or timed-retrieval device and retrieval mechanism.

Ropeless fishing gear: Fixed fishing gear that operates without persistent buoy lines. This definition includes fixed gear rigged with an on-demand device or timed-retrieval device that triggers a retrieval mechanism, as well as fixed gear that can only be retrieved by grappling.

Ropeless system: Combination of technologies and devices that allow for the deployment, retrieval, and marking of fixed gear positions without persistent buoy lines. This definition excludes the technology needed to share and display digital gear marks. This definition includes, but is not limited to, on-demand systems and timed-retrieval systems.

Timed-retrieval device: Equipment that uses a pre-set timer or a degradable galvanic link to trigger a retrieval mechanism.

Timed-retrieval fishing gear: Fixed gear equipped with at least one timed-retrieval device.

Timed-retrieval system: Combination of technologies and devices, including a timed-retrieval device, that allow for the deployment, retrieval, and marking of fixed gear positions without persistent buoy lines. This definition excludes the technology needed to share and display digital gear marks. A timed-retrieval system is a type of ropeless system.

Persistent buoy line: Traditional fixed gear endline or vertical line that extends from the fishing gear on the seafloor to the physical surface marker for the entirety of the soak time.

IV. Other

Please note that this is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

This RFI is issued solely for information and planning purposes; it does not constitute a request for proposals, applications, proposal abstracts, or quotations. This RFI does not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, NMFS is not seeking proposals through this RFI and will not accept unsolicited proposals. Choosing not to respond to this RFI does not preclude participation in any future procurement, if conducted.

(Authority: 16 U.S.C. 1801 *et seq.;* 16 U.S.C. 5101 *et seq.;* Consolidated Appropriations Act, 2023, Division JJ, Title I, Section 101 *et seq.*)

Dated: July 13, 2026.

Shannon Bettridge,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–14363 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF865]

Gulf Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The Gulf Fishery Management Council (Gulf Council) will hold a 2 day in-person meeting of its Standing and Shrimp Scientific and Statistical Committees (SSC).

DATES: The meeting will be held in-person on Tuesday, July 21 and Wednesday, July 22, 2026, from 9 a.m.–5 p.m., EDT daily.

ADDRESSES: The meeting will take place at the Gulf Council's office located at 4107 W. Spruce Street, Suite 200, Tampa, FL 33607. Hybrid connection information will be available on the Council's website at *https://www.gulfcouncil.org* and clicking on the ''meeting tab''.

Council address: Gulf Fishery Management Council, 4107 W. Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Mr. Ryan Rindone, Lead Fishery Biologist, Gulf Fishery Management Council; *ryan.rindone@gulfcouncil.org,* telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION:

Tuesday, July 21, 2026; 9 a.m.–5 p.m. EDT

The meeting will begin with introductions and adoption of agenda, review and approval of Meeting Minutes and Summary from the May 2026 SSC webinar meeting, and Scope of Work.

The SSCs will review and discuss Estimation of Shrimp Trawl Bycatch Methodology and Gray Triggerfish Bycatch Estimation, including presentations, background materials and SSC Discussion.

The SSC will also receive recommendations from the Working Group on Shrimp Trawl Bycatch for Finfish.

The SSCs will then review the Minimum Threshold Number of Federal Gulf Shrimp Permits, including presentations, background materials and SSC Discussion.

Public comments, if any, will be heard at the end of the day.

Wednesday, July 22, 2026; 9 a.m.–5 p.m. EDT

The SSC will review and discuss Fisheries Integrated Modeling System Peer-review, Gulf King Mackerel Landings and Length Composition Data from Mexico, Gulf Tilefish Data Triage and Stock Evaluation Options, and the Greater Amberjack Count and the planned SEDAR Assessment for Gulf Greater Amberjack; including presentations, background materials and SSC Discussion and Recommendations.

Public comments, if any, will be heard at the end of the day followed by the review of any Other Business items.

— Meeting Adjourns

The meeting will also be broadcast via webinar. You may register to listen in only by visiting *https://www.gulfcouncil.org* and clicking on the SSC meeting on the calendar.

The Agenda is subject to change, and the latest version along with other meeting materials will be posted on *https://www.gulfcouncil.org* as they become available.

Although other non-emergency issues not on the agenda may come before the Scientific and Statistical Committees for discussion, in accordance with the Magnuson-Stevens Fishery Conservation and Management Act (MSA), those issues may not be the subject of formal action during this meeting. Actions of the Scientific and Statistical Committee will be restricted to those issues specifically identified in the agenda and any issues arising after publication of this notice that require emergency action under Section 305(c) of the MSA, provided the public has been notified of the Council's intent to take-action to address the emergency.

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

Dated: July 14, 2026.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–14360 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF880]

Fisheries of the Gulf of America; Southeast Data, Assessment, and Review; Public Meeting

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

ACTION: Notice of webinar.

SUMMARY: The Southeast Data Assessment and Review (SEDAR) 105 assessment process of Gulf gag grouper will consist of a series of assessment webinars. See **SUPPLEMENTARY INFORMATION.**

DATES: The SEDAR 105 Topical Working Group Red Tide Mortality I webinar will be held August 5, 2026, from 1—4 p.m. Eastern Time.

ADDRESSES:

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

Meeting address: The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (See **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366. Email: *Julie.neer@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with the National Marine Fisheries Service and the Atlantic and Gulf States Marine Fisheries Commissions have implemented the SEDAR process. SEDAR is a participatory process for developing, evaluating and reviewing information used for fisheries management advice. This multi-step process for determining the status of fish stocks in the Southeast Region may include (1) a Data stage, and (2) an Assessment stage, and (3) a Review stage. Each stage produces a report summarizing decisions made during that stage. A final stock assessment report is produced at the end of a SEDAR process documenting data sets used, model configurations and the opinions from the independent peer review. Participants for SEDAR projects are appointed by the Gulf, South Atlantic, and Caribbean Fishery Management Councils and National Marine Fisheries Service Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants may include data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations; International experts; and staff of Councils, Commissions, and state and Federal agencies.

The items of discussion during the SEDAR 105 Topical Working Groups Data Recommendations webinar are as follows:

Participants will review the data analyses and make recommendations.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: Note: The times and sequence specified in this agenda are subject to change.

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

Dated: July 14, 2026.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–14380 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF876]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Climate and Ecosystem Steering Committee via webinar to consider actions affecting New England fisheries in the exclusive economic zone (EEZ). Recommendations from this group will be brought to the full Council for formal consideration and action, if appropriate.

DATES: This webinar will be held on Monday, July 27, 2026, at 9 a.m. EST.

Webinar registration URL information:

https://nefmc-org.zoom.us/meeting/register/p8VdVDnKS9KnNTkpeJkSRw.

ADDRESSES:

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Cate O'Keefe, Ph.D., Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Climate and Ecosystem Steering Committee will meet to receive an update on the forthcoming Northeast Climate Vulnerability Analysis 2.0. They will also discuss on-ramps for climate and ecosystem information into management. The Committee will receive a report from a recent Council workshop on Dynamic Reference Points. Also, on the agenda is to discuss other ongoing Inflation Reduction Act funded projects, as needed. Other business will be discussed, if necessary.

Although non-emergency issues not contained on the agenda may come before this Council for discussion, those issues may not be the subject of formal action during this meeting. Council action will be restricted to those issues specifically listed in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take final action to address the emergency. The public also should be aware that the meeting will be recorded. Consistent with 16 U.S.C. 1852, a copy of the recording is available upon request.

Special Accommodations

This meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Cate O'Keefe, Ph.D., Executive Director, at (978) 465–0492, at least 5 days prior to the meeting date.

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

Dated: July 14, 2026.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–14357 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF897]

South Atlantic Fishery Management Council (Council)—Public Meetings

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

ACTION: Notice of public hearings.

SUMMARY: The South Atlantic Fishery Management Council (Council) will hold three in-person public hearings and one webinar hearing pertaining to amendment 60 to the Fishery Management Plan (FMP) for the Snapper Grouper Fishery of the South Atlantic Region. This amendment considers removing the 2-for-1 requirement for obtaining a snapper grouper commercial transferable permit; revising stowage requirements and species restrictions for commercial vessels with longline gear on board to allow switching to or from this gear during a commercial trip, increasing trip limits for several snapper grouper species, and requiring sale of all snapper grouper harvested by commercial vessels.

DATES: The in-person hearings public hearings will take place on August 10, 11, and 19, 2026, beginning at 6 p.m., EDT. The webinar hearing will take place on August 31, 2026, beginning at 6 p.m., EDT. Registration for webinar is required. For specific dates and times, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES:

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405. Information, including a link to webinar registration will be posted on the Council's website at: *https://safmc.net/public-hearings-and-scoping/* when it becomes available.

In-Person Meeting Locations

Monday, August 10, 2026: North Carolina Division of Marine Fisheries Central District Office, 5285 Highway 70 West, Morehead City, NC 28557; phone: (252) 515–5500.

Tuesday, August 11, 2026: Brunswick County Administrative Building, 30 Government Center Drive NE, Bolivia, NC 28422; phone: (910) 253–2017.

Wednesday, August 19, 2026: Heckscher Drive Community Club, Inc., 9364 Heckscher Drive, Jacksonville, Florida 32226; phone: (904) 759–6996.

FOR FURTHER INFORMATION CONTACT: Ashley Oliver, Outreach Coordinator, SAFMC; phone (843) 571–4366 or toll free (866) SAFMC–10; FAX (843) 769–4520; email: *Ashley.Oliver@safmc.net.*

SUPPLEMENTARY INFORMATION: A public hearing document, an online public comment form, and other materials will be posted to the Council's website at *https://safmc.net/public-hearings-and-scoping/* as they become available. Written comments should be addressed to John Carmichael, Executive Director, SAFMC, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405. Written comments must be received by September 1, 2026, at 5 p.m. During the hearings Council staff will provide an overview of actions being considered in the amendment. Staff will answer clarifying questions on the presented information and the proposed actions. Following the presentation and questions, the public will have the opportunity to provide comments on the amendment.

Amendment 60 to the Snapper Grouper FMP

The amendment aims to increase the long-term stability of the commercial fishery by maintaining the current number of permits and to increase flexibility, adaptability, access, and economic profitability in the snapper grouper commercial sector. The amendment proposes to remove the 2-for-1 requirement for obtaining a transferable snapper grouper (SG 1) commercial permit, which would facilitate transfer of permits, thereby increasing active participation of permit holders in the fishery. Revising bottom longline gear stowage requirements and species restrictions would provide additional flexibility for commercial fishermen that use bottom longline gear to be able to deploy multiple gears within a trip, thereby improving trip efficiency while maintaining law enforcement's ability to monitor the gear used to catch snapper grouper species. The amendment includes several actions to consider increasing commercial trip limits for greater amberjack, vermilion snapper, red porgy, hogfish (Georgia-North Carolina stock), red grouper, gray triggerfish, and golden tilefish (hook-and-line only) to better achieve optimum yield and

increase trip efficiency. Finally, the amendment proposes to require sale of all commercially harvested snapper grouper, which would improve reporting accuracy and promote commercial snapper grouper permits to be solely used to harvest fish for sale.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: July 14, 2026.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–14375 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF867]

Endangered Species; File No. 29736

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

ACTION: Notice; receipt of application.

SUMMARY: Notice is hereby given that Katrina Phillips, Ph.D., Dauphin Island Sea Lab 101, Bienville Blvd., Dauphin Island, AL 36528, has applied in due form for a permit to take loggerhead (*Caretta caretta*), green (*Chelonia mydas*), Kemp's ridley (*Lepidochelys kempii*), hawksbill (*Eretmochelys imbricata*), and leatherback (*Dermochelys coriacea*) sea turtles for purposes of scientific research.

DATES: Written comments must be received on or before August 17, 2026.

ADDRESSES: The application and related documents are available for review by selecting ''Records Open for Public Comment'' from the ''Features'' box on the Applications and Permits for Protected Species home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 29736 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 29736 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Amy Hapeman or Erin Markin, Ph.D., (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit is requested under the authority of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

The applicant proposes to study juvenile, subadult, and adult sea turtle demography and distribution in the northern Gulf of America. Researchers would capture up to 60 green, 7 hawksbill, 60 Kemp's ridley, 40 loggerhead, and 1 leatherback sea turtles by tangle and dip net annually. Researchers would perform the following procedures on sea turtles prior to their release: epibiota removal; flipper tag; passive integrated transponder tag; biologically sample (skin swab, blood, scute, fecal, and skin biopsy); measure; weigh; and photograph/video. A subset of green, Kemp's ridley, and loggerhead sea turtles may receive a transmitter attachment. The permit is requested for 10 years.

Dated: July 14, 2026.

Larissa Plants,

Acting Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2026–14383 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF875]

Gulf Fishery Management Council; Public Meetings

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

ACTION: Notice; public hearings and webinars.

SUMMARY: The Gulf Fishery Management Council (Gulf Council) will hold two public hearings via webinar to solicit public comments on For-Hire Electronic Reporting.

DATES: The public hearing webinars will take place Thursday, August 13 and Monday, August 17, 2026. The webinars will begin at 6 p.m. EDT and will conclude no later than 8 p.m. EDT. For specific dates and times, see **SUPPLEMENTARY INFORMATION**. Written public comments must be received on or before 5 p.m. EDT on August 17, 2026.

ADDRESSES: Please visit the Gulf Council website at *https://www.gulfcouncil.org for* meeting materials and webinar registration information.

Meeting addresses: The public hearings will be held via virtual webinars. For dates and times see **SUPPLEMENTARY INFORMATION** below.

Council address: Gulf Fishery Management Council, 4107 W Spruce Street, Suite 200, Tampa, FL 33607; telephone: (813) 348–1630.

FOR FURTHER INFORMATION CONTACT: Emily Muehlstein; Public Information Officer; *emily.muehlstein@gulfcouncil.org,* Gulf Fishery Management Council; telephone: (813) 348–1630.

SUPPLEMENTARY INFORMATION: The agenda for the virtual public hearings is as follows: Council staff will begin with a brief presentation on the Generic Amendment to modify the Reef Fish and Coastal Migratory Pelagic Fishery Management Plans to Modify the Gulf For-Hire Data Collection Program. The Amendment considers defining a mechanism and timing for for-hire data reporting, requiring trip notification and effort reporting, and establishing economic reporting for for-hire vessels.

Staff and a Council member will be available to answer any questions, and the public will have the opportunity to provide testimony on the amendment and other related testimony.

Scheduled Webinars:

Thursday, August 13, 2026; via webinar

Monday, August 17, 2026; via webinar

Visit *https://www.gulfcouncil.org* website and click on the ''meetings and public hearings'' tab for registration information. After registering, you will receive a confirmation email containing information about joining the webinar.

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

Dated: July 14, 2026.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–14370 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF884]

International Whaling Commission; 70th Meeting; Announcement of Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: This notice announces the date, time, and access information of the public meeting being held, in a virtual format, prior to the 70th meeting of the International Whaling Commission (IWC).

DATES: The public meeting will be held August 7, 2026 at 2 p.m. EDT.

ADDRESSES: The meeting will be held in a virtual/online format. Attendees must register in advance to attend the public meeting at the following link: *https://noaanmfs-meets.webex.com/weblink/register/r9cdc9744baf07d17de58d871bb33b17e.*

FOR FURTHER INFORMATION CONTACT: Madison Harris, *Madison.Harris@noaa.gov* or (301) 427–8371.

SUPPLEMENTARY INFORMATION: The Secretary of Commerce is responsible for implementing the domestic obligations of the United States under the International Convention for the Regulation of Whaling, 1946. The U.S. IWC Commissioner has responsibility for the preparation and negotiation of U.S. positions on international issues concerning whaling and for all matters involving the IWC. The U.S. IWC Commissioner is staffed by the Department of Commerce and assisted by the Department of State, and the Marine Mammal Commission.

The IWC will hold its 70th meeting in Hobart, Australia from September 28-October 2, 2026. Additional information about the IWC meeting, including a draft agenda for the meeting, is posted on the IWC Secretariat's website at *https://iwc.int/events-and-workshops/iwc70-2026.*

NOAA will hold a public meeting on August 7, 2026 to discuss the upcoming IWC meeting. U.S. persons and entities with an interest in U.S. whale conservation and management policy may participate and share views about the topics and proposals to be discussed at the meeting of IWC. The information obtained from this session will help the U.S. government in its preparations for the Commission meeting, including engagement with other IWC Member Governments, consideration of proposals, and formulation of U.S. positions.

The August 7 meeting will be held at 2 p.m. EDT in a virtual format. Meeting access and conferencing platform information will be sent to those who register. To participate, interested persons must register in advance via the following link: *https://noaanmfs-meets.webex.com/weblink/register/r9cdc9744baf07d17de58d871bb33b17e.*

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Madison Harris, *Madison.Harris@noaa.gov* or (301) 427–8371, by July 17, 2026.

Dated: July 14, 2026.

Alexa Cole,

Director, Office of International Affairs, Trade, and Commerce, National Marine Fisheries Service.

[FR Doc. 2026–14381 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XF896]

South Atlantic Fishery Management Council (Council)—Public Meetings

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

ACTION: Notice of a meeting.

SUMMARY: The South Atlantic Fishery Management Council's (Council) Scientific and Statistical Committee (SSC) will hold a meeting on August 12, 2026.

DATES: The SSC meeting will be held via webinar from 9 a.m. to 12 p.m. EDT on August 12, 2026.

ADDRESSES:

Meeting Address: The meeting will be held via webinar. Registration is required and will be available at: *https://safmc.net/events/august-2026-ssc-meeting/.*

Council address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N. Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Dr. Judd Curtis, Quantitative Fishery Scientist, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone 843/571–4366 or toll free 866/SAFMC–10; FAX 843/769–4520; email: *judd.curtis@safmc.net.*

SUPPLEMENTARY INFORMATION: The meeting is open to the public via webinar as it occurs. Webinar registration is required. Information regarding webinar registration is available from the Council's website at: *https://safmc.net/events/august-2026-ssc-meeting/.* The meeting agenda, briefing book materials, and online comment form will be posted to the Council's website 2 weeks prior to the meeting. Written comment on SSC agenda topics is to be distributed to the Committee through the Council office, similar to all other briefing materials. For this meeting, the deadline for submission of written comment is 12 p.m. EDT August 12, 2026.

The meeting agenda will include discussion of the South Atlantic Spawning Special Management Zones; review of the terms of reference for the upcoming red grouper, snowy grouper, and vermilion snapper stock assessments, and an evaluation of stock risk ratings under the acceptable biological catch control rule. The SSC will receive updates to SSC workgroup and Southeast Data, Assessment, and Review (SEDAR) panels and conduct other business as needed. The SSC will provide guidance to staff and make recommendations for Council consideration.

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for auxiliary aids should be directed to the council office (see **ADDRESSES**) 5 days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: July 14, 2026.

Rey Israel Marquez,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2026–14362 Filed 7–15–26; 8:45 am]

BILLING CODE 3510–22–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Deletions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed deletions from the Procurement List.

SUMMARY: The Committee is proposing to delete service(s) from the Procurement List that were furnished by nonprofit agencies employing persons

who are blind or have other severe disabilities.

DATES: Comments must be received on or before: August 15, 2026.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 250 E Street SW, Suite 3100, Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: For further information or to submit comments contact: Michael R. Jurkowski, Telephone: (703) 489–1322, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Deletions

The following service(s) are proposed for deletion from the Procurement List:

Service(s)

Service Type: Custodial Service
Mandatory For: National Park Service, NE Region, Frederick Law Olmsted Historic Site Barn and House, John Fitzgerald Kennedy NHS and Longfellow House, Washington's Headquarters NHS, Brookline, MA, 99 Warren Street, Brookline, MA
Authorized Source of Supply: Community Workshops, Inc., Boston, MA
Contracting Activity: DEPARTMENT OF THE INTERIOR, NER SUPPLY MABO(45000)
Service Type: Janitorial/Custodial
Mandatory For: Fort Collins Federal Office Building, 301 South Howes Street, Fort Collins, CO, 301 South Howes Street, Fort Collins, CO
Contracting Activity: GENERAL SERVICES ADMINISTRATION, GSA/PBS/FACILITIES MGMT, ACQUISITION MGNT & REAL ESTATE ACQUISITION
Service Type: Custodial and Related Services
Mandatory For: GSA PBS Region 9, Carson City Federal Building, Carson City, NV, 705 N Plaza, Carson City, NV
Authorized Source of Supply: Bona Fide Conglomerate, Inc., El Cajon, CA
Contracting Activity: GENERAL SERVICES ADMINISTRATION, PBS R9 AMD SERVICES CONTRACTING BRANCH
Service Type: Custodial Services
Mandatory For: William R. Burke Courthouse: Third Street and Lufkin Avenue, Lufkin, TX
Contracting Activity: GENERAL SERVICES ADMINISTRATION, FPDS AGENCY COORDINATOR

Michael R. Jurkowski,

Director, Business Operations.

[FR Doc. 2026–14305 Filed 7–15–26; 8:45 am]

BILLING CODE 6353–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2026–OS–1552]

Privacy Act of 1974; System of Records

AGENCY: Defense Logistics Agency, Department of Defense (DoD)

ACTION: Rescindment of a System of Records Notice (SORNs).

SUMMARY: In accordance with the Privacy Act of 1974, the Defense Logistics Agency (DLA) is providing notice to rescind a system of records titled ''DLA Hometown News Release,'' S190.10. The system of records was established for the purpose of distributing information on activities and accomplishments of DLA military and civilian personnel to hometown newspapers and broadcast stations throughout the United States. These records are now covered under the Defense Visual Information Distribution Service (DVIDS), DPA 04.

DATES: The rescindment of these SORNs is effective August 17, 2026.

ADDRESSES: You may submit comments, identified by docket number and title, by either of the following methods:

* *Federal Rulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Director of Administration and Management, Oversight and Compliance Directorate, Regulatory Division, 4800 Mark Center Drive, Attn: Mailbox 24, Suite 05F16, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the internet at *https://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Monica Owczarzak, Senior Privacy Officer, Information Governance and Compliance Division, Chief Digital and AI Office (J6D), 8725 John J. Kingman Road, Fort Belvoir, VA 22060–6221, 571–684–0406.

SUPPLEMENTARY INFORMATION:

I. Background

The Defense Logistics Agency (DLA) system of records DLA Hometown News Releases, S190.10 (April 17, 20213; 78 FR 22854) was established for the purpose of distributing information on activities and accomplishments of DLA military and civilian personnel to hometown newspapers and broadcast stations throughout the United States. These records are now covered under the Defense Visual Information Distribution Service (DVIDS), DPA 04 (November 14, 2022; 87 FR 68140).

DoD SORNs have been published in the **Federal Register** and are available at the Oversight and Compliance Directorate, Privacy and Civil Liberties Division website at *https://pclt.defense.gov/DIRECTORATES/Privacy-and-Civil-Liberties-Directorate/Privacy/SORNS.*

II. Privacy Act

Under the Privacy Act, a ''system of records'' is a group of records under the control of an agency from which information is retrieved by the name of an individual or by some identifying number, symbol, or other identifying particular assigned to the individual. In the Privacy Act, an individual is defined as a U.S. citizen or alien lawfully admitted for permanent residence.

In accordance with 5 U.S.C. 552a(r) and Office of Management and Budget (OMB) Circular No. A–108, DoD has provided a report of this rescindment to OMB and Congress.

SYSTEM NAME AND NUMBER:

DLA Hometown News Releases, S190.10.

HISTORY:

April 17, 2013; 78 FR 22854; June 24, 2011; 76 FR 37082.

Dated: July 14, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026–14376 Filed 7–15–26; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Renewal of Department of Defense Federal Advisory Committee-National Security Education Board

AGENCY: Department of Defense (DoD).

ACTION: Renewal of Federal advisory committee.

SUMMARY: The DoD (referred to herein as ''the Department,'' ''Department of War'' or ''DoW'') is publishing this notice to announce that it is renewing the National Security Education Board (NSEB) as a non-discretionary Federal advisory committee.

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of War, 703–692–5952.

SUPPLEMENTARY INFORMATION: The NSEB is being renewed in pursuant to 50 United State Code (U.S.C.) 1903 and accordance with the provisions of chapter 10 of Title 5, U.S.C. (commonly known as ''the Federal Advisory Committee Act'' or ''FACA'') and 41 Code of Federal Regulations (CFR) 102–3.50(a). The charter and contact information for the NSEB's Designated Federal Officer (DFO) is found at: *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation.* Pursuant to 50 U.S.C. 1902(a)(3), the NSEB shall consult on the National Security Scholarship, Fellowships, and Grant Program as described in more detail in 50 U.S.C. Ch. 37.

Pursuant to 50 U.S.C. 1903(b), the NSEB shall be composed of the following fourteen individuals or the representatives of such individuals:

1. The Secretary of Defense, who shall serve as the Chair of the NSEB.
2. The Secretary of Education.
3. The Secretary of State.
4. The Secretary of Commerce.
5. The Secretary of Homeland Security.
6. The Secretary of Energy.
7. The Director of National Intelligence.
8. The Chair of the National Endowment for the Humanities.
9. Six individuals appointed by the President, who shall be experts in the fields of international, language, area, and counterproliferation studies education and who may not be officers or employees of the Federal Government.

Members of the NSEB appointed by the President shall be appointed for a period specified by the President at the time of their appointment, but not to exceed four years. NSEB members who are not full-time or permanent part-time Federal civilian officers or employees, or active-duty members of the Uniformed Services, shall be appointed as experts or consultants pursuant to 5 U.S.C. 3109 to serve as special government employee members. NSEB members who are full-time or permanent part-time Federal civilian officers or employees, or active-duty members of the Uniformed Services, shall be appointed pursuant to 41 CFR 102–3.130(a) to serve as regular government employee members. Pursuant to 50 U.S.C. 1903(c), individuals appointed by the President shall receive no compensation for service on the NSEB. All members shall receive reimbursement of official NSEB-related travel and per diem.

The public or interested organizations may submit written statements to the NSEB about the NSEB's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the NSEB. All written statements shall be submitted to the DFO for the NSEB, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: July 14, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026–14378 Filed 7–15–26; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Renewal of Department of Defense Federal Advisory Committee-Board of Regents, Uniformed Services University of the Health Sciences

AGENCY: Department of Defense (DoD).

ACTION: Renewal of Federal advisory committee.

SUMMARY: The DoD (referred to herein as ''the Department,'' ''Department of War'' or ''DoW'') is publishing this notice to announce that it is renewing the Board of Regents, Uniformed Services University of the Health Sciences (BoR USUHS) as a non-discretionary Federal advisory committee.

FOR FURTHER INFORMATION CONTACT: Jim Freeman, Advisory Committee Management Officer for the Department of War, 703–692–5952.

SUPPLEMENTARY INFORMATION: The BoR USUHS is being renewed in pursuant to section 2113a of title 10, United States Code (U.S.C.) and in accordance with the provisions of chapter 10 of Title 5, U.S.C. (commonly known as ''the Federal Advisory Committee Act'' or ''FACA'') and 41 Code of Federal Regulations (CFR) 102–3.50(a). The charter and contact information for the BoR USUHS's Designated Federal Officer (DFO) is found at: *https://www.facadatabase.gov/FACA/apex/FACAPublicAgencyNavigation.*

The BoR USUHS provides independent advice and recommendations on matters pertaining to carrying out the Secretary's responsible to conduct the business of the Uniformed Services University of the Health Sciences (''the University''). And on matters critical to the full accreditation and successful operation of the University.

Pursuant to 10 U.S.C. 2113a(b), the BoR USUHS shall consist of 16 members appointed by the Secretary of War and the Deputy Secretary of War (''the Department of War (DoW) Appointing Authority''), as follows:

a. nine people outstanding in the fields of health care, higher education administration, or public policy, who shall be appointed from civilian life by the DoW Appointing authority;

b. the Secretary of Defense, or his or her designee, who shall be an ex officio member;

c. the Director of the Defense Health Agency, who shall be an ex officio member;

d. the Surgeons General of the Uniformed Services, who shall be ex officio members; and

e. the President of the University, who shall be a non-voting ex officio member.

BoR USUHS members who are not ex officio members shall be appointed by the DoW Appointing Authority, pursuant to 10 U.S.C. 2113a(b)(1) and (c) for a six-year term of service except that:

a. any member appointed to fill a vacancy occurring before the expiration of the term for which his or her predecessor was appointed shall be appointed for the remainder of such term; and,

b. any member whose term of office has expired shall continue to serve until his or her successor is appointed.

Appointments for BoR USUHS members who are not ex officio members shall be renewed on an annual basis in accordance with DoW policy and procedures. No member, unless approved by the DoW Appointing Authority in writing, may serve on more than two DoW Federal advisory committees at one time or serve more than two consecutive terms of service on an advisory committee, to include its subcommittees.

BoR USUHS members who are not full-time or permanent part-time Federal civilian officers or employees, nor active-duty members of the Uniformed Services, shall be appointed as experts or consultants pursuant to 5 U.S.C. 3109 to serve as special government employee (SGE) members. BoR USUHS members who are full-time or permanent part-time Federal civilian officers or employees, or active-duty members of the Uniformed Services, shall be designated pursuant to 41 CFR 102–3.130(a) to serve as regular government employee (RGE) members.

Pursuant to 10 U.S.C. 2113a(d), the DoW Appointing Authority shall appoint the BoR USUHS chair for a term

of service of one-to-two years, with annual renewal, which shall not exceed the member's approved BoR USUHS appointment, in accordance with DoW policy and procedures.

All members of the BoR USUHS are appointed to exercise their own best judgement on behalf of the DoW, without representing any particular point of view, and to discuss and deliberate in a manner that is free from conflicts of interest.

Pursuant to 10 U.S.C. 2113a(e), BoR USUHS members, who are not ex officio members, shall be entitled to receive compensation. In accordance with a May 5, 2022 decision by the Secretary of Defense, each BoR USUHS members appointed consistent with 10 U.S.C. 2113a(b)(1), shall be entitled to receive compensation at the daily GS–15, step 10 level rate, with locality pay, while attending conferences or meetings or otherwise performing official duties as a member of the BoR USUHS. All BoR USUHS members shall be eligible for official BoR USUHS-related travel and per diem.

The public or interested organizations may submit written statements to the BoR USUHS about the BoR USUHS's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meeting of the BoR USUHS. All written statements shall be submitted to the DFO for the BoR USUHS, and this individual will ensure that the written statements are provided to the membership for their consideration.

Dated: July 14, 2026.

Stephanie J. Bost,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2026–14377 Filed 7–15–26; 8:45 am]

BILLING CODE 6001–FR–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL26–81–000]

Kammer Juniata Transmission, LLC; Notice of Institution of Section 206 Proceeding and Refund Effective Date

On July 10, 2026, the Commission issued an order in Docket No. EL26–81–000 pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e, instituting an investigation to determine whether Kammer Juniata Transmission, LLC's proposed Formula Rate Template is unjust, unreasonable, unduly discriminatory or preferential, or otherwise unlawful. *Kammer Juniata Transmission, LLC* 196 FERC ¶ 61,015 (2026).

The refund effective date in Docket No. EL26–81–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL26–81–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214 (2025), within 21 days of the date of issuance of the order.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. From FERC's Home Page on the internet, this information is available on eLibrary. The full text of this document is available on eLibrary in PDF and Microsoft Word format for viewing, printing, and/or downloading. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field. User assistance is available for eLibrary and the FERC's website during normal business hours from FERC Online Support at 202–502–6652 (toll free at 1–866–208–3676) or email at *ferconlinesupport@ferc.gov,* or the Public Reference Room at (202) 502–8371, TTY (202)502–8659. Email the Public Reference Room at *public.referenceroom@ferc.gov.*

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFile'' link at *http://www.ferc.gov.* In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Debbie-Anne A. Reese, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Dated: July 13, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–14340 Filed 7–15–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings in Existing Proceedings

Docket Numbers: RP26–969–001.

Applicants: Natural Gas Pipeline Company of America LLC.

Description: Tariff Amendment: Supplement Filing to Amendment to a Negotiated Rate Agreement Filing- to be effective 7/2/2026.

Filed Date: 7/10/26.

Accession Number: 20260710–5182.

Comment Date: 5 p.m. ET 7/22/26.

Any person desiring to protest in any the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern Time on the specified comment date.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Dated: July 13, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–14339 Filed 7–15–26; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG26–273–000.

Applicants: Zama Renewables LLC.

Description: Zama Renewables LLC submits Notice of Self–Certification of Exempt Wholesale Generator Status.

Filed Date: 7/10/26.

Accession Number: 20260710–5226.

Comment Date: 5 p.m. ET 7/31/26.

Docket Numbers: EG26–274–000.

Applicants: Moonraker BESS LLC.

Description: Moonraker BESS LLC submits Notice of Self–Certification of Exempt Wholesale Generator Status.

Filed Date: 7/10/26.

Accession Number: 20260710–5231.

Comment Date: 5 p.m. ET 7/31/26.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1586–013; ER10–1630–013.

Applicants: Wolf Hills Energy, LLC, Big Sandy Peaker Plant, LLC.

Description: Triennial Market Power Analysis for Northeast Region of Big Sandy Peaker Plant, LLC, et al.

Filed Date: 6/30/26.

Accession Number: 20260630–5376.

Comment Date: 5 p.m. ET 8/31/26.

Docket Numbers: ER10–1595–018; ER10–1598–018; ER20–1641–007.

Applicants: Southern Illinois Generation Company, LLC, Lincoln Generating Facility, LLC, Crete Energy Venture, LLC.

Description: Triennial Market Power Analysis for Northeast Region of Crete Energy Venture, LLC, et al.

Filed Date: 6/30/26.

Accession Number: 20260630–5372.

Comment Date: 5 p.m. ET 8/31/26.

Docket Numbers: ER12–348–009; ER15–1378–005; ER26–1680–001.

Applicants: Amber Energy Services, LLC, Mercuria Commodities Canada Corporation, Mercuria Energy America, Inc.

Description: Triennial Market Power Analysis for Northeast Region of Mercuria Energy America, Inc., et al.

Filed Date: 6/30/26.

Accession Number: 20260630–5378.

Comment Date: 5 p.m. ET 8/31/26.

Docket Numbers: ER17–1217–009; ER25–1980–002; ER25–3311–002.

Applicants: Montpelier Solar, LLC, Clinton Solar, LLC, Total Gas & Power North America, Inc.

Description: Triennial Market Power Analysis for Northeast Region of TotalEnergies Gas & Power North America, Inc, et al.

Filed Date: 6/30/26.

Accession Number: 20260630–5374.

Comment Date: 5 p.m. ET 8/31/26.

Docket Numbers: ER18–239–004; ER16–29–004; ER18–234–004; ER18–236–004; ER18–237–004; ER18–238–004.

Applicants: GSP Schiller LLC, GSP White Lake LLC, GSP Merrimack LLC, GSP Newington LLC, Greenidge Generation LLC, GSP Lost Nation LLC.

Description: Triennial Market Power Analysis for Northeast Region of GSP Lost Nation LLC, et al.

Filed Date: 6/30/26.

Accession Number: 20260630–5377.

Comment Date: 5 p.m. ET 8/31/26.

Docket Numbers: ER20–1912–004; ER24–1608–002.

Applicants: Hardin Solar Energy III, LLC, Blooming Grove Wind Energy Center LLC.

Description: Triennial Market Power Analysis for Northeast/Region of Blooming Grove Wind Energy Center LLC, et al.

Filed Date: 6/30/26.

Accession Number: 20260630–5370.

Comment Date: 5 p.m. ET 8/31/26.

Docket Numbers: ER21–1225–007; ER22–867–004.

Applicants: Long Ridge Retail Electric Supplier LLC, Long Ridge Energy Generation LLC.

Description: Triennial Market Power Analysis for Northeast Region of Long Ridge Energy Generation LLC, et al.

Filed Date: 6/30/26.

Accession Number: 20260630–5371.

Comment Date: 5 p.m. ET 8/31/26.

Docket Numbers: ER21–1755–019; ER23–1642–016; ER14–2500–028; ER24–280–009.

Applicants: Hartree-Meadowlands Newark, LLC, Newark Energy Center, LLC, Stored Solar J&WE, LLC, Hartree Partners, LP.

Description: Triennial Market Power Analysis for Northeast Region of Hartree Partners, LP, et al.

Filed Date: 6/30/26.

Accession Number: 20260630–5375.

Comment Date: 5 p.m. ET 8/31/26.

Docket Numbers: ER24–3011–003; ER25–2250–002; ER24–2236–002; ER24–2237–002; ER24–2238–003; ER24–2239–003; ER24–2240–003; ER24–2241–002; ER24–2242–003; ER25–2249–002; ER24–2243–003.

Applicants: Reworld Union (NJ), LLC, Reworld SEMASS Limited Partnership, Reworld REC, LLC, Reworld Plymouth, LLC, Reworld Niagara I, LLC, Reworld Hempstead Company, Reworld Haverhill Associates, LLC, Reworld Fairfax, LLC, Reworld Essex Company, Reworld Delaware Valley, LLC, Reworld Camden County, L.P.

Description: Triennial Market Power Analysis for Northeast Region of Reworld Camden County, L.P., et al.

Filed Date: 6/30/26.

Accession Number: 20260630–5373.

Comment Date: 5 p.m. ET 8/31/26.

Docket Numbers: ER26–3137–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Cancellation of ICSA, Service Agreement No. 5563; AB2–032/AB2–153 to be effective 9/9/2026.

Filed Date: 7/10/26.

Accession Number: 20260710–5199.

Comment Date: 5 p.m. ET 7/31/26.

Docket Numbers: ER26–3138–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Termination of DEA, SA No. 7236 between PJM and BGE to be effective 8/31/2026.

Filed Date: 7/10/26.

Accession Number: 20260710–5200.

Comment Date: 5 p.m. ET 7/31/26.

Docket Numbers: ER26–3139–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Termination of DEA, SA No. 7254 between PJM and PECO to be effective 8/31/2026.

Filed Date: 7/10/26.

Accession Number: 20260710–5203.

Comment Date: 5 p.m. ET 7/31/26.

Docket Numbers: ER26–3140–000.

Applicants: PJM Interconnection, L.L.C.

Description: Tariff Amendment: Notice of Termination of DEA, SA No. 7062 between PJM and PPL to be effective 8/31/2026.

Filed Date: 7/10/26.

Accession Number: 20260710–5210.

Comment Date: 5 p.m. ET 7/31/26.

Docket Numbers: ER26–3141–000.

Applicants: MATL LLP.

Description: § 205(d) Rate Filing: Attachment C Revisions to be effective 9/30/2026.

Filed Date: 7/13/26.

Accession Number: 20260713–5004.

Comment Date: 5 p.m. ET 8/3/26.

Docket Numbers: ER26–3142–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, SA No. 8027; Queue No. AC2–186/AC2–187/AC2–188 to be effective 9/12/2026.

Filed Date: 7/13/26.

Accession Number: 20260713–5021.

Comment Date: 5 p.m. ET 8/3/26.

Docket Numbers: ER26–3143–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, Service Agreement No. 8028; Queue No. AD1–100 to be effective 9/12/2026.

Filed Date: 7/13/26.

Accession Number: 20260713–5088.

Comment Date: 5 p.m. ET 8/3/26.

Docket Numbers: ER26–3144–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2026–07–13_SA 3432 MEC–MEC 1st Rev GIA (J476) to be effective 7/6/2026.

Filed Date: 7/13/26.

Accession Number: 20260713–5090.

Comment Date: 5 p.m. ET 8/3/26.

Docket Numbers: ER26–3145–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2026–07–13_SA 3920 Duke-IN Solar 3rd Rev GIA (J1234 J1235) to be effective 7/6/2026.

Filed Date: 7/13/26.

Accession Number: 20260713–5094.

Comment Date: 5 p.m. ET 8/3/26.

Docket Numbers: ER26–3147–000.

Applicants: Southwestern Public Service Company, Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Southwest Power Pool, Inc. submits tariff filing per 35.13(a)(2)(iii: 4909 Cone Renewable Energy Project & SPS Facilities Service Agreement to be effective 9/12/2026.

Filed Date: 7/13/26.

Accession Number: 20260713–5170.

Comment Date: 5 p.m. ET 8/3/26.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, contact the Office of Public Participation at (202) 502–6595 or *OPP@ferc.gov.*

Dated: July 13, 2026.

Carlos D. Clay,

Deputy Secretary.

[FR Doc. 2026–14338 Filed 7–15–26; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2026–3103; FRL–13427–01–OLEM]

Good Samaritan Remediation Permit for the Bodie Mine Project

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Bodie Mine is a mine site located in Okanogan County, Washington. On June 11, 2026, Trout Unlimited Inc. (Trout Unlimited) applied for a Good Samaritan remediation permit pursuant to the Good Samaritan Remediation of Abandoned Hardrock Mines Act of 2024 (2024 Good Samaritan Act or Act). The EPA has preliminarily determined that the application is complete and meets all applicable requirements of the Act. The EPA has also made the preliminary determination that the site and parties are eligible for a Good Samaritan permit, the activities are low risk, and the activities will result in measurable progress towards achieving improved soil, sediment compared to baseline conditions at the site. After the comment period closes and all comments have been considered, the EPA will determine whether to grant the permit.

DATES: Comments must be received on or before August 17, 2026.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–HQ–OLEM–2026–3103, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center, Office of Mountains, Deserts and Plains Docket, Mail Code 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460.
- *Hand Delivery or Courier:* EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays).

Instructions: All submissions received must include the Docket ID No. for this document. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the public review and comment process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Jamey Watt, Office of Land and Emergency Management, Office of Mountains, Deserts and Plains, Environmental Protection Agency, 1200 Pennsylvania Ave. NW; telephone number: (202) 566–0196; email address: *watt.jamey@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

Written Comments

Submit your comments, identified by Docket ID No. EPA–HQ–OLEM–2026–3103, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received on its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI), Proprietary Business Information (PBI), or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion on all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). Please visit *https://www.epa.gov/dockets/commenting-epa-dockets* for additional submission methods; the full EPA public comment policy; information about CBI, PBI, or multimedia submissions; and general guidance on making effective comments.

II. General Information

The Good Samaritan Remediation of Abandoned Hardrock Mines Act of 2024 (Good Samaritan Act or Act) was signed into law on December 17, 2024 (Public Law 118–155). The Act creates a pilot program that authorizes EPA to issue up to 15 remediation permits for eligible

projects to qualified ''Good Samaritans'' to voluntarily clean up ''abandoned hardrock mine sites.'' These permits enable Good Samaritans and Cooperating Persons to carry out remediation activities while being protected from certain liability risks under the Comprehensive Environmental Response, Compensation, and Liability Act and the Clean Water Act, provided the work complies with the terms of the permit. Specifically, Good Samaritan projects, as compared to baseline conditions, must make measurable progress towards achieving applicable water quality standards, improved soil quality, improved sediment quality, other improved environmental or safety conditions, or reductions in the threats to soil, sediment, or water quality or other environmental or safety conditions.

This notice for public review and comment is prepared in support of a Bodie Mine Good Samaritan remediation permit pursuant to the 2024 Good Samaritan Act and is limited to the scope of activities proposed under that application. The Bodie Mine is a mine site located at 1144 Toroda Creek Road, Bodie, WA 98859 in Okanogan County, Washington. The proposed remediation activities will excavate and remove up to 790 tons of contaminated soil from the streambank and contaminated sediments from the streambed along 400 linear feet of Toroda Creek. After the contaminated soil and sediment are removed, the streambank will be reconstructed and stabilized using coir lifts, riprap and native revegetation techniques that will minimize the possibility for future erosion. This proposed activity is estimated to eliminate approximately 104 tons of contaminated tailing deposits from eroding into Toroda Creek each year.

Based on the information included in the Bodie Mine Good Samaritan remediation permit application and the draft NEPA Environmental Assessment of the proposed project, the EPA has preliminarily determined that the application is complete and meets all applicable requirements of section 4(c) of the Act. The EPA has also made preliminary determinations that are required under section 4(m) of the Act, including that the site and parties are eligible, the proposed action is a low-risk activity that will make measurable progress toward achieving improvements in environmental conditions compared to baseline conditions, and the proposed action is otherwise consistent with the Act. Specifically, the EPA is proposing to make the following determinations:

(1) Trout Unlimited Inc. qualifies as a Good Samaritan. Trout Unlimited had no role in the creation of the historic mine residue at the site and is not a past or present owner of the site (see Trout Unlimited application cover letter dated June 11, 2026, information in their Bodie Mine Environmental Information Document dated June 3, 2026, and EPA's Decision Document dated June 17, 2026, all documents included in the *regulations.gov* docket for public review).

(2) Geo-Mineral Exploration Inc. qualifies as a Cooperating Person. Geo-Mineral Exploration Inc. had no role in the creation of the historic mine residue at the site and cannot afford to comply with potentially applicable requirements under either the Comprehensive Environmental Response, Compensation, and Liability Act or the Clean Water Act (see Trout Unlimited application cover letter dated June 11, 2026 and information in their Bodie Mine Environmental Information Document dated June 3, 2026, and EPA's Decision Document dated June 17, 2026, all documents included in the *regulations.gov* docket for public review).

(3) Strider Construction Inc. qualifies as a Cooperating Person. Strider Construction Inc., the remediation contractor, had no role in the creation of the historic mine residue at the site and is not a responsible owner or operator (see Trout Unlimited and Strider Construction's application addendum dated June 24, 2026 and EPA's Decision Document, both are included in the *regulations.gov* docket for public review).

(4) The project is designed to remediate historic mine residue at an abandoned hardrock mine site to protect human health and the environment (see the 2023 Toroda Creek Mine Tailings Erosion Elimination Work Plan included in the *regulations.gov* docket for public review).

(5) The proposed project is designed to meet all goals set forth in the application and they are acceptable to the EPA (see the 2023 Toroda Creek Mine Tailings Erosion Elimination Work Plan and the Bodie Mine Environmental Information Document dated June 3, 2026, both documents included in the *regulations.gov* docket for public review).

(6) The proposed activities, as compared to the baseline conditions described in the application, will make measurable progress toward achieving—

a. Improved soil quality;

b. Improved sediment quality;

c. Other improved environmental or safety conditions; and

d. Reductions in threats to soil, sediment, or water quality or other environmental or safety conditions.

The proposed activities will excavate and remove up to 790 tons of contaminated soil from the streambank and contaminated sediments from the streambed along 400 linear feet of Toroda Creek. After the contaminated soil and sediment are removed, the streambank will be reconstructed and stabilized using coir lifts, riprap and native revegetation techniques that will minimize the possibility for future erosion. This proposed activity is estimated to eliminate approximately 104 tons of tailing deposits from eroding into Toroda Creek each year (see the Bodie Mine Environmental Information Document dated June 3, 2026, which is included in the *regulations.gov* docket for public review).

(7) The overall objectives of reclamation at Toroda Creek are to reduce the current and/or threatened release of hazardous substances to the environment, protect human health and the environment by minimizing direct contact with contaminants, and prevent degradation of adjacent lands. By halting the active erosion of Toroda Creek into the mine tailings along the proposed project reach, this project will minimize pollution from added siltation as well as toxics including arsenic, cadmium, lead, mercury, selenium, copper, and zinc currently found in the tailings on the site (see the 2023 Toroda Creek Mine Tailings Erosion Elimination Work Plan and the Bodie Mine Environmental Information Document dated June 3, 2026, both documents included in the *regulations.gov* docket for public review).

(8) Trout Unlimited has adequately demonstrated, for purposes of the scope and remediation goals of this project, that it:

a. Has the proper and appropriate experience and capacity to complete the project;

b. Will complete the project;

c. Has the financial and other resources to address contingencies; and

d. Has granted the EPA access to and provided the EPA the authority to review the records related to compliance with the draft permit.

(See the 2023 Toroda Creek Mine Tailings Erosion Elimination Work Plan, the Bodie Mine Environmental Information Document dated June 3, 2026, EPA's Decision Document dated June 17, 2026, and the draft Bodie Mine Good Samaritan Permit language, all are

included in the *regulations.gov* docket for public review.)

(9) The proposed project poses a low risk to the environment, as the methods of remediation are frequently and successfully used, potential negative consequences are minimal, and the NEPA Environmental Assessment results in a Finding of No Significant Impact (FONSI) (see the Draft NEPA Environmental Assessment for the project included in the *regulations.gov* docket for public review).

(10) Trout Unlimited and the EPA's efforts did not identify a past or present owner or other party that meets the definition of a responsible owner or operator for the site. In particular, the EPA has not identified (i) any person that is legally responsible under section 301 of the Clean Water Act for a discharge that originates from the abandoned hardrock mine site, and has the financial ability to comply with the requirements described in that section, or (ii) a present or past owner or operator or other person that is liable with respect to a release or threat of release of a hazardous substance, pollutant, or contaminant associated with the historic mine residue at or from the abandoned hardrock mine site under section 104, 106, 107, or 113 of the Comprehensive Environmental Response, Compensation, and Liability Act, and has the financial ability to comply with each requirement described in those sections, as applicable.

(See Trout Unlimited's application cover letter dated June 11, 2026, information in their Bodie Mine Environmental Information Document dated June 3, 2026, and EPA's Decision Document dated June 17, 2026, all documents are included in the *regulations.gov* docket for public review).

The EPA has developed this notice pursuant to the 2024 Good Samaritan Act and in support of the Administration's commitment to transparency in all aspects of the EPA's work and to demonstrate EPA's progress toward making the 2024 Good Samaritan Act pilot program a success.Additional EPA Good Samaritan information can be found at *https://www.epa.gov/cleanups/good-samaritan-remediation-abandoned-hardrock-mines-program.*

Thomas D. Croci,

Acting Assistant Administrator, Office of Land and Emergency Management.

[FR Doc. 2026–14361 Filed 7–15–26; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OGC–2026–3697; FRL–13392–01–OGC]

Proposed Consent Decree; Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with the Clean Air Act, as amended (CAA or the Act), notice is given of a proposed consent decree in *Center for Biological Diversity et al.* v. *Lee Zeldin, No. 3:25–cv–6568–AMO.* On August 5, 2025, Plaintiffs Center for Biological Diversity and Sierra Club filed a complaint in the United States District Court, Northern District of California, San Francisco Division. The EPA designated various areas of the country as nonattainment with respect to the 2010 SO_2 NAAQS. States that contain areas that are designated as nonattainment are required to provide State Implementation Plan submissions to the EPA within 18 months of the effective date of designations. The EPA is providing notice of this proposed consent decree, which would resolve all claims in the case by establishing deadlines for the EPA to take final action as specified in the decree.

DATES: Written comments on the proposed consent decree must be received by August 17, 2026.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2026–3697, online at *https://www.regulations.gov* (EPA's preferred method). Follow the online instructions for submitting comments.

Instructions: All submissions received must include the Docket ID number for this action. Comments received may be posted without change to *https://www.regulations.gov*, including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Additional Information about Commenting on the Proposed Consent Decree'' heading under the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Karen Bianco, Air and Radiation Law Office, Office of General Counsel, U.S. Environmental Protection Agency; telephone (202) 564–3298; email address *bianco.karen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining a Copy of the Proposed Consent Decree

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2026–3697) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744 and the telephone number for the OEI Docket is (202) 566–1752.

The electronic version of the public docket for this action contains a copy of the proposed consent decree and is available through *https://www.regulations.gov.* You may use *https://www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

II. Additional Information About the Proposed Consent Decree

The appropriate EPA official shall:

1. No later than August 28, 2026, sign a notice of final rulemaking pursuant to CAA section 110(k)(2)–(4), 42 U.S.C. 7410(k)(2)–(4) to approve, disapprove, conditionally approve, or approve in part and conditionally approve or disapprove in part, the October 3, 2023 Hayden, AZ SO_2 SIP revision;

2. No later than March 1, 2027, sign a notice of final rulemaking pursuant to CAA section 110(k)(2)–(4), 42 U.S.C. 7410(k)(2)–(4) to approve, disapprove, conditionally approve, or approve in part and conditionally approve or disapprove in part, the October 24, 2022 Navarro County, TX SO_2 SIP revision;

3. No later than December 18, 2026, sign a notice of final rulemaking pursuant to CAA section 110(k)(2)–(4), 42 U.S.C. 7410(k)(2)–(4) to approve, disapprove, conditionally approve, or approve in part and conditionally approve or disapprove in part, the February 9, 2023 Sullivan County, TN SO_2 SIP revision; and

4. No later than July 30, 2027, sign a notice of final rulemaking pursuant to CAA section 110(k)(2)–(4), 42 U.S.C. 7410(k)(2)–(4) to approve, disapprove, conditionally approve, or approve in part and conditionally approve or

disapprove in part, the October 24, 2022 Howard and Hutchinson Counties, TX SO_2 SIP revisions.

5. No later than 15 business days after signature of each final action under the Consent Decree, EPA shall send notice of the action to the Office of the Federal Register for review and publication in the **Federal Register**.

6. After EPA has completed the actions set forth in this Consent Decree, notice of each final action required by Paragraph 3 has been published in the **Federal Register**, and the parties have resolved the issue of costs of litigation (including reasonable attorney fees), EPA may move to have this Consent Decree terminated and the above-captioned matter shall be dismissed with prejudice. Plaintiffs shall have 14 calendar days to respond to such motion, unless the parties stipulate to a longer time.

7. The deadlines established by the Consent Decree may be extended (a) by written stipulation of Plaintiffs and EPA and filed with the Court, or (b) by the Court upon motion by any party for good cause shown pursuant to the Federal Rules of Civil Procedure and upon consideration of any response by the non-moving party and any reply.

8. If a lapse in EPA appropriations occurs within 120 days prior to any deadline for final action in the Consent Decree, all such deadlines shall be extended automatically one day for each day of the lapse in appropriations. Nothing in this Paragraph shall preclude EPA from seeking an additional extension of time through modification of the Consent Decree.

III. Additional Information About Commenting on the Proposed Consent Decree

Submit your comments, identified by Docket ID No. EPA–HQ–OGC–2026–3697, via *https://www.regulations.gov.* Once submitted, comments cannot be edited or removed from this docket. EPA may publish any comment received to its public docket. Do not submit to EPA's docket at *https://www.regulations.gov* any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.* For additional information about submitting information identified as CBI, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this document. Note that written comments containing CBI and submitted by mail may be delayed and deliveries or couriers will be received by scheduled appointment only.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *https://www.regulations.gov* website to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an ''anonymous access'' system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment.

Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

Gautam Srinivasan,

Associate General Counsel.

[FR Doc. 2026–14254 Filed 7–15–26; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–13484–01–R6]

Clean Air Act Operating Permit Program; Order on Petition for Objection to State Operating Permit for Mitsubishi Chemical America, Inc., MCA Geismar Site

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petition.

SUMMARY: The Environmental Protection Agency (EPA) Administrator signed an order dated June 9, 2026, denying a petition dated September 9, 2024, from RISE St. James, Healthy Gulf, Louisiana Bucket Brigade, Sierra Club, and Earthjustice (Petitioners). The petition requested that the EPA object to a Clean Air Act (CAA) title V operating permit issued by the Louisiana Department of Environmental Quality (LDEQ) to Mitsubishi Chemical America, Inc. for its MCA Geismar Site located in Geismar, Ascension Parish, Louisiana.

FOR FURTHER INFORMATION CONTACT: Dr. Andy Chase; EPA Region 6 Air Permits Section; telephone number: (214) 665–2732; email address: *chase.andy@epa.gov.* The final order and petition are available electronically at: *https://www.epa.gov/title-v-operating-permits/title-v-petition-database.*

SUPPLEMENTARY INFORMATION: The EPA received a petition from RISE St. James, Healthy Gulf, Louisiana Bucket Brigade, Sierra Club, and Earthjustice dated September 9, 2024, requesting that the EPA object to the issuance of operating permit no. 0180–00233–V0, issued by Louisiana Department of Environmental Quality (LDEQ) to Mitsubishi Chemical America, Inc.'s MCA Geismar Site in Geismar, Ascension Parish, Louisiana. On June 9, 2026, the EPA Administrator issued an order denying the petition. The order itself explains the basis for the EPA's decision.

Sections 307(b) and 505(b)(2) of the CAA provide that a petitioner may request judicial review of those portions of an order that deny issues in a petition. Any petition for review shall be filed in the United States Court of Appeals for the appropriate circuit no later than September 14, 2026.

Dated: July 7, 2026.

James McDonald,

Director, Air and Radiation Division, Region 6.

[FR Doc. 2026–14257 Filed 7–15–26; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)).

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue, NW, Washington DC 20551–0001, not later than August 17, 2026.

A. Federal Reserve Bank of Dallas (Lindsey Wieck, Director, Mergers & Acquisitions) 2200 North Pearl Street, Dallas, Texas 75201–2272. Comments can also be sent electronically to *Comments.applications@dal.frb.org:*

1. *Ark Financial Holding, Inc., Cooper, Texas;* to become a bank holding company by acquiring Cooper Lake Financial Corporation, and thereby indirectly acquiring The First National Bank in Cooper, both of Cooper, Texas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–14373 Filed 7–15–26; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage de novo, or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue, NW, Washington DC 20551–0001, not later than August 17, 2026.

A. Federal Reserve Bank of Chicago (Christopher Koopmans, Senior Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414. Comments can also be sent electronically to *Comments.applications@chi.frb.org:*

1. *Brookfield Bancshares, Inc., Brookfield, Illinois;* to merge with NSTS Bancorp, Inc., and thereby indirectly acquire North Shore Trust and Savings, both of Waukegan, Illinois, and thereby engage in operating a savings association pursuant to section 225.28(b)(4)(ii) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–14374 Filed 7–15–26; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (Act) (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the applications are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The public portions of the applications listed below, as well as other related filings required by the Board, if any, are available for immediate inspection at the Federal Reserve Bank(s) indicated below and at the offices of the Board of Governors. This information may also be obtained on an expedited basis, upon request, by contacting the appropriate Federal Reserve Bank and from the Board's Freedom of Information Office at *https://www.federalreserve.gov/foia/request.htm.* Interested persons may express their views in writing on the standards enumerated in paragraph 7 of the Act.

Comments received are subject to public disclosure. In general, comments received will be made available without change and will not be modified to remove personal or business information including confidential, contact, or other identifying information. Comments should not include any information such as confidential information that would not be appropriate for public disclosure.

Comments regarding each of these applications must be received at the

Reserve Bank indicated or the offices of the Board of Governors, Benjamin W. McDonough, Secretary of the Board, 20th Street and Constitution Avenue NW, Washington, DC 20551–0001, not later than July 31, 2026.

A. Federal Reserve Bank of Philadelphia (William Spaniel, Senior Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105–1521. Comments can also be sent electronically to *Comments.applications@phil.frb.org:*

1. *GAH Capital, LLC and GAH Capital Trust, both of Palm Beach, Florida; Philip A. Norcross, individually and as co-trustee of GAH Capital Trust, Philadelphia, Pennsylvania; and Susan D. Hudson, as co-trustee of GAH Capital Trust, Palm Beach, Florida;* as a group acting in concert, to acquire additional voting shares of Mid Penn Bancorp, Inc., Harrisburg, Pennsylvania, and thereby indirectly acquire additional voting shares of Mid Penn Bank, Millersburg, Pennsylvania.

B. Federal Reserve Bank of St. Louis (Holly A. Rieser, Senior Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *The Gerald L. Moon Family Trust, Shirley M. Moon, individually and as trustee, both of Effingham, Illinois;* to acquire voting shares of Omni Bancorp, Inc., and thereby indirectly acquire voting shares of Crossroads Bank, both of Effingham, Illinois.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Associate Secretary of the Board.

[FR Doc. 2026–14372 Filed 7–15–26; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Patient Safety Organizations: Expired Listing for the Informed Patient Safety Organization (IPSO)

AGENCY: Agency for Healthcare Research and Quality (AHRQ), Department of Health and Human Services (HHS).

ACTION: Notice of delisting.

SUMMARY: The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule) authorizes AHRQ, on behalf of the Secretary of HHS, to list as a patient safety organization (PSO) an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' by the Secretary if it is found to no longer meet the requirements of the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act) and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. The listing for Informed Patient Safety Organization (IPSO), PSO number P0252, a component entity of Informed Surgical, Inc. has expired, and AHRQ has delisted the PSO accordingly.

DATES: The delisting was effective at 12:00 Midnight ET (2400) on July 6, 2026.

ADDRESSES: The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. Both directories can be accessed electronically at the following HHS website: *https://www.pso.ahrq.gov/listed.*

FOR FURTHER INFORMATION CONTACT: Cathryn Bach, Center for Quality Improvement and Patient Safety, AHRQ, 5600 Fishers Lane, MS 07E01D, Rockville, MD 20857; Telephone (toll free): (866) 403–3697; Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act, 42 U.S.C. 299b-21 to 299b-26, and the related Patient Safety Rule, 42 CFR part 3, published in the **Federal Register** on November 21, 2008 (73 FR 70732–70814), establish a framework by which individuals and entities that meet the definition of provider in the Patient Safety Rule may voluntarily report information to PSOs listed by AHRQ, on a privileged and confidential basis, for the aggregation and analysis of patient safety work product.

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity are to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, when a PSO chooses to voluntarily relinquish its status as a PSO for any reason, or when a PSO's listing expires. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of PSOs.

Section 3.104(e)(1) of the Patient Safety Rule specifies that a PSO's listing, unless revoked or relinquished earlier, automatically expires at midnight of the last day of the three-year listing period if, prior to this deadline, the required certifications for a new three-year listing are not submitted by the PSO and accepted by AHRQ. These conditions were not met. Accordingly, Informed Patient Safety Organization (IPSO), PSO number P0252, a component entity of Informed Surgical, Inc., was delisted effective at 12:00 Midnight ET (2400) on July 6, 2026.

More information on PSOs can be obtained through AHRQ's PSO website at *http://www.pso.ahrq.gov.*

Roger D. Klein,

Director.

[FR Doc. 2026–14313 Filed 7–15–26; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Meeting of the Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Advisory Board on Radiation and Worker Health (ABRWH). This meeting is open to the public, but without an oral public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. The public is also welcome to listen to the meeting by joining the audio conference (information below). The audio conference line has 150 ports for callers.

DATES: The meeting will be held on October 8, 2026, from 11 a.m. to 1 p.m., EDT.

Written comments must be received on or before October 1, 2026.

ADDRESSES: You may submit comments by mail to: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226. Email: *ocas@cdc.gov.*

Written comments received in advance of the meeting will be included in the official record of the meeting.

Meeting Information: The USA toll-free dial-in number is 1–888–994–4478; the passcode is 249193631. The Meeting ID: 286 533 548 251 834; passcode is: Rs7WP9Sg, and the Web conference by Teams meeting connection: *https://teams.microsoft.com/meet/286533548251834?p=vEbJ5Pb8VculYlegd7.*

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226, Telephone: (513) 533–6800, Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines, which have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 14109 (September 29, 2023) on March 22, 2024. Unless continued by the President, the Advisory Board will terminate on September 30, 2027, consistent with Executive Order 14354 of September 29, 2025.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Considered: The agenda will include discussions on the following: Program updates; updates from workgroup and subcommittee reports; update on the status of SEC petitions; and planning for a December 2026 Advisory Board meeting. Agenda items are subject to change as priorities dictate. For additional information, please contact Toll Free 1–800–232–4636.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

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Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2026–14311 Filed 7–15–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2026–0892]

Order Under Sections 362 and 365 of the Public Health Service Act Continuing the Suspension of the Right To Introduce Certain Persons From Countries Where a Quarantinable Communicable Disease Exists

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), a component of the Department of Health and Human Services (HHS), announces it is issuing an Order under Section 362 and 365 of the Public Health Service Act, and associated implementing regulations, continuing the suspension of the right to introduce certain persons from countries where an outbreak of a quarantinable communicable disease exists. This Order was issued on July 13, 2026, and shall remain in effect through 4:59 p.m. Eastern Daylight Time (EDT) on Wednesday, August 12, 2026. This Order may be amended or rescinded prior to that time at the discretion of the Director.

DATES: This action took effect July 13, 2026, at 5:00 p.m. EDT. Written comments must be received on or before July 31, 2026.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2026–0892 by either of the methods listed below. Do not submit comments by email. CDC does not accept comments by email.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Global Migration Health, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H16–4, Atlanta, GA 30329.

Instructions: All submissions received must include the agency name and Docket Number. All relevant comments received will be posted without change to *http://regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Matthew J. Buzzelli, Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS V18–2, Atlanta, GA 30329. Phone: 404–639–7000. Email: *cdcregulations@cdc.gov.*

SUPPLEMENTARY INFORMATION: On May 18, 2026, the Senior Official Carrying out the Delegable Duties of the Director of the Centers for Disease Control and Prevention signed an Order prohibiting the introduction of certain persons who have departed from, or were otherwise present within, specified countries during the last 21 days. On May 22, 2026, the Assistant Secretary for Health (ASH), HHS, signed an Amended Order that reflected updates to 42 CFR 71.40(f), which no longer provided an exemption for lawful permanent residents from such orders. CDC accepted comments on both the original Order and Amended Order through June

22, 2026. On June 21, 2026, the ASH signed a new 30-day Order continuing the previous Order, without change, and provided a 15-day comment period. During this time CDC received five comments, which are addressed below. On July 13, 2026, the ASH signed a new order continuing the previous Order without change and providing updates on the current epidemiologic situation and status of the outbreak. With this Order, CDC continues the suspension of the right to introduce certain persons who have departed from, or were otherwise present within, specified countries during the last 21 days. This Order is effective for a period of 30 days.

Response To Comments on Previous Orders

Comment: One commenter argues that CDC lacks authority to exempt U.S. citizens from the scope of the Order and requests that CDC rescind the exemption. The commenter contends that section 362 of the Public Health Service Act authorizes suspension of the introduction of ''persons'' without distinguishing between U.S. citizens and noncitizens and asserts that public health considerations outweigh any constitutional concerns. The commenter further argues that CDC should exercise its authorities more broadly in responding to the Ebola outbreak.

Response: CDC appreciates this comment, however it is outside the scope of the continued Order. This Order is consistent with CDC's foreign quarantine regulations, including 42 CFR 71.40, which exclude U.S. citizens and U.S. nationals from the suspension authority. CDC is therefore making no changes in response to this comment.

Comment: Another commenter strongly opposed the previous order noting that citizens should have the right to return to the United States given the country's capacity to deal with special pathogens like Ebola.

Response: CDC appreciates this comment. The continued Order does not apply to U.S. citizens or U.S. nationals, who are exempt under 42 CFR 71.40(f).

Comment: Three of the commenters requested that CDC reconsider allowing lawful permanent residents (LPRs) to return under the same screening and monitoring protocols that apply to U.S. citizens as was allowed in the original May 18, 2026, Order.

Response: CDC appreciates these comments. With respect to LPRs, the continued Order is consistent with CDC's current foreign quarantine regulations. The removal of the exemption for LPRs resulted from amendments to 42 CFR 71.40(f) and is outside the scope of this Order. Accordingly, CDC is making no changes in response to this comment.

Commen Two of these commenters also requested that Uganda be evaluated independently and removed from the list of countries noting that since the outbreak began, Uganda has implemented significant measures to reduce the risk of importation from the DRC, including restrictions on cross-border passenger travel, enhanced border screening, and additional public health controls for travelers entering from affected areas.

Response: CDC appreciates this comment but does not agree that Uganda should be removed from the list of designated countries or evaluated independently of the broader regional outbreak at this time. Available epidemiologic information indicates ongoing transmission and the potential for rapid changes in the outbreak. Because the outbreak remains interconnected across national borders, CDC's assessment must consider regional epidemiology, including transmission dynamics in neighboring countries. Accordingly, CDC has determined that applying the Order to persons who have been present in the DRC, Uganda, or South Sudan during the preceding 21 days remains the most effective and administratively practical approach to reducing the risk of Ebola disease introduction into the United States while the public health assessment continues.

CDC carefully considered all comments and determined that they did not warrant changes to the requirements of the Order issued June 21, 2026. The new Order, issued on July 13, 2026, provides updated information regarding the status of the Ebola disease outbreak and CDC response efforts and maintains the previous travel restrictions. CDC will accept comments for this Order using docket CDC–2026–0892. A copy of the Order is provided below and a copy of the signed Order can be found at https://www.cdc.gov/port-health/legal-authorities/evdorder.html.

U.S. Department of Health and Human Services Centers for Disease Control and Prevention (CDC)

Order Under Sections 362 & 365 of the Public Health Service Act (42 U.S.C. 265, 268) and 42 CFR § 71.40

Continuing the Suspension of the Right to Introduce Certain Persons from Countries Where A Quarantinable Communicable Disease Exists

I. Executive Summary

The Centers for Disease Control and Prevention (CDC), a component of the U.S. Department of Health and Human Services (HHS), issues this Order pursuant to Sections 362 and 365 of the Public Health Service (PHS) Act, 42 U.S.C. 265, 268, and their implementing regulations. This Order continues the suspension of the right to introduce ''covered aliens,'' as defined herein, into the United States for a period of thirty days, subject to the outcome of an ongoing comprehensive public health risk assessment. This Order is necessary to protect the health of the United States from the serious risk posed by the introduction of Ebola disease into the United States by covered aliens based on the outbreak of Ebola disease caused by the Bundibugyo virus confirmed present in Democratic Republic of the Congo (DRC) and Uganda.

This Order applies to covered aliens who have departed from, or were otherwise present within, DRC, Uganda, or South Sudan during the last 21 days (regardless of their country of origin). This Order is based on an assessment of the most recently available data and current conditions regarding the Ebola disease outbreak.

This Order is time-limited and shall be in effect for 30 days from the date of issuance. This Order is intended to address the serious risk of introduction of Ebola disease into the United States, while allowing the U.S. Government to continue an ongoing assessment of the current and evolving conditions of the Ebola disease outbreak in consultation with other stakeholders.

This Order is severable from previously issued Orders under Sections 362 and 365 of the Public Health Service (PHS) Act, 42 U.S.C. 265, 268, and their implementing regulations under 42 CFR part 71. Any provision of this Order held to be invalid or unenforceable by its terms, or as applied to any person or circumstance, shall be construed so as to continue to give the maximum effect to the provision permitted by law, unless such holding shall be one of utter invalidity or unenforceability.

II. Authority, Scope, and Purpose

I issue this Order pursuant to Sections 362 and 365 of the Public Health Service (PHS) Act, 42 U.S.C. 265, 268, and their implementing regulations under 42 CFR part 71,[1] which authorize the CDC Director to suspend the right to

[1] Control of Communicable Diseases; Foreign Quarantine: Suspension of the Right to Introduce and Prohibition of Introduction of Persons into United States from Designated Foreign Countries or Places for Public Health Purposes, 85 FR 56424 (Sept. 11, 2020), as amended by 91 FR 31362 (May 27, 2026); 42 CFR 71.40.

introduce [2] persons into the United States when the Director determines that the existence of a quarantinable communicable disease in a foreign country or place creates a serious danger of the introduction of such disease into the United States and the danger is so increased by the introduction of persons from the foreign country or place that a temporary suspension of the right of such introduction is necessary to protect public health.

This Order applies to persons who have departed from, or were otherwise present within, DRC, Uganda, and South Sudan during the last 21 days (regardless of their country of origin), including lawful permanent residents of the United States, subject to the exceptions detailed below. For purposes of this Order, I refer to persons covered by the Order as ''covered aliens.''

This Order does *not* apply to the following:

- U.S. citizens and U.S. nationals; [3]
- Members of the armed forces of the United States and associated personnel, U.S. government personnel serving overseas, associated personnel, and their spouses and children, subject to required assurances; [4]
- Persons whom customs officers determine, with approval from a supervisor, should be excepted from this Order based on the totality of the circumstances, including consideration of significant law enforcement, officer and public safety, humanitarian, and public health interests. The U.S. Department of Homeland Security (DHS) will consult with CDC regarding the standards for such exceptions to help ensure consistency with current CDC guidance and public health recommendations; and
- Persons who would otherwise be subject to this Order, who are permitted to enter the United States based on an exception provisionally granted by CDC with confirmation based on a public health assessment at time of entry under a DHS-approved process documented and shared with CDC which includes appropriate public health mitigation protocols, per CDC guidance.

The purpose of this Order is twofold. First, this Order aims to continue minimizing the number of covered aliens entering the United States who have been within countries experiencing a known or suspected outbreak of Ebola disease and thereby reduce the risk of introduction of Ebola disease into the United States. Second, this Order is intended to facilitate an ongoing public health assessment and risk profile of the Ebola disease outbreak. Thirty days is the amount of time necessary for CDC to conduct an updated public health assessment and determine whether there has been a material change in the outbreak trajectory. Such information will enable the acting CDC Director to make an informed determination regarding what restrictions are necessary going forward and provide the opportunity for the development of a comprehensive mitigation and containment plan in consultation with stakeholders.

III. Factual Basis

A. Ebola Disease

Viral hemorrhagic fever refers to a group of severe illnesses caused by certain viruses that damage the body's blood vessels and affect the ability of the blood to clot properly. Viral hemorrhagic fevers include diseases such as Ebola, Marburg, Lassa fever, and dengue hemorrhagic fever.

Bundibugyo virus disease (BVD) is a severe and often fatal illness caused by one of the viruses in the Ebola family. Ebola disease outbreaks occur mainly in parts of sub-Saharan Africa and can spread rapidly in communities with limited healthcare resources. Ebola disease caused by the Bundibugyo virus is a rare form of Ebola first identified during an outbreak in Bundibugyo District, Uganda, in 2007. Bundibugyo virus is one of several species within the orthoebolavirus family and causes symptoms similar to other forms of Ebola, including fever, weakness, vomiting, diarrhea, and, in severe cases, hemorrhagic complications and organ failure. The disease spreads through direct contact with infected bodily fluids or contaminated materials.

The incubation period for Ebola disease caused by the Bundibugyo virus is typically between 2 and 21 days, with most people developing symptoms within 4 to 10 days after exposure. During this incubation period, infected persons do not spread the virus until symptoms begin.

Screening for Bundibugyo virus disease focuses on identifying symptoms and possible exposure history, such as recent travel to affected areas or contact with infected aliens. Suspected patients are evaluated for symptoms including fever, weakness, vomiting, diarrhea, and bleeding, and laboratory confirmation is performed using specialized tests such as PCR (polymerase chain reaction) to detect the virus in blood and other body fluid samples. Health authorities also use temperature checks, contact tracing, and isolation procedures to prevent transmission.

There are currently no widely approved vaccines or specific antiviral treatments for the Bundibugyo strain of Ebola disease. Treatment mainly consists of supportive care, including intravenous fluids, electrolyte replacement, oxygen support, pain and fever management, and treatment of secondary infections. Early medical care significantly improves survival chances. Robust public health measures such as early detection, rapid isolation, strong infection prevention measures (*i.e.,* use of personal protective equipment [PPE]), and monitoring of contacts are critical to controlling outbreaks and reducing deaths. A clinical trial of monoclonal antibodies is presently underway in DRC.[5] However, experts expect it will be several months before these therapeutics are potentially available for wider use.

B. Ongoing Bundibugyo Virus Disease Outbreak

The confirmed ongoing outbreak of Ebola virus disease caused by the Bundibugyo virus in DRC and Uganda continues to escalate in intensity. The outbreak remains centered in eastern DRC's Ituri Province, although cases have been identified in North Kivu, South Kivu, Haut-Uele, and Tshopo provinces. This geographic expansion is concerning, particularly given that response efforts are still not at the scale required for outbreak containment. On June 15, 2026, when the last Order was issued, DRC reported 837 confirmed cases across 31 health zones. As of July 12, 2026, DRC reports 1,873 confirmed cases and 672 deaths across 41 health zones, with cases more than doubling since issuance of the June 22 Order.

As recently as July 10, 2026, the ongoing Bundibugyo Ebola virus outbreak in DRC continues to spread despite response efforts. In the outbreak's epicenter, an estimated 80 percent of newly confirmed cases are not linked to known contacts, indicating substantial undetected community transmission.[6] Recent assessments

[2] *Suspension of the right to introduce* means to cause the temporary cessation of the effect of any law, rule, decree, or order pursuant to which a person might otherwise have the right to be introduced or seek introduction into the United States. 42 CFR 71.40(b)(5).

[3] 42 CFR 71.40(f).

[4] 42 CFR 71.40(e)(1) and (2).

[5] WHO, *Patient enrolment begins in a scientific trial to identify the first effective treatments for Bundibugyo virus disease, https://www.who.int/news/item/02-07-2026-patient-enrolment-begins-in-a-scientific-trial-to-identify-the-first-effective-treatments-for-bundibugyo-virus-disease* (last accessed July 12, 2026).

[6] Bonnerot, C., Reuters, *Congo Ebola outbreak still spreading largely undetected, WHO official says,* available at *https://www.reuters.com/business/healthcare-pharmaceuticals/congo-ebola-outbreak-*

indicate that the true magnitude of the outbreak may be two to four times greater than reported surveillance data suggest. Surveillance challenges persist in the most heavily affected areas, with conflict and insecurity, weak health infrastructure, and relatively porous borders in the region complicating containment efforts. Although contact tracing efforts are underway, they remain insufficient because the expected number of contacts has not yet been identified and the daily follow-up necessary to rapidly detect symptomatic individuals and ensure their prompt isolation has not been achieved.

As of July 12, 2026, Uganda reports 20 confirmed cases of Ebola disease and two confirmed deaths, as well as one probable case and one probable death. All cases in Uganda have been epidemiologically linked to the ongoing outbreak in DRC, with cross-border importations have occurred, resulting in secondary transmission among family members and caregivers [7] Ugandan authorities have activated emergency response systems, expanded surveillance, and strengthened screening at borders and health facilities. Uganda has significant prior experience managing Ebola disease outbreaks, including the Sudan virus strain outbreak in 2025, which improved preparedness and response capacity. Although the outbreak in Uganda has been concentrated in Kampala and despite Uganda's response efforts, continued overland travel from DRC poses an ongoing risk of cross-border transmission, particularly among healthcare workers and in western Ugandan districts that serve as points of entry for travelers seeking medical care.

To date, South Sudan has not reported any confirmed Ebola disease cases in the current outbreak.[8] However, it is considered at high risk because of its close border with affected areas in eastern DRC and Uganda, limited healthcare infrastructure, and cross-border population movement. Regional and international agencies, including WHO and Africa CDC, are supporting preparedness measures, surveillance, and coordination among the three countries to prevent wider spread. Despite these efforts there continues to be a risk that the outbreak in DRC and Uganda could spread to South Sudan through cross-border travel by infected individuals during the virus's incubation period, when they have been exposed but are not yet showing symptoms.

Travelers moving between affected countries and major international transit hubs could unknowingly carry the Bundibugyo virus before becoming ill. Such travelers may spread the outbreak beyond the affected countries and ultimately reach the United States. DRC, Uganda, and South Sudan are connected to the global aviation network through a series of regional and international transit hubs that provide pathways into the United States. Travelers departing from outbreak-affected regions frequently transit through densely populated metropolitan airports such as Addis Ababa Bole International Airport (ADD), Jomo Kenyatta International Airport (NBO) in Nairobi, Brussels Airport (BRU), Hamad International Airport (DOH) in Doha, Dubai International Airport (DXB), and Istanbul Airport (IST), all of which maintain extensive passenger connectivity to major U.S. gateway airports including John F. Kennedy International Airport (JFK), Washington Dulles International Airport (IAD), Hartsfield-Jackson Atlanta International Airport (ATL), Chicago O'Hare International Airport (ORD), and Los Angeles International Airport (LAX). These international transportation corridors support continuous movement of travelers between Central and East Africa and major U.S. metropolitan centers, increasing the likelihood that aliens exposed to Ebola disease could enter the United States before symptoms become apparent. Complex multi-leg itineraries and the rapid pace of international travel create substantial challenges for identifying potentially infected travelers before arrival.

A traveler infected in outbreak regions of DRC and Uganda may transit through multiple countries and major international airports before developing fever or other clinical signs of disease. The risk of Bundibugyo virus disease introduction into the United States is heightened by the virus's incubation period, which can extend up to 21 days, allowing infected persons to travel internationally while asymptomatic and therefore unlikely to be detected through routine symptom-based screening measures. The current outbreak has already demonstrated this risk: a physician infected while providing patient care in DRC traveled internationally before becoming ill and was diagnosed only after arriving in France.[9] That case required extensive public health coordination, including federal, state, and local government efforts to identify, notify, and monitor potentially exposed U.S. citizens, demonstrating that a single infected traveler can impose significant cross-border public health response demands even without onward transmission occurring within the United States. Accordingly, the interconnected nature of global air travel presents a credible pathway for Bundibugyo virus disease importation into the United States, underscoring the importance of aggressive surveillance, traveler monitoring, airport public health screening, healthcare preparedness, and rapid containment capabilities.

While the France case illustrates the public health challenges posed by infected travelers moving internationally before becoming symptomatic, the ongoing outbreak has also demonstrated that substantial U.S. public health resources may be required to respond to an Ebola exposure or infection in any U.S. citizen. On July 10, 2026, CDC announced that an additional U.S. citizen working for a humanitarian organization in DRC had tested positive for Bundibugyo virus disease.[10] The individual, who was not involved in direct patient care,[11] prompted an extensive U.S. public health response. CDC, in coordination with the humanitarian organization, initiated contact tracing, exposure risk assessments, and monitoring activities to identify high-risk contacts and evaluate potential exposures among humanitarian personnel who had recently returned to, or are planning to return to, the United States. The Department of State arranged medical evacuation outside of DRC for treatment. This incident demonstrates that even when an infected U.S. citizen remains overseas, the outbreak can require substantial U.S. public health resources to identify, assess, and monitor potentially exposed individuals associated with international humanitarian operations.

Travelers utilizing air transit pathways originating in or passing through DRC, Uganda, and South Sudan

still-spreading-largely-undetected-who-official-says-2026-07-10/ (last accessed July 12, 2026).

[7] CDC internal data.

[8] CDC, *Ebola Outbreak: Current Situation, https://www.cdc.gov/ebola/situation-summary/index.html* (last visited June 17, 2026).

[9] World Health Organization, *WHO Director-General's opening remarks at the media briefing—24 June 2026,* available at *https://www.who.int/news-room/speeches/item/who-director-general-s-opening-remarks-at-the-media-briefing—24-june-2026* (last accessed July 12, 2026).

[10] CDC, CDC Statement on Ebola Outbreak in the Democratic Republic of Congo and Uganda: 7/10/26, *https://www.cdc.gov/media/releases/2026/cdc-ebola-outbreak-in-democratic-republic-of-congo-and-uganda.html* (last accessed July 12, 2026).

[11] Walsh, D. and Yoon, J., *U.S. Citizen Tests Positive for Ebola in Democratic Republic of Congo, https://www.nytimes.com/2026/07/11/world/africa/dr-congo-ebola-american-us-citizen.html?unlocked_article_code=1.w1A.A4kv.spNPZlf8jap6&smid=url-share* (last accessed July 12, 2026).

include non-U.S. citizens, including regional migrants, foreign contract workers, humanitarian personnel, business travelers, students, refugees, and third-country nationals moving through international aviation hubs in Africa, the Middle East, and Europe. Many travelers entering U.S.-bound itineraries from these pathways may do so under temporary visas, refugee or asylum processing mechanisms, international organizational travel, or multi-country itineraries that obscure their original point of departure. As a result, public health screening and border security systems face heightened operational complexity in identifying travelers with recent exposure histories linked to Ebola-affected regions, particularly when travelers originate from or transit through multiple jurisdictions prior to arrival at major U.S. metropolitan airports.

CDC issued a Level 2 Travel Health Notice (THN, practice enhanced precautions) for Ituri and North Kivu provinces of DRC and a Level 1 THN (practice usual precautions) for Uganda on May 15, 2026.[12] On May 18, 2026,[13] CDC escalated the Level 2 THN for to a Level 3 THN (reconsider nonessential travel) for Ituri and North Kivu Provinces; South Kivu was added to the Level 3 on May 22, 2026. On May 27, 2026, the THN for Uganda was elevated to a Level 2. On June 15, 2026 CDC issued a Level 2 THN for the remainder of DRC and Uganda.[14] This modification reflects the geographic distribution of reported cases and does not indicate a reduced level of concern regarding the outbreak, which continues to expand in affected areas and poses a risk of further transmission and geographic spread.

CDC modeling indicates that, absent rapid and sustained public health interventions, the outbreak could become one of the largest Ebola epidemics ever recorded.[15] The analysis further demonstrates that early identification of cases, contact tracing, isolation and treatment of symptomatic persons, community engagement, and safe burial practices are critical to reducing transmission and mitigating outbreak growth.[16] CDC has concluded that the current outbreak is already the largest known outbreak of Bundibugyo virus disease and that large-scale, sustained public health measures are necessary to prevent further international spread of the disease and to reduce the risk of introduction of infected persons into the United States.[17] Commensurate with the deterioration of the epidemiological situation in DRC, CDC escalated its response to the outbreak to a Level 1, the highest level within the agency's Graduated Response Framework.[18] Designating the response as a Level 1 indicates the gravity of the situation and allows additional staffing support from across the response, with immediate lines of communication with agency leadership.

Restricting entry of covered aliens into the United States reduces the volume of higher-risk international arrivals requiring public health monitoring and follow-up. By limiting the number of potentially exposed travelers entering through major U.S. ports of entry, federal, state, and local public health authorities have concentrated finite surveillance, screening, contact tracing, quarantine management, and medical monitoring resources on returning U.S. citizens and U.S. nationals, including those who have worked in the outbreak areas.

Paired with the DHS arrival restrictions redirecting travelers to specific U.S. airports,[19] this approach has reduced operational strain on airport screening systems, CDC port health stations, public health laboratories, and healthcare facilities responsible for evaluating suspected Bundibugyo virus disease cases. It also has improved the ability of authorities to conduct detailed exposure assessments, ensure compliance with monitoring requirements during the 21-day incubation period, rapidly identify symptomatic travelers, and allocate specialized isolation and treatment capacity more effectively. In the context of a rapidly evolving Bundibugyo virus disease outbreak with significant cross-border mobility, prioritizing surveillance efforts toward a smaller and more traceable traveler population has strengthened the overall effectiveness of U.S. disease containment and border health security operations.

IV. Legal Basis for This Order Under Sections 362 and 365 of the Public Health Service Act and 42 CFR 71.40

CDC is issuing this Order pursuant to sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265, 268) and the implementing regulation at 42 CFR 71.40. In accordance with these authorities, the CDC Director is permitted to prohibit, in whole or in part, the introduction into the United States of persons from designated foreign countries (or one or more political subdivisions or regions thereof) or places, only for such period of time that the Director deems necessary to avert the serious danger of the introduction of a quarantinable communicable disease,[20] by issuing an Order in which the Director determines that:

(1) By reason of the existence of any quarantinable communicable disease in a foreign country (or one or more political subdivisions or regions thereof) or place there is serious danger of the introduction of such quarantinable communicable disease into the United States; and

(2) This danger is so increased by the introduction of persons from such country (or one or more political subdivisions or regions thereof) or place that a suspension of the right to introduce such persons into the United States is required in the interest of public health.[21]

Section 362 and the implementing regulation provide the Director with a public health tool to suspend introduction of persons not only to prevent the introduction of a quarantinable communicable disease, but also to aid in continued efforts to mitigate spread of that disease.[22]

The term ''introduction into the United States'' is defined in 42 CFR 71.40 as ''the movement of a person from a foreign country (or one or more political subdivisions or regions thereof) or place, or series of foreign countries or places, into the United States so as to bring the person into contact with persons or property in the United States, in a manner that the Director determines

[12] CDC, *Ebola Bundibugyo Virus Disease in Parts of the Democratic Republic of the Congo, https://wwwnc.cdc.gov/travel/notices/level3/ebola-democratic-republic-of-the-congo* (last accessed June 16, 2026). CDC subsequently updated the notice on May 22, 2026, as the outbreak expanded to additional provinces, while maintaining the Level 3 designation.

[13] CDC, *Ebola Bundibugyo Virus Disease in the Democratic Republic of the Congo and Uganda, https://wwwnc.cdc.gov/travel/notices/level2/ebola-drc-uganda* (last accessed June 17, 2026).

[14] CDC, *Ebola Bundibugyo Virus Disease in Parts of the Democratic Republic of the Congo, https://wwwnc.cdc.gov/travel/notices/level3/ebola-democratic-republic-of-the-congo* (last accessed June 16, 2026).

[15] Mooring EQ, Koval WT, Routledge I, et al. *Modeled Scenario Projections for the Ebola Disease Outbreak Caused by Bundibugyo Virus, 2026.* MMWR Morb Mortal Wkly Rep 2026;75:285–289. DOI: *http://dx.doi.org/10.15585/mmwr.mm7522e1.*

[16] *Id.*

[17] *Id.*

[18] CDC, Internal Decision Memo, June 26, 2026.

[19] DHS, Arrival Restrictions Applicable to Flights Carrying Persons Who Have Recently Traveled From or Were Otherwise Present Within the Democratic Republic of the Congo, Uganda, or South Sudan, 91 FR 29896 (May 21, 2026).

[20] *See* Exec. Order No. 13,295, Revised List of Quarantinable Communicable Diseases (April 2, 2003) (adding viral hemorrhagic fevers, including Ebola, to the U.S. federal list of quarantinable communicable diseases).

[21] 42 U.S.C. 265; 42 CFR 71.40.

[22] 85 FR 56424 at 56425–26.

to present a risk of transmission of a quarantinable communicable disease to persons, or a risk of contamination of property with a quarantinable communicable disease.'' 42 CFR 71.40(b)(1). Similarly, the term ''serious danger of the introduction of such quarantinable communicable disease into the United States'' is defined as, ''the probable introduction of one or more persons capable of transmitting the quarantinable communicable disease into the United States, even if persons or property in the United States are already infected or contaminated with the quarantinable communicable disease.'' 42 CFR 71.40(b)(3).

Section 71.40(b)(2) defines ''[p]rohibit, in whole or in part, the introduction into the United States of persons'' in Section 362 to mean ''to prevent the introduction of persons into the United States by suspending any right to introduce into the United States, physically stopping or restricting movement into the United States.'' *See also* 42 U.S.C. 265 (authorizing the prohibition when the danger posed by the communicable disease ''is so increased by the introduction of persons . . . from such country . . . that a suspension of the right to introduce such persons . . . is required in the interest of public health'').

As stated in the Final Rule for 42 CFR 71.40, CDC ''may, in its discretion, consider a wide array of facts and circumstances when determining what is required in the interest of public health in a particular situation . . . includ[ing] . . . [t]he overall number of cases of disease; any large increase in the number of cases over a short period of time; the geographic distribution of cases; any sustained (generational) transmission; the method of disease transmission; morbidity and mortality associated with the disease; the effectiveness of contact tracing; the adequacy of state and local health care systems; and the effectiveness of state and local public health systems and control measures.'' [23]

As stated in 42 CFR 71.40, this Order does not apply to U.S. citizens, U.S. nationals, members of the armed forces of the United States and associated personnel if the Secretary of War provides assurance to the Director that the Secretary of War has taken or will take measures such as quarantine or isolation, or other measures maintaining control over such individuals, to prevent the risk of transmission of the quarantinable communicable disease into the United States, or United States government employees or contractors on orders abroad, or their accompanying family members who are on their orders or are members of their household, if the Director receives assurances from the relevant head of agency and determines that the head of the agency or department has taken or will take measures such as quarantine or isolation, to prevent the risk of transmission of a quarantinable communicable disease into the United States.[24]

In addition, this Order does not apply to additional classes of persons excepted by the CDC Director. Creating exceptions in the Order is consistent with Section 362 and 42 CFR 71.40. Section 362 explicitly states that the prohibition of introduction into the United States may be ''in whole or in part.'' This phrase is also included in section 71.40(a) and, as explained in the Final Rule, is intended to allow the Director to narrowly tailor the use of the authority to what is required in the interest of public health.[25] As noted in the Final Rule for 42 CFR 71.40, the CDC Director may also take into account international obligations and humanitarian concerns.[26] Pursuant to this capability, CDC is therefore excepting certain categories of persons, as described herein.

This Order will be in effect for 30 days to avert the serious danger of the introduction, transmission, and spread of Ebola disease into the United States. Finally, as directed by 42 CFR 71.40(c), this Order sets out the following:

(1) The foreign countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited;

(2) The period of time or circumstances under which the introduction of any persons or class of persons into the United States is being prohibited;

(3) The conditions under which that prohibition on introduction will be effective, in whole or in part, including any relevant exceptions that the Director determines are appropriate;

(4) The means by which the prohibition will be implemented; and

(5) The serious danger posed by the introduction of the quarantinable communicable disease in the foreign country or countries (or one or more political subdivisions or regions thereof) or places from which the introduction of persons is being prohibited.

V. Determination and Implementation

Based on the foregoing, I hereby determine that Ebola disease, a highly transmissible quarantinable communicable disease, is confirmed present in DRC and Uganda. There is a material risk that the outbreak will spread to South Sudan. I also determine that the prevalence of Ebola disease in these foreign countries constitutes a serious danger of the introduction of this disease into the United States due to the limited screening and testing and mitigation measures currently available. Finally, I determine that a temporary 30-day suspension of the right to introduce covered aliens is necessary to protect the public health from the serious danger of the introduction of Ebola disease into the United States, pending an ongoing public health assessment of the Ebola disease outbreak.

I consulted with the Department of State, DHS, and other federal departments as needed before I issued this Order and requested that DHS aid in the enforcement of this Order because CDC does not have the capability, resources, or personnel needed to do so.[27] As part of the consultation, DHS developed operational plans for implementing this Order. These plans are consistent with the language of this Order.

Although this Order is not a rule subject to notice and comment under the Administrative Procedure Act (APA) and is issued with immediate effect, in order to ensure that the forthcoming public health risk assessment is informed by public input, the Order is being issued with a simultaneous 15-day comment period.

This Order takes effect at 5:00 p.m. Eastern Daylight Time on Monday, July 13, 2026. For individuals intending to travel to the United States by air, the Order will apply to flights departing after 4:59 p.m. Eastern Daylight Time on Tuesday, July 13, 2026.

* * * * *

In testimony whereof, the Assistant Secretary for Health, U.S. Department of Health and Human Services, has hereunto set his hand at Washington, DC this 14th day of July, 2026.

Dated: 07/14/2026.

Admiral Brian Christine, MD, Assistant Secretary for Health (ASH) and Head of the United States Public Health Service (USPHS) Commissioned Corps, Department of Health and Human Services.

Public Participation

Interested persons or organizations are invited to participate by submitting

[23] *Id.* at 56444.

[24] 42 CFR 71.40(e) and (f).

[25] 85 FR 56424 at 56444.

[26] *Id.* at 56447.

[27] 42 U.S.C. 268; 42 CFR 71.40(d).

written views, recommendations, and data so that the public can provide input that may inform the forthcoming public health risk assessment and whether any subsequent exercise of this authority is necessary.

Please note that comments received, including attachments and other supporting materials, are part of the public record and are subject to public disclosure. Comments will be posted on *https://www.regulations.gov.* Therefore, do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near duplicate examples of a mass-mail campaign. Do not submit comments by email. CDC does not accept comment by email.

Authority

The authority for this order is Sections 362 and 365 of the Public Health Service Act (42 U.S.C. 265, 268), as amended.

Dated: July, 14, 2026.

Brian Christine,

Admiral, Assistant Secretary for Health (ASH) and Head of the United States Public Health Service (USPHS) Commissioned Corps, Department of Health and Human Services.

[FR Doc. 2026–14365 Filed 7–15–26; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10450 and CMS–643]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by August 17, 2026.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment.

Information Collection

1. *Type of Information Collection Request:* Revision of a currently approved Information Collection; *Title of Information Collection:* Consumer Assessment of Healthcare Providers and Systems (CAHPS) Survey for Merit-based Incentive Payment Systems (MIPS); *Use:* This is a request to revise the information collection for the CAHPS for MIPS Survey. The CAHPS for MIPS survey is used in the Quality Payment Program (QPP) to collect data on fee-for-service Medicare beneficiaries' experiences of care with eligible clinicians participating in MIPS and is designed to gather only the necessary data that CMS needs for assessing physician quality performance, and related public reporting on physician performance, and should complement other data collection efforts. The survey consists of the core Agency for Healthcare Research and Quality (AHRQ) CAHPS Clinician & Group Survey, version 3.0, plus additional survey questions to meet CMS's information and program needs. The survey information is used for quality reporting, the compare tool on the Medicare.gov website, and annual statistical experience reports describing MIPS data for all MIPS eligible clinicians.

This 2026 information collection request addresses the requirements related to the statutorily required quality measurement. The CAHPS for MIPS survey results in burden to three different types of entities: groups, virtual groups, and subgroups; vendors; and beneficiaries associated with administering the survey. Virtual groups are subject to the same requirements as groups and subgroups; therefore, we will refer only to ''groups'' as an inclusive term for all entities unless otherwise noted.

The revision consists of a change to the vendor participation form to collect cost information from survey vendors. The collection of this cost information was proposed in the CY 2025 PFS final rule (*89 FR 62010*) and (*89 FR 62123*). The revision also includes changes to the vendor participation form to collect information related to the addition of web to the existing mail-phone administration protocol. The addition of web as the first mode of administration was proposed in the CY 2026 PFS final rule (*90 FR 49266*) and (*90 FR 49760*).

The changes to the vendor participation form consist of:

- 2 new items to collect information on cost
- 1 new item to collect information related to web administration of the survey
- 12 items revised to collect information related to web administration of the survey

The cost information is readily available to survey vendors, as a result adding it to the vendor participation form does not affect burden. The web survey requires vendors to collect additional information to complete the vendor participation form. We estimate an additional hour of burden for a total of 11 hours per application, an increase to the 10 hours per application first established in the CY 2018 Quality Payment Program final rule (*82 FR 30216*). We also assume this change would not affect survey vendor participation. *Form Number:* CMS–10450 (OMB control number: 0938–1222); Frequency: Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions and Individuals and Households; *Number of Respondents:* 26,976; *Total Annual Responses:* 26,976; *Total Annual Hours:* 6,139 (For policy questions regarding this collection contact Julie Johnson at 410–786–1507.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Hospice Survey and Deficiencies Report Form and Supporting Regulations; *Use:* A hospice is a heath care entity that provides palliative care (relief of pain and uncomfortable symptoms), as opposed to curative care, to terminally ill individuals. In addition to meeting the patient's medical needs, hospice care addresses the physical, psychosocial, and spiritual needs of the patient, as well as psychosocial needs of the patient's family/caregiver related to the terminal illness. The emphasis of the hospice program is on keeping the hospice patient at home with family and friends as long as possible.

The CMS–643 form is primarily a coding worksheet designed to facilitate data collection during a hospice survey for Medicare participation. It is used to collect several data elements related to patient health and safety, record reviews and data about the specific hospice's operations, staffing and demographics. CMS has made several revisions to this form based on duplication of collected information from the CMS–643 and the CMS–417 form titled ''Hospice Request for Certification in the Medicare Program'' (OMB Control number: 0938–0313). The CMS–643 is completed by surveyors during onsite survey activity and poses minimal to no burden on the hospice provider.

The data collected on the CMS–643 form is entered into the internet Quality Improvement and Evaluation System (iQIES) surveyor database during the course of an initial, recertification or complaint survey. Hospice surveyors that have access to the electronic iQIES system while onsite at a hospice, can enter the CMS–643 form data directly into the system. If this access is not available to the surveyor, they can record their finding directly onto the CMS–643 form and input the data into the system later. We removed the requirement for the surveyors to sign CMS–643 to certify their findings as this process has been automated once information is entered into the iQIES database. *Form Number:* CMS–643 (OMB control number: 0938–0379); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 7,029; *Total Annual Responses:* 2,343; *Total Annual Hours:* 1,172. (For policy questions regarding this collection contact Caecilia Andrews at 410–786–2190.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–14364 Filed 7–15–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10398 #17, #34 and #95 and CMS–10434 #15, #22, #26, and #47]

Medicaid and Children's Health Insurance Program (CHIP) Generic Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: On May 28, 2010, the Office of Management and Budget (OMB) issued Paperwork Reduction Act (PRA) guidance related to the ''generic'' clearance process. Generally, this is an expedited process by which agencies may obtain OMB's approval of collection of information requests that are ''usually voluntary, low-burden, and uncontroversial collections,'' do not raise any substantive or policy issues, and do not require policy or methodological review. The process requires the submission of an overarching plan that defines the scope of the individual collections that would fall under its umbrella. On October 23, 2011, OMB approved our initial request to use the generic clearance process under control number 0938–1148 (CMS–10398). It was last approved on April 26, 2021, via the standard PRA process which included the publication of 60- and 30-day **Federal Register** notices. The scope of the April 2021 umbrella accounts for Medicaid and CHIP State plan amendments, waivers, demonstrations, and reporting. This **Federal Register** notice seeks public comment on one or more of our collection of information requests that we believe are generic and fall within the scope of the umbrella. Interested persons are invited to submit comments regarding our burden estimates or any other aspect of this collection of information, including: the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by July 30, 2026.

ADDRESSES: When commenting, please reference the applicable form number (CMS–10398 #/CMS–10434 #) and the OMB control number (0938-). To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address:

CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: CMS–10398 #/CMS–10434 #/OMB control number: 0938–, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in

this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/medicare/regulations-guidance/legislation/paperwork-reduction-act-1995/pra-listing.*

FOR FURTHER INFORMATION CONTACT: William N. Parham at 410–786–4669.

SUPPLEMENTARY INFORMATION: Following is a summary of the use and burden associated with the subject information collection(s). More detailed information can be found in the collection's supporting statement and associated materials (see **ADDRESSES**).

Generic Information Collections

1. *Title of Information Collection:* CHIP State Plan Eligibility; *Type of Information Collection Request:* Revision of an active collection of information request; *Use:* Section 71112 of the Working Families Tax Cut (WFTC) Act (Pub. L. 119–21) amended section 2102(b)(1)(B) of the Social Security Act by retaining the state option to provide retroactive CHIP eligibility while limiting states from beginning coverage any earlier than two months prior to the month of application. This 2026 iteration adds a new template (CS22, ''Retroactive Eligibility for Children and/or Pregnant Women'') that includes required eligibility attestations for the state to document state assurances/elections and verification processes, including that the State will provide coverage during a ROP (reasonable opportunity period) of at least 90 days; *Form Number:* CMS–10398 #17 (OMB control number: 0938–1148); *Frequency:* Once and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 41; *Total Annual Responses:* 41; *Total Annual Hours:* 820. (For policy questions regarding this collection contact Abby Kahn at 410–786–4321.)

2. *Title of Information Collection:* Model Application Template and Instructions for State Child Health Plan Under Title XXI of the Social Security Act, State Children's Health Insurance Program; *Type of Information Collection Request:* Revision of an active collection of information request; *Use:* Section 71103 of the WFTC legislation adds new paragraph (88) under section 1902(a) of the Social Security Act with corresponding amendments to section 2107(e)(1) to create new state plan requirements related to address verification. Beginning no later than January 1, 2027, the 50 States and the District of Columbia must regularly obtain updated address information from reliable data sources while Medicaid/CHIP managed care contracts must require prompt transmission to the state of updated address information obtained or verified directly with the individual.

This 2026 iteration also adds several new state assurances and updates existing requirements in the CHIP state plan template. The state must attest that each contracted managed care entity or plan promptly transmits to the state any enrollee address information it receives directly from the enrollee or verifies directly with the enrollee and that the state regularly obtains updated address information for Medicaid and CHIP enrollees from reliable data sources.

Consistent with our February 8, 2024 (89 FR 8758) final rule CMS–0057–F (RIN 0938–AU87) this iteration amends the quality assurance for prior authorizations in the CHIP state plan template. States must provide a narrative description of methods used to ensure prior authorization determination timeframes are met within 7 calendar days for standard requests and 72 hours for expedited requests. States must also provide an assurance that prior authorization data will be posted on the state's website by March 31 for data from the previous calendar year. We estimate all states with a separate CHIP will be required to submit a SPA to attest to compliance with the provisions of CMS–0057–F.

Revisions to the template require the state to: attest that it has a process to regularly obtain address information for enrolled individuals and attest that it uses specified reliable data sources for updated address information. It also requires the state to describe its quality oversight for prior authorization determination timeframes.

Form Number: CMS–10398 #34 (OMB control number: 0938–1148); *Frequency:* Annual; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 41; *Total Annual Responses:* 82; *Total Annual Hours: 328.* (For policy questions regarding this collection contact Abby Kahn at 410–786–4321.)

3. *Title of Information Collection:* Home and Community Based Services (HCBS) Quality Measure Set (QMS) Reporting; *Type of Information Collection Request:* New collection of information; *Use:* This new collection of information supports reporting requirements for states participating in the Money Follows the Person (MFP) demonstration. As a condition of award under the MFP demonstration, participating state Medicaid agencies are required to report on measures included in the Home and Community-Based Services (HCBS) Quality Measure Set (QMS) beginning September 1, 2026; *Form Number:* CMS–10398 #95 (OMB control number: 0938–1148); *Frequency:* Biennial and once; *Affected Public:* Individuals and households, and State, Local, or Tribal Governments; *Number of Respondents:* 48,048; *Total Annual Responses:* 24,024; *Total Annual Hours:* 109,200. For policy questions regarding this collection contact Melanie Brown at 410–786–1095.

4. *Title of Information Collection:* Medicaid State Plan Eligibility; *Type of Information Collection Request:* Revision of an active collection of information request; *Use:* This 2026 iteration incorporates revisions related to sections 71103, 71107, and 71112 of the WFTC legislation. The revisions are associated with RU S95 (Regularly Obtain Address Information for Enrolled Individuals) for section 71103; RU S94 (Eligibility Process) and RU S96 (Frequency of Renewals of Eligibility) for section 71107; and RU S85 (Beginning Dates of Eligibility) for section 71112; *Form Number:* CMS–10434 #15 (OMB control number: 0938–1188); *Frequency:* Once and occasionally; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 56; *Total Annual Responses:* 56; *Total Annual Hours:* 1,120. (For policy questions regarding this collection contact Abby Kahn at 410–786–4321.)

5. *Title of Information Collection:* Health Home State Plan Amendment (SPA); *Type of Information Collection Request:* Revision of an active collection of information request; *Use:* Information submitted via the Health Home State Plan Amendment (SPA) web-based application is used by CMS to analyze a State's proposal to implement Section 1945 and/or Section 1945A of the Act. Section 1945 provides a State plan option to provide coordinated care through a health home program for individuals with chronic conditions while Section 1945A provides a State plan option to provide coordinated care through a health home program for children with medically complex conditions; *Form Number:* CMS–10434 #22 (OMB control number: 0938–1188); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 35; *Total Annual Responses:* 35; *Total Annual Hours:* 2,800. (For policy questions regarding this collection contact Sara Rhoades at 410–786–4484.)

6. *Title of Information Collection:* Child and Adult Core Set Measures; *Type of Information Collection Request:* Revision of an active collection of information request; Use: For federal

fiscal year (FFY) 2026, States are required to submit data on 25 Child Core Set and 10 behavioral health Adult Core Set mandatory quality measures. We also added two new optional stratification standards to state reporting: foster care status (Child measures only) and Medicaid expansion status (Adult measures only).

States will be required to report stratified data for 2026 on: 12 Child Core Set measures and 5 Adult Core Set behavioral health measures. As per usual practice, states can choose to voluntarily submit data on up to two provisional measures and three utilization measures on the Child Core Set and up to 23 voluntary measures, two provisional measures, and one utilization measure on the Adult Core Set and provide measurement data stratified by race, ethnicity, sex (male/female), geography (urban/rural), foster care status (Child measures only) or Medicaid expansion status (Adult measures only). Questions related to stratification have been provided as a separate reviewable units (RUs) and revised to include foster care status and Medicaid expansion standards.

For the mandatory measures on the Child and Adult Core Sets, the burden estimate has been updated to reflect efficiencies in state reporting, improvements in the reporting system, and the requirement to stratify 50% of these measures. For the voluntary measures on the Adult Core Set, the burden estimate has been updated to reflect the number of states who have reported these measures since mandatory reporting was implemented.

For the annual exemption request, the burden estimate has been updated based on the number of states who submitted exemption requests since mandatory reporting began.

Form Number: CMS–10434 #26 (OMB control number: 0938–1188); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 61,293; *Total Annual Responses:* 61,431; *Total Annual Hours:* 85,489. (For policy questions regarding this collection contact Virginia (Gigi) Raney at 410–786–6117.)

7. *Title of Information Collection:* Health Home Core Sets; *Type of Information Collection Request:* Revision of an active collection of information request; *Use:* Information submitted via the Health Home Core Sets web-based application is used by CMS to analyze the Health Home programs. Through the establishment of sections 1945 and 1945A of the Social Security Act (the Act) states may elect a new Health Homes service option under the Medicaid state plan that could help states address and receive additional federal support for enhanced integration and care coordination for Medicaid eligible individuals with chronic conditions, such as mental health conditions, including substance use disorders, asthma, diabetes, heart disease, overweight, and medically complex children. *Form Number:* CMS–10434 #47 (OMB control number: 0938–1188); *Frequency:* Yearly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 45; *Total Annual Responses:* 45; *Total Annual Hours:* 4,350. (For policy questions regarding this collection contact Sara Rhoades at 410–786–4484.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2026–14359 Filed 7–15–26; 8:45 am]

BILLING CODE 4169–69–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for Office of Management and Budget Review; Evaluation of the Next Generation Child Support Employment Services Demonstration

AGENCY: Office of Child Support Enforcement, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Office of Child Support Enforcement (OCSE), Administration for Children and Families (ACF), Department of Health and Human Services, is proposing to collect data for a new implementation and outcomes study, Evaluation of the Next Generation Child Support Employment Services Demonstration (NextGen).

DATES: Comments due August 17, 2026.

ADDRESSES: The public may view and comment on this information collection request at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202607-0970-006.* You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: OCSE proposes data collection activity as part of NextGen. In August 2024, OCSE issued eight grants and two section 1115 waivers to 10 child support agencies to provide employment and other support services to noncustodial parents:

- Los Angeles County, CA
- Sacramento and Stanislaus Counties, CA
- Cherokee Nation
- Lac Courte Oreilles
- Louisiana
- Minnesota
- Nooksack (waiver)
- Ponca (waiver)
- Virginia
- Washington

The goal is to increase the consistency of child support payments through improved employment and earnings. NextGen is a 5-year project; the first year and a half will be dedicated to planning and piloting demonstration programs, followed by three and a half years of full implementation. NextGen sites will receive technical assistance as they plan, pilot, and implement their programs. The technical assistance team will also conduct an evaluation that will include implementation and outcome studies. The NextGen demonstration will yield important information about the best practices and challenges regarding child support-led employment and other support services and partnerships in a variety of settings. Evaluating this information will produce insights on the development and implementation of these partnerships, and the employment and child support-related outcomes they can generate for parents and families. The evaluation will help local, state, and tribal child support agencies design and implement child support-led employment programs in ways that work for their local communities.

NextGen sites will receive technical assistance throughout the 5-year demonstration. The goal of the technical assistance is to help sites deliver strong programs to noncustodial parents, including helping them adapt to services as needed. The information collection activity for technical assistance will include providing sites with a Management Information System (MIS) to use for NextGen enrollment and case management. NextGen staff will enter information about received services into the MIS system. These data will help staff as they deliver the intervention. An overview of the NextGen evaluation's implementation and outcomes studies follow.

1. Implementation study. The goal of the implementation study is to document variation in program implementation, such as program structures, enrollment strategies, employment and child support services offered, program partnerships and

linkages, and local policy or economic factors. The design and implementation elements will contextualize the outcomes study's findings and serve as important sources of insight regarding the startup, operation, and sustainability strategies for child support-led employment services. Key information collection activities for the implementation study will include:

- MIS data for participants who consent to be in the study to understand participant characteristics and how they responded to NextGen services
- Semi-structured interviews with child support staff and staff from partner organizations
- Semi-structured interviews with program participants to learn about their experiences in the NextGen program

2. *Outcomes study.* The goal of the outcomes study is to measure and assess relevant outcomes, including changes in employment and earnings, and child support payment amounts and consistency. Child support administrative data will be used to obtain outcomes information about NextGen participants' child support orders, payments, child support debt, and enforcement history during the 12 months before and after enrollment. Data from the National Directory of New Hires will be collected to report outcomes on employment and earnings for all participants. Other activities include collecting and analyzing baseline data about NextGen participants from the MIS who consent to be in the evaluation.

This 30-Day Notice covers the following data collection activities:

- MIS to track program enrollment, baseline information, and program participation
- Staff and community partner interview topic guide
- Participant interview topic guide

Respondents: Respondents for this information collection include grantee and tribal waiver staff and partners, and study participants. Specific respondents per instrument are outlined in the burden table below.

Annual Burden Estimates

Data collection is expected to take place over a 3-year period and annual burden has been calculated to reflect this timeline. ACF will submit an extension request to OMB when necessary, prior to the initial expiration date.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
MIS to track program participation	5,400	1	1.5	8,100	2,700
Staff and community partner interview topic guide	100	1	1.00	100	33
Participant interview topic guide	100	1	1.00	100	33
Estimated Total Annual Burden Hours					2,766

Authority: 42 U.S.C. 651 *et seq.* and 42 U.S.C. 1315.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–14279 Filed 7–15–26; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[Office of Management and Budget #: 0970–0426]

Submission for Office of Management and Budget Review; Child and Family Services Plan, Annual Progress and Services Report, and Annual Budget Expenses Request and Estimated Expenditures (Child and Family Services–101)

AGENCY: Children's Bureau, Administration for Children and Families, Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Children's Bureau (CB), Administration for Children and Families (ACF) is requesting a 3-year extension of the collection of information under the Child and Family Services Plan (CFSP), the Annual Progress and Services Report (APSR), and the Annual Budget Expenses Request and Estimated Expenditures (Child and Family Services (CFS)–101) collection (Office of Management and Budget #: 0970–0426, expiration July 31, 2026). There are minor changes to the CFS–101 form and changes to the way the information is collected in narrative form to reduce burden and decrease duplicative reporting. The annual collection of Monthly Caseworker Visit Data has been discontinued in the CFSP/APSR and data from Care Analysis and Reporting System will be used instead.

DATES: Comments due August 17, 2026.

ADDRESSES: The public may view and comment on this information collection request at: *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202607-0970-007.* You can also obtain copies of the proposed collection of information by emailing *infocollection@acf.hhs.gov.* Identify all emailed requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: Currently, under title IV–B, subparts 1 and 2 of the Social Security Act (the Act), states, territories, and tribes are required to submit a CFSP (45 CFR 1357.15(a)(1)). The CFSP outlines activities the state, tribe, or territory will carry out in administering programs and services to promote the safety, permanency, and well-being of children and families, including, as applicable, those activities conducted under the John H. Chafee Foster Care Program for Successful Transition to Adulthood (section 477 of the Act) and the state grant authorized by the Child Abuse Prevention and Treatment Act. By June 30 of each year, states, territories, and tribes are also required to submit an APSR and a financial report called the CFS–101. The APSR is a yearly report that discusses progress made by a state, territory, or tribe in accomplishing the goals and objectives cited in its CFSP (45 CFR 1357.16(a)). The APSR contains updated information about service needs and organizational capacities throughout the 5-year plan period and includes information on the use of other grant programs where annual reporting is required. The CFS–101 has 3 parts. Part I is an annual budget request for the upcoming fiscal year (FY). Part II includes a summary of planned expenditures by program area for the upcoming FY, the estimated number of individuals or families to be served, and the geographical service area. Part III includes actual expenditures by program area, numbers of families and individuals served by

program area, and the geographic areas served for the last complete FY.

The Supporting America's Children and Families Act, Public Law 118–258, was signed into law on January 4, 2025. This law reauthorizes and amends title IV–B programs. The new title IV–B reporting requirements will be added to the CFSP/APSR instructions. New requirements under title IV–B, subpart 3 requires that CB reduce administrative burden on the title IV–B program to eliminate duplication and streamline reporting requirements to reduce the number of hours required for compliance by at least 15 percent in coordination with activities required under the Paperwork Reduction Act. CB has already begun these activities to gather input to streamline reporting and reduce burden.

Respondents: Currently, states, territories, and tribes must complete the CFSP, APSR, and CFS–101. There are approximately 180 tribal entities that currently receive IV–B funding. There are 53 states (including the Commonwealth of Puerto Rico, the District of Columbia, and the Virgin Islands) that must complete the CFSP, APSR, and CFS–101.

Annual Burden Estimates: Burden estimates have been adjusted to reflect the updates to the APSR and the CFSP and the elimination of the caseworker visit data. The average burden per response for the APSR has been reduced from 82 hours to 50 hours and for the CFSP it has been reduced from 123 hours to 90 hours. Overall, this is a 48 percent reduction in burden associated with this information collection.

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
APSR	233	3	50	34,950	11,650
CFSP	47	1	90	4,230	1,410
CFS–101, Part I, Part II, and III	233	3	5	3,495	1,165
Estimated Total Annual Burden Hours					14,225

Authority: Title IV–B, subparts 1, 2, and 3 of the Social Security Act (the Act), and title IV–E, section 477 of the Act; sections 106 and 108 of CAPTA (42 U.S.C. 5106a. and 5106d.); and Supporting America's Children and Families Act, Pub. L. 118–258, signed into law on January 4, 2025.

Mary C. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2026–14304 Filed 7–15–26; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–7606]

Process for FDA Data Requests To Inform Certain Over-the-Counter Monograph Drug Activities; Procedure

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the process for FDA to issue Data Requests for the submission of data from the public to help inform certain future over-the counter (OTC) monograph drug activities, including development of FDA-initiated proposed orders to modify conditions described in an OTC monograph. FDA is issuing this notice to inform the public and interested parties of the process that FDA is implementing to issue these Data Requests.

DATES: The announcement of the process is published in the **Federal Register** on July 16, 2026.

FOR FURTHER INFORMATION CONTACT: Michael Boblitz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–002, 301–837–7651.

SUPPLEMENTARY INFORMATION:

I. Background

Section 505G of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355h) sets forth the framework for the regulation of OTC monograph drugs.[1] OTC monograph drugs may be marketed without a new drug application approved under section 505 of the FD&C Act (21 U.S.C. 355) if they meet the requirements of section 505G of the FD&C Act, as well as other applicable requirements. An OTC monograph set forth in a final order under section 505G for a therapeutic category of drugs describes the conditions, such as active ingredients, uses (indications), doses, routes of administration, labeling, and testing, under which OTC monograph drugs within such therapeutic category are generally recognized as safe and effective (GRASE) for their intended use. The conditions described in an OTC monograph may be amended, revoked, or otherwise modified in accordance with a final order issued under section 505G(b) of the FD&C Act.[2] Either FDA or a requestor[3] can initiate the order process in section 505G(b). A requestor can initiate the order process by submitting an OTC monograph order request[4] with respect to certain drugs, classes of drugs, or combinations of drugs.[5] FDA may opt to announce Data Requests described in this notice to help inform certain future OTC monograph drug activities, including development of FDA-initiated proposed orders.

II. Procedures for Data Requests

When FDA seeks data and information from the public to help inform certain OTC monograph drug activities, such as development of a potential FDA-initiated proposed order to add a GRASE condition to an OTC monograph, FDA intends to announce a Data Request on the OTC Monographs@FDA portal at *https://www.accessdata.fda.gov/scripts/cder/omuf/.* The Data Request will include instructions on the submission of the data and information to FDA, including

[1] Per section 744L(5) of the FD&C Act, an ''OTC monograph drug'' is defined as a nonprescription drug without an approved new drug application which is governed by the provisions of section 505G.

[2] Under section 505G(b)(1) of the FD&C Act, ''The Secretary may, on the initiative of the Secretary or at the request of one or more requestors, issue an administrative order determining whether there are conditions under which a specific drug, a class of drugs, or a combination of drugs, is determined to be . . . (i) not subject to section 503(b)(1) [*i.e.,* nonprescription]; and (ii) generally recognized as safe and effective under section 201(p)(1)''.

[3] Under section 505G(q)(3) of the FD&C Act (21 U.S.C. 355h(q)), the term *requestor* refers to any person or group of persons marketing, manufacturing, processing, or developing an OTC monograph drug.

[4] An OTC monograph order request means a request for an order submitted under section 505G(b)(5) of the FD&C Act (see section 744L(7) of the FD&C Act).

[5] See section 505G(b)(5) of the FD&C Act.

with respect to confidential information. The Data Request will also include instruction on how submissions may be viewed by the public. Additionally, interested parties and the public generally may sign up for FDA email mailing lists on the OTC Monographs@FDA portal to receive messages and alerts when FDA announces a Data Request described in this notice or other OTC monograph drug activities. FDA also intends to list future planned Data Requests of the type described in this notice in its Annual Forecast for Planned Monograph Activities, which is a nonbinding list issued each year of planned OTC monograph drug activities that FDA intends to initiate over the ensuing 3 years. It is available on the OTC Monographs@FDA portal.

This notice is not intended to announce the process with respect to requests for data to inform finalization of GRASE determinations for drugs described in section 505G(a)(3) of the FD&C Act (GRASE finalizations). The process FDA will use to request data packages to support GRASE finalizations will be announced in a future notice before any related crowdsourcing on that process, as described in the Over-the-Counter Monograph User Fee Program Performance Goals and Procedures—Fiscal Years 2026–2030 document (OMUFA II commitment letter).[6] In addition, this notice is unrelated to the following:

- any future **Federal Register** notice to solicit stakeholder feedback on test methods described in OTC monographs and the Test Methods Crowdsourcing described in section I.H of the OMUFA II commitment letter;
- the submission of relevant data and other information by a requestor (including a group of joint requestors) in an OTC monograph order request (OMOR)[7] submitted under section 505G(b)(5) of the FD&C Act;
- the requirement under section 505G(b)(2) of the FD&C Act to provide for a public comment period on a proposed order; and
- the requirement under section 505G(b)(4) of the FD&C Act, addressing certain expedited safety orders, to provide for a public comment period on an interim final order.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–14283 Filed 7–15–26; 8:45 am]

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[6] The OMUFA II commitment letter can be accessed at *https://www.fda.gov/media/182750/download.*

[7] OTC monograph order request (OMOR) is defined in section 744L(7) of the FD&C Act for purposes of user fees supporting FDA activities under section 505G of the FD&C Act and refers to a request for FDA to issue an administrative order pursuant to a request submitted under section 505G(b)(5) of the FD&C Act.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Chimeric Antigen Receptors Targeting the Gamma Delta (γδ) T-Cell Receptor

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees for a set of Chimeric Antigen Receptors (CARs) that target the γδ T-Cell Receptor.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Andrew Burke, Ph.D. Senior Technology Transfer Manager at Email: *burkear@mail.nih.gov* or Phone: 240–276–5484.

SUPPLEMENTARY INFORMATION: T cells express two main types of receptors based on the proteins that make up the T-cell receptor (TCR) heterodimers: αβ (alpha beta) and γδ (gamma delta). T cells expressing the γδ TCR are detected at lower frequencies compared with T cells expressing the αβ TCR. γδ T cells make up 0.3–10% of peripheral blood T cells. The γδ TCR is expressed on the cell surface of several aggressive cancers, including—but not limited to—hepatosplenic T-cell lymphoma, primary cutaneous γδ T-cell lymphoma and T-cell acute lymphoblastic leukemia (T–ALL). These cancers carry poor prognosis as they are often resistant to chemotherapy. In addition, to their roles in cancer development, γδ T cells may also play role in autoimmune diseases, including psoriasis, rheumatoid arthritis, multiple sclerosis and myositis. There is evidence that γδ T cells are involved in initiation or persistence of these autoimmune diseases. To this end, new treatment options are needed for γδ T-cell malignancies and autoimmune diseases.

Researchers at the National Cancer Institute (NCI) have developed several CARs targeting the γδ TCR. These CARs can specifically bind to and immunologically recognize human γδ TCR. Binding of the CAR to the γδ TCR elicits an immune response that allows for killing of cells expressing this TCR.

''This Notice is in accordance with 37 CFR 404.4 Authority to grant licenses.''

NIH Reference Number: E–214–2024.

Related Technologies: N/A.

Product Type: Oncology | Immunology.

Therapeutic Area(s): Therapeutic.

Development Stage: Pre-clinical (*in vivo* validation).

Publications:

- Kochenderfer JN, et al. Development of Novel Chimeric Antigen Receptors Targeting the Gamma-Delta (γδ) T-Cell Receptor. (*https://doi.org/10.1182/blood-2024-204126*).

Patents: PCT/US2025/040252, filed August 1, 2025.

Potential Commercial Applications

- Enables the GMP production of personalized T cell therapy products targeting tumor specific mutations with a high percentage of engineered cells.

Competitive Advantages

- Increased therapeutic benefit due to enhanced persistence and performance following adoptive T cell transfer.
- Increased therapeutic benefit due to improved surface expression of the therapeutic TCR αβ.
  - TCR alpha/beta chains substantially eliminate the risk of mis-pairing with the endogenous alpha/beta chain sequences expressed by the host cell.
- Improved manufacturing since the population is highly enriched for the desired engineered cells.
  - Greatly increases the frequency of tumor-specific T cells following expansion, exceeding what is achieved using alternative methods to generate mutation- or tumor-specific T cells.

Collaboration Opportunity: Researchers at the NCI seek licensing for TCR-engineered T cells that will facilitate the ACT process.

Dated: July 13, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–14344 Filed 7–15–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Selective Expansion of Engineered TCR–T Cells for Use in Adoptive Cell Immunotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks capable licensees interested in commercializing T cell receptor (TCR)-engineered T cells expressing murine/human hybrid receptors.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Andrew Burke, Ph.D. at Email: *burkear@mail.nih.gov* or Phone: 240–276–5484.

SUPPLEMENTARY INFORMATION: TCR–T therapies, particularly those targeting patient-specific neoantigens, remain a promising approach to the treatment metastatic cancers. Contemporary gene engineering techniques permit both the targeted integration of the exogenous receptor(s) and further genetic manipulation of the host cells to enhance persistence and performance following adoptive transfer (*e.g.,* through disruption of immune checkpoints such as (*CISH* or *PD1*). However, these techniques often suffer from low transduction efficiencies and may result in the generation of infusion products with sub-optimal percentages of targeted cells.

NCI scientists designed a new method that enables the selective expansion of T lymphocytes, under GMP conditions, that have been engineered to stably express a murine-human hybrid TCR. These hybrid TCRs consist of human variable regions and murine constant regions. The inventive approach uses irradiated feeder cells and an anti-mouse TCR beta constant region antibody (*e.g.,* H57) to provide stimulation, enabling the specific activation and expansion of T cells transduced with the hybrid TCRs. Critically, replacement of the OKT3 activating antibody from the standard rapid expansion protocol with one specific for the TCR murine constant region prevents the outgrowth of non-transduced cells. Consequently, the new method produces a cell population highly enriched for the desired engineered cells.

NCI seeks to market this method, which is analogous to an antigen-specific stimulation of the T cell, to companies interested in developing personalized ACT companies interested in developing personalized ACT.

''This Notice is in accordance with 37 CFR 404.4 Authority to grant licenses.''

NIH Reference Number: E–143–2024–0.

Related Technologies: E–101–2024–0.

Product Type: Oncology | Immunology.

Therapeutic Area(s): Therapeutic.

Development Stage: Clinical Phase II.

Publications:

- Parkhurst M, et al. Adoptive transfer of personalized neoantigen-reactive TCR-transduced T cells in metastatic colorectal cancer: phase 2 trial interim results. (PMID 38992129).
- Kim SP, et al. Adoptive cellular therapy with autologous tumor-infiltrating lymphocytes and T-cell receptor-engineered T cells targeting common p53 neoantigens in human solid tumors. (PMID 35749374).
- Lowery FL, et al. Molecular signatures of antitumor neoantigen-reactive T cells from metastatic human cancers. (PMID 35113651).

Patents: Filed internationally.

Potential Commercial Applications:

- Enables the GMP production of personalized T cell therapy products targeting tumor specific mutations with a high percentage of engineered cells.

Competitive Advantages:

- Increased therapeutic benefit due to enhanced persistence and performance following adoptive T cell transfer.
- Increased therapeutic benefit due to improved surface expression of the therapeutic TCR αβ.
  - TCR alpha/beta chains substantially eliminate the risk of mis-pairing with the endogenous alpha/beta chain sequences expressed by the host cell.
- Improved manufacturing since the population is highly enriched for the desired engineered cells.
  - Greatly increases the frequency of tumor-specific T cells following expansion, exceeding what is achieved using alternative methods to generate mutation- or tumor-specific T cells.

Collaboration Opportunity: Researchers at the NCI seek licensing for TCR-engineered T cells that will facilitate the ACT process.

Dated: July 13, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–14346 Filed 7–15–26; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government Owned Invention Available for License: Method of Manufacturing Papilloma Infiltrating Lymphocyte (PIL) Cell Therapy Products as a Treatment for Patients With Chronic Viral Infection(s)

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute (NCI) seeks research co-development partners and/or licensees for development of papilloma-infiltrating lymphocytes (PIL) as treatment for patients with chronic human papillomavirus (HPV) 6 or 11 infections.

FOR FURTHER INFORMATION CONTACT: Inquiries related to this license opportunity should be directed to: Suna Gulay French, Ph.D., Technology Transfer Manager, NCI, Technology Transfer Center, Email: *suna.gulay@nih.gov* or Phone: 240–276–7424.

SUPPLEMENTARY INFORMATION: Recurrent respiratory papillomatosis (RRP) and anogenital condyloma are caused by chronic infection with human papillomavirus (HPV) types 6 or 11. These conditions lead to the development of papillomatous growths in different regions of the body. RRP affects the upper aerodigestive tract, condylomas the anogenital area. In RRP, growths in the aerodigestive tract can cause dysphonia, dyspnea and—in severe cases—airway obstruction. This may lead to recurrent pneumonia or respiratory failure.

Current treatment for RRP primarily involves repeated surgical debulking or laser ablation to manage symptoms. However, the virus often persists in a latent state, resulting in continual papilloma regrowth. The need for frequent procedures exposes patients to cumulative anesthetic and surgical risks, emotional distress, significantly diminished quality of life and persistent healthcare costs. There are no approved systemic therapies for chronic HPV 6 or 11-related conditions despite progress in localized treatments such as surgery and laser ablation. This highlights a clear unmet need for effective, curative therapies.

Researchers at the NCI have developed a novel adoptive cell therapy approach to target conditions driven by HPV types 6 or 11. They successfully identified and preferentially expanded HPV 6 and/or 11-specific T cells from papilloma tissue obtained from RRP

patients. These PILs demonstrated the ability to eliminate papillomatous tissue. Relatedly, a T cell manufacturing method holds promise for developing cell-based therapies for widespread use in chronic HPV 6/11-related conditions—including RRP and anogenital condyloma. Notably, the ability to isolate and expand antigen-specific lymphocytes from non-cancerous growths represents an exciting advancement in the field of adoptive cell therapy—potentially paving the way for treating a broader range of non-malignant diseases.

The Center for Immuno-Oncology and the Surgical Oncology Program of the NCI, Center for Cancer Research are actively seeking industry partners to support the clinical development and commercialization of this approach. It is particularly well-suited for biotech firms focused on T cell therapies or addressing HPV-related diseases. Strategic collaboration could accelerate market entry and unlock significant value in an area with high unmet medical need.

''This Notice is in accordance with 37 CFR 404.4 Authority to grant licenses.''

NIH Reference Number: E–143–2024–0.

Related Technologies: N/A.

Product Type: Infectious Disease | Immunology.

Therapeutic Area(s): Therapeutic.

Development Stage: Pre-clinical (*in vivo* validation).

Publications:

- Bai K, Norberg SM, Sievers C, Meyer T, et al. Durable response in a patient with recurrent respiratory papillomatosis treated with immune checkpoint blockade. (*https://doi.org/10.1002/hed.27144*).

Patents: PCT/US2025/051640, filed October 20,2025.

Potential Commercial Applications

- Immunotherapy for chronic HPV-related conditions such as RRP and anogenital condyloma.
- Development of personalized T cell therapies targeting HPV 6 or HPV 11 infections.
- Generation of T cell receptor (TCR) libraries for research and therapeutic purposes.

Competitive Advantages

- Addresses lack of approved systemic therapies for chronic HPV 6 or 11-related conditions.
- Potential to treat both non-cancerous and cancerous HPV-related conditions.
- PILs represent novel therapeutic approach.
- Drug development for RRP may qualify for regulatory incentives due to the rarity of the disease.
- Increased therapeutic efficacy from the ability to produce oligoclonal T cell populations.
- Selective expansion of T cells with high specificity for HPV 6 or HPV 11 antigens.
- Methodology applicable to both therapeutic and preventative treatments for chronic HPV infections.

Collaboration Opportunity: Researchers at the NCI seek licensing and/or co-development research collaborations for PIL in treatment for chronic HPV6/11-associated diseases.

Dated: July 13, 2026.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2026–14347 Filed 7–15–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Analytics and Statistics for Population Research Panel B Study Section.

Date: August 13–14, 2026.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Ivan Tadeu Rebustini, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 594–2467, *ivan.rebustini@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Contract Research Organization for the NIAAA Medications Development Clinical Trials Network.

Date: August 18, 2026.

Time: 10:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate contract proposals.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Alicia Mariel Jais, PHMD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, (301) 435–3343, *mariel.jais@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Contracts: Clinical Research Products Management Center (CRPMC).

Date: August 25, 2026.

Time: 10:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate contract proposals.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Vishakha Sharma, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Dr., Bethesda, MD 20892, 301–594–2297, *vishakha.sharma@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–25–444: Cancer Center Support Grants.

Date: August 26–27, 2026.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Address: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Meeting Format: Virtual Meeting.

Contact Person: Eun Ah Cho, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–359, *EunAh.Cho@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 13, 2026.

Sterlyn H. Gibson,

Program Specialist, Office of Federal Advisory Committee Policy.

[FR Doc. 2026–14343 Filed 7–15–26; 8:45 am]

BILLING CODE 4167–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Project: Application for the Reviewer Contact Information Form (OMB No. 0930–0255)—Reinstatement

Section 501(h) of the Public Health Service (PHS) Act (42 U.S.C. 290aa), 2 CFR 200.205, and DHHS Grants Policy directs the Assistant Secretary of the Substance Abuse and Mental Health Services Administration (SAMHSA) to establish a merit review committee to carry out the merit review requirements for applications received for discretionary grant programs. SAMHSA administers large discretionary grant programs under authorization of Title V, and, for many years, SAMHSA has funded discretionary grants to provide substance use and mental health services, research, technical assistance, and training to advance behavioral health and to improve the lives of individuals living with mental and substance use disorders, and their families.

In support of its merit review efforts, SAMHSA desires to continue to expand the quantity and experience of peer reviewers it recruits for their merit reviews of discretionary grant applications. To accomplish that end, SAMHSA has determined that it is important to proactively seek the inclusion of new and qualified individuals. Accordingly, SAMHSA has developed an application form for use by individuals who wish to apply to serve as SAMHSA peer reviewers.

The application form has been developed to capture the essential information about the individual applicants. The most consistent method to accomplish this is through completion of a standard form by all interested people which captures their knowledge, education, and expertise, in a consistent manner. SAMHSA will use the information provided on the form to identify appropriate peer reviewers. Depending on their knowledge, education, and expertise, applicants may be invited to serve on merit review committees.

The following changes are proposed in the form:

1. Changed ''Gender'' to ''Sex''.
2. Removed ''Transgender'' and ''Prefer not to Answer'' from Sex category.
3. Removed Ethnicity category and combined it with Race/Ethnicity.
4. Added ''Middle Eastern or North African'' under Race/Ethnicity.
5. Removed ''Mixed Race'' from Race/Ethnicity category.
6. Removed ''LGBTQ'' and ''Minorities (African American, Hispanic or Latino, etc.)'' from Secondary Expertise.
7. Removed the SAMSHA Values That Promote Positive Behavioral Health Statement on page 4.

The following table shows the annual response burden estimate.

Number of respondents	Responses/ respondent	Burden/responses (hours)	Total burden hours
300	1	1.5	450

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

Alicia Broadus,

Public Health Advisor.

[FR Doc. 2026–14320 Filed 7–15–26; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc. (Thorofare, NJ) as a Commercial Gauger and Laboratory

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

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc. (Thorofare, NJ), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Camin Cargo Control, Inc. (Thorofare, NJ), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of September 30, 2025.

DATES: Camin Cargo Control, Inc. (Thorofare, NJ) was approved and accredited as a commercial gauger and laboratory as of September 30, 2025. The next triennial inspection date will be scheduled for September 2028.

FOR FURTHER INFORMATION CONTACT: Robert P. Munivez, Laboratories and Scientific Services, U.S. Customs and Border Protection, 4150 Interwood South Parkway, Houston, TX 77032, tel. 281–560–2900.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Camin Cargo Control, Inc., 1301 Metropolitan Ave, Thorofare, NJ 08066, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

Camin Cargo Control, Inc. (Thorofare, NJ) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapter	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
11	Physical Properties Data.
12	Calculation of Petroleum Quantities.
17	Marine Measurement.

Camin Cargo Control, Inc. (Thorofare, NJ), is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–05	D4928	Standard Test Method for Water in Crude Oils by Coulometric Karl Fischer Titration.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–46	D5002	Standard Test Method for Density, Relative Density, and API Gravity of Crude Oils by Digital Density Analyzer.
27–48	D4052	Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products and Liquid Fuels (Mini Method).
N/A	D130	Standard Test Method for Corrosiveness to Copper from Petroleum Products by Copper Strip Test.
N/A	D2699	Standard Test Method for Research Octane Number of Spark-Ignition Engine Fuel.
N/A	D2700	Standard Test Method for Motor Octane Number of Spark-Ignition Engine Fuel.
N/A	D3606	Standard Test Method for Determination of Benzene and Toluene in Spark Ignition Fuels by Gas Chromatography.
N/A	D5453	Standard Test Method for Determination of Total Sulfur in Light Hydrocarbons, Spark Ignition Engine Fuel, Diesel Engine Fuel, and Engine Oil by Ultraviolet Fluorescence.
N/A	D5769	Standard Test Method for Determination of Benzene, Toluene, and Total Aromatics in Finished Gasolines by Gas Chromatography/Mass Spectrometry.

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (281) 560–2900. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov.* Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Aine M. Ramirez,

Laboratory Director, Houston Laboratory, Laboratories and Scientific Services.

[FR Doc. 2026–14309 Filed 7–15–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc. (East Providence, RI) as a Commercial Gauger and Laboratory

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

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc. (East Providence, RI), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Camin Cargo Control, Inc. (East Providence, RI), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 19, 2025.

DATES: Camin Cargo Control, Inc. (East Providence, RI) was approved and accredited as a commercial gauger and laboratory as of August 19, 2025. The next triennial inspection date will be scheduled for August 2028.

FOR FURTHER INFORMATION CONTACT: Robert P. Munivez, Laboratories and Scientific Services, U.S. Customs and Border Protection, 4150 Interwood South Parkway, Houston, TX 77032, tel. 281–560–2900.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Camin Cargo Control, Inc., 66 Commercial Way, East Providence, RI 02914, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

Camin Cargo Control, Inc. (East Providence, RI) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapter	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
12	Calculation of Petroleum Quantities.
17	Marine Measurement.

Camin Cargo Control, Inc. (East Providence, RI), is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–48	D4052	Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter.

CBPL No.	ASTM	Title
27–53	D2709	Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge.
27–54	D1796	Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method (Laboratory Procedure).
27–57	D7039	Standard Test Method for Sulfur in Gasoline and Diesel Fuel by Monochromatic Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products and Liquid Fuels (Mini Method).
N/A	D97	Standard Test Method for Pour Point of Petroleum Products.
N/A	D130	Standard Test Method for Corrosiveness to Copper from Petroleum Products by Copper Strip Test.
N/A	D2500	Standard Test Method for Cloud Point of Petroleum Products and Liquid Fuels.
N/A	D3606	Standard Test Method for Determination of Benzene and Toluene in Spark Ignition Fuels by Gas Chromatography.
N/A	D5599	Standard Test Method for Determination of Oxygenates in Gasoline by Gas Chromatography and Oxygen Selective Flame Ionization Detection.
N/A	D5769	Standard Test Method for Determination of Benzene, Toluene, and Total Aromatics in Finished Gasolines by Gas Chromatography/Mass Spectrometry.
N/A	D5773	Standard Test Method for Cloud Point of Petroleum Products and Liquid Fuels (Constant Cooling Rate Method).
N/A	D5949	Standard Test Method for Pour Point of Petroleum Products (Automatic Pressure Pulsing Method).
N/A	D5972	Standard Test Method for Freezing Point of Aviation Fuels (Automatic Phase Transition Method).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (281) 560–2900. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*.

Aine M. Ramirez,

Laboratory Director, Houston Laboratory, Laboratories and Scientific Services.

[FR Doc. 2026–14308 Filed 7–15–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc. (Garden City, GA) as a Commercial Gauger and Laboratory

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

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc. (Garden City, GA), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Camin Cargo Control, Inc. (Garden City, GA), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of December 17, 2025.

DATES: Camin Cargo Control, Inc. (Garden City, GA) was approved and accredited as a commercial gauger and laboratory as of December 17, 2025. The next triennial inspection date will be scheduled for December 2028.

FOR FURTHER INFORMATION CONTACT: Robert P. Munivez, Laboratories and Scientific Services, U.S. Customs and Border Protection, 4150 Interwood South Parkway, Houston, TX 77032, tel. 281–560–2900.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Camin Cargo Control, Inc., 24 Telfair Place, Garden City, GA 31415, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

Camin Cargo Control, Inc. (Garden City, GA) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapter	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
12	Calculation of Petroleum Quantities.
17	Marine Measurement.

Camin Cargo Control, Inc. (Garden City, GA), is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–46	D5002	Standard Test Method for Density, Relative Density, and API Gravity of Crude Oils by Digital Density Analyzer.

CBPL No.	ASTM	Title
27–48	D4052	Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter.
27–50	D93	Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester.
27–53	D2709	Standard Test Method for Water and Sediment in Middle Distillate Fuels by Centrifuge.
27–54	D1796	Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method (Laboratory Procedure).
27–57	D7039	Standard Test Method for Sulfur in Gasoline and Diesel Fuel by Monochromatic Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–58	D5191	Standard Test Method for Vapor Pressure of Petroleum Products and Liquid Fuels (Mini Method).
N/A	D4007	Standard Test Method for Water and Sediment in Crude Oil by the Centrifuge Method (Laboratory Procedure).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (281) 560–2900. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories*.

Aine M. Ramirez,

Laboratory Director, Houston Laboratory, Laboratories and Scientific Services.

[FR Doc. 2026–14306 Filed 7–15–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Accreditation and Approval of Camin Cargo Control, Inc. (Corpus Christi, TX) as a Commercial Gauger and Laboratory

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

ACTION: Notice of accreditation and approval of Camin Cargo Control, Inc. (Corpus Christi, TX), as a commercial gauger and laboratory.

SUMMARY: Notice is hereby given, pursuant to CBP regulations, that Camin Cargo Control, Inc. (Corpus Christi, TX), has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes for the next three years as of August 26, 2025.

DATES: Camin Cargo Control, Inc. (Corpus Christi, TX) was approved and accredited as a commercial gauger and laboratory as of August 26, 2025. The next triennial inspection date will be scheduled for August 2028.

FOR FURTHER INFORMATION CONTACT: Robert P. Munivez, Laboratories and Scientific Services, U.S. Customs and Border Protection, 4150 Interwood South Parkway, Houston, TX 77032, tel. 281–560–2900.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to 19 CFR 151.12 and 19 CFR 151.13, that Camin Cargo Control, Inc., 7201 Sedwick Rd., Corpus Christi, TX 78409, has been approved to gauge petroleum and certain petroleum products and accredited to test petroleum and certain petroleum products for customs purposes, in accordance with the provisions of 19 CFR 151.12 and 19 CFR 151.13.

Camin Cargo Control, Inc. (Corpus Christi, TX) is approved for the following gauging procedures for petroleum and certain petroleum products from the American Petroleum Institute (API):

API chapter	Title
3	Tank Gauging.
7	Temperature Determination.
8	Sampling.
12	Calculation of Petroleum Quantities.
17	Marine Measurement.

Camin Cargo Control, Inc. (Corpus Christi, TX), is accredited for the following laboratory analysis procedures and methods for petroleum and certain petroleum products set forth by the U.S. Customs and Border Protection Laboratory Methods (CBPL) and American Society for Testing and Materials (ASTM):

CBPL No.	ASTM	Title
27–01	D287	Standard Test Method for API Gravity of Crude Petroleum and Petroleum Products (Hydrometer Method).
27–02	D1298	Standard Test Method for Density, Relative Density, or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.
27–03	D4006	Standard Test Method for Water in Crude Oil by Distillation.
27–04	D95	Standard Test Method for Water in Petroleum Products and Bituminous Materials by Distillation.
27–06	D473	Standard Test Method for Sediment in Crude Oils and Fuel Oils by the Extraction Method.
27–08	D86	Standard Test Method for Distillation of Petroleum Products at Atmospheric Pressure.
27–11	D445	Standard Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity).
27–13	D4294	Standard Test Method for Sulfur in Petroleum and Petroleum Products by Energy-Dispersive X-ray Fluorescence Spectrometry.
27–14	D2622	Standard Test Method for Sulfur in Petroleum Products by Wavelength Dispersive X-Ray Fluorescence Spectrometry.
27–46	D5002	Standard Test Method for Density, Relative Density, and API Gravity of Crude Oils by Digital Density Analyzer.
27–48	D4052	Standard Test Method for Density, Relative Density, and API Gravity of Liquids by Digital Density Meter.
27–54	D1796	Standard Test Method for Water and Sediment in Fuel Oils by the Centrifuge Method (Laboratory Procedure).

Anyone wishing to employ this entity to conduct laboratory analyses and gauger services should request and receive written assurances from the entity that it is accredited or approved by the U.S. Customs and Border Protection to conduct the specific test or gauger service requested. Alternatively, inquiries regarding the specific test or gauger service this entity is accredited or approved to perform may be directed to the U.S. Customs and Border Protection by calling (281) 560–2900. The inquiry may also be sent to *CBPGaugersLabs@cbp.dhs.gov*. Please reference the website listed below for a complete listing of CBP approved gaugers and accredited laboratories. *http://www.cbp.gov/about/labs-scientific/commercial-gaugers-and-laboratories.*

Aine M. Ramirez,

Laboratory Director, Houston Laboratory, Laboratories and Scientific Services.

[FR Doc. 2026–14307 Filed 7–15–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

Notice of Issuance of Final Determination Concerning Philips North America LLC Ultrasound System 5100 POC Series

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

ACTION: Notice of final determination.

SUMMARY: This document provides notice that U.S. Customs and Border Protection (CBP) has issued a final determination concerning the country of origin of the Philips North America LLC Ultrasound System 5100 POC Series. Based upon the facts presented, CBP has concluded that the last substantial transformation of the Philips North America LLC Ultrasound System 5100 POC Series occurs in the United States.

DATES: The final determination was issued on July 10, 2026. A copy of the final determination is attached. Any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of this final determination no later than August 17, 2026.

FOR FURTHER INFORMATION CONTACT: Reema Bogin, Valuation and Special Programs Branch, Regulations and Rulings, Office of Trade, at (202) 325–7703.

SUPPLEMENTARY INFORMATION: Notice is hereby given that on July 10, 2026, CBP issued a final determination concerning the country of origin of the Philips North America LLC Ultrasound System 5100 POC Series for purposes of Title III of the Trade Agreements Act of 1979. This final determination, Headquarters Ruling Letter (HQ) H346632, was issued at the request of Philips North America LLC. under procedures set forth at 19 CFR part 177, subpart B, which implements Title III of the Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–18). In the final determination, CBP has concluded that the last substantial transformation of the Philips North America LLC Ultrasound System 5100 POC Series occurs in the United States.

Section 177.29, CBP Regulations (19 CFR 177.29), provides that a notice of final determination shall be published in the **Federal Register** within 60 days of the date the final determination is issued. Section 177.30, CBP Regulations (19 CFR 177.30), provides that any party-at-interest, as defined in 19 CFR 177.22(d), may seek judicial review of a final determination within 30 days of publication of such determination in the **Federal Register**.

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

90 K Street NE – 10th Floor
Washington, DC 20229-1177

U.S. Customs and Border Protection

HQ H346632

July 10, 2026

OT:RR:CTF:VS H346632 RRB
CATEGORY: Origin
Kevin J. Maynard, Wiley Rein LLP, 2050 M St NW, Washington, DC 20036
RE: U.S. Government Procurement; Title III, Trade Agreements Act of 1979 (19 U.S.C. 2511); Subpart B, Part 177, CBP Regulations; Philips North America LLC; Country of Origin of Ultrasound System 5100 POC Series; Substantial Transformation

Dear Mr. Maynard:

This is in response to your request, dated April 3, 2025, on behalf of your client, Philips North America LLC (''Philips''), for a final determination concerning the country of origin of its Ultrasound System 5100 POC Series (''Philips Ultrasound System''), pursuant to Title III of the Trade Agreements Act of 1979 (''TAA''), as amended (19 U.S.C. 2511 *et seq.*), and subpart B of Part 177, U.S. Customs and Border Protection (''CBP'') Regulations (19 CFR 177.21 *et seq.*). Philips is a party-at-interest within the meaning of 19 CFR 177.22(d)(1) and § 177.23(a) and is therefore entitled to request this final determination.

FACTS

The merchandise at issue is the Philips Ultrasound System, which is used to perform diagnostic ultrasound imaging by transmitting and processing sound waves to create a visual representation of a patient's internal organs and tissues. It consists of a number of components and major subassemblies from various countries, including the United States, all of which are assembled together and programmed with proprietary system software at Philips' facility in Bothell, Washington.

You state that each Philips Ultrasound System consists of more than 200 individual subcomponent parts (including screws and fasteners) that are from a variety of different countries. You further explain that according to the costed bill of materials submitted with your request, approximately 53% to 56% of the material cost of the Philips Ultrasound System are costs of subcomponents that are manufactured in the United States or a TAA-designated country, including critical components such as the display monitor and the control panel.[1] The

[1] This exhibit consists of an Excel spreadsheet with separate tabs for the costed bill of materials for

Continued

remaining 44% to 47% of the material cost of the Philips Ultrasound System represents subcomponents from non-TAA-designated countries. Non-material costs, such as assembly, are discussed below.

You state that the Philips Ultrasound System can be grouped together into the following major subassemblies: (1) an E-box, which generates electrical signals that are transmitted to the transducer to generate soundwaves for generating patient images, and then receives signals back from the transducer that are turned into diagnostic images using Philips' proprietary software; (2) a cart subassembly, which provides the physical structure that houses all of the hardware, power supply, and electronics that comprise the finished system, allows medical professionals to transport and position the system for use, and organizes and stores cables and other accessories; (3) a transducer, which receives signals from the E-box and generates a high-pressured wave (*i.e.,* soundwave) that is propagated toward the patient tissue medium (*e.g.,* organ, bone) to produce a diagnostic image, and also receives echoed soundwaves that are reflected from the tissue medium while transmitting that information back to the E-box for processing into an image; (4) a display monitor, which receives signals from the E-box and displays the images for user interpretation; (5) a control panel, which allows the user to turn the system on and off, as well as a touch pad and knobs for more tactile response for viewing and modifying the imaging parameters during clinical exams; and (6) proprietary system software, which controls and unifies all of the discrete functions of the finished system, including generating and processing ultrasound waves and converting into diagnostic images.

You explain that the assembly of the Philips Ultrasound System occurs in two phases. In the first phase, which takes places in Mexico, a third-party manufacturer assembles various subcomponents together to produce the E-box and cart subassemblies. In the second phase, which takes place in the United States, the E-box and cart subassemblies are assembled with the transducer and control panel (both of which are assembled in the United States) and the display monitor (sourced from a TAA country) into the finished product, which is programmed with Philips' proprietary software.

the ''Standard'' and ''Pro'' transducer configurations of the subject Philips Ultrasound System.

Assembly Process in Mexico

E-Box and Cart Subassemblies

As stated above, a third-party manufacturer in Mexico assembles and integrates the E-box and cart subassemblies. During the first step, which takes approximately 35 minutes to complete, more than 146 individual components, including the PC module, printed circuit board assemblies (''PCBAs''), and various hardware components, are assembled together to produce the E-box. During the second step, which also takes approximately 35 minutes to complete, 35 different hardware components, including screws, clamps, and brackets, are assembled together to produce the cart subassembly. During the third step, which also takes approximately 35 minutes to complete, the E-box and cart are assembled and wired together. Once this is completed, a test version of Philips' proprietary software, which was compiled into object code in the United States, is loaded onto the subassemblies. This test version of the software is only valid for a set duration to allow for testing, after which it will no longer launch to the ultrasound application. The hard drives are re-formatted during the next phase.

You state that in total, the assembly operations in Mexico involve approximately 200 components and will take approximately 450 minutes to complete, consisting of 105 minutes of assembly, 100 minutes for loading the test version software, 110 minutes for testing, and 135 minutes for material handling and packaging. You further state that the E-box and cart subassemblies, which have been assembled and wired together, are unable to function as an ultrasound system prior to the final assembly and programming operations that will be performed in the United States.

Assembly Process in the United States

Transducer Subassembly

Assembly operations in the United States are performed at two separate Philips facilities in Reedsville, Pennsylvania, and Bothell, Washington. At the Pennsylvania facility, the transducer subassembly is assembled from various components, including a sensor from a non-TAA-designated country and a cable assembly from the United States. This is followed by various testing operations on each transducer subassembly. In total, the transducer assembly and testing operations performed at the Pennsylvania facility take approximately 90 minutes to complete (approximately 20 minutes of assembly plus approximately 70 minutes of testing).[2] You provided our office with a confidential and proprietary list of assembly steps that occur in the United States.

Final Assembly

The next stage of assembly operations in the United States moves to Philips' facility in Washington. Assembly operations here include final assembly, integration, and testing of the finished Philips Ultrasound System. Here, the E-box and cart are assembled together with the transducer, the display monitor (sourced from a TAA-designated country), the control panel (sourced from a third-party manufacturer in the United States), and other minor components and accessories (*e.g.,* storage bins, gel and cable holder, probe holder, and printer subassemblies) to produce the finished ultrasound system. As part of the final assembly operations, a final, updated version of the system software, which was developed in both the United States and a non-TAA-designated country and compiled into object code in the United States, is programmed onto the E-box. In total, the assembly operations performed at the Washington facility involve 26 components and take approximately 320 minutes to complete (approximately 40 minutes of assembly, 100 minutes of programming time, 140 minutes for testing, and 40 minutes for order configuration, such as picking accessories).

In combination, the two stages of the assembly process at Philips' facilities in the United States involve approximately 32 components and take approximately 410 minutes to complete (60 minutes of assembly, 100 minutes of programming the system with software, 210 minutes for testing, and 40 minutes for order configuration). You state that only after these final assembly and programming operations have been completed in the United States is the Philips Ultrasound System able to function as an ultrasound system.

Upon request from our office, you also provided color exploded-view diagrams of each subcomponent and manufacturing process flow charts for the production of the E-box, cart subassembly, and final assembly operations. In response to additional inquiry from our office, you also

[2] You state that there are two configurations of the Philips Ultrasound System. One configuration uses a ''Standard'' transducer, while the other configuration uses a ''Pro'' transducer. You confirm that the transducer subassembly used in both of these configurations is assembled and tested in the United States as part of the final assembly process.

provided an updated costed bill of materials for the Philips Ultrasound System and for the transducer subassembly.

Issue

What is the country of origin of the Philips Ultrasound System for purposes of U.S. Government procurement?

Law and Analysis

CBP issues country of origin advisory rulings and final determinations as to whether an article is or would be a product of a designated country or instrumentality for the purpose of granting waivers of certain ''Buy American'' restrictions in U.S. law or practice for products offered for sale to the U.S. Government, pursuant to subpart B of Part 177, 19 CFR 177.21 *et seq.,* which implements Title III, Trade Agreements Act of 1979, as amended (19 U.S.C. 2511–2518).

CBP's authority to issue advisory rulings and final determinations stems from 19 U.S.C. 2515(b)(1), which states:

> For the purposes of this subchapter, the Secretary of the Treasury shall provide for the prompt issuance of advisory rulings and final determinations on whether, under section 2518(4)(B) of this title, an article is or would be a product of a foreign country or instrumentality designated pursuant to section 2511(b) of this title.

Emphasis added.

The Secretary of the Treasury's authority mentioned above, along with other customs revenue functions, are delegated to the Secretary of Homeland Security via Treasury Department Order (TO) 100–20 ''Delegation of Customs revenue functions to Homeland Security,'' dated October 30, 2024, and are subject to further delegations to CBP (*see also* 19 CFR part 177, subpart B).

The rule of origin set forth in 19 U.S.C. 2518(4)(B) states:

> An article is a product of a country or instrumentality only if (i) it is wholly the growth, product, or manufacture of that country or instrumentality, or (ii) in the case of an article which consists in whole or in part of materials from another country or instrumentality, it has been substantially transformed into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was so transformed.

See also 19 CFR 177.22(a).

In rendering advisory rulings and final determinations for purposes of U.S. Government procurement, CBP applies the provisions of subpart B of Part 177 consistent with the Federal Acquisition Regulation (''FAR''). *See* 19 CFR 177.21. In this regard, CBP recognizes that the FAR restricts the U.S. Government's purchase of products to U.S.-made or designated country end products for acquisitions subject to the TAA. *See* 48 CFR 25.403(c)(1).

The FAR, 48 CFR 25.003, defines ''U.S.-made end product'' as:

> . . . an article that is mined, produced, or manufactured in the United States or that is substantially transformed in the United States into a new and different article of commerce with a name, character, or use distinct from that of the article or articles from which it was transformed.

The FAR, 48 CFR 25.003, defines ''designated country end product'' as:

> . . . a WTO GPA [World Trade Organization Government Procurement Agreement] country end product, an FTA [Free Trade Agreement] country end product, a least developed country end product, or a Caribbean Basin country end product.

Once again, we note that the Philips Ultrasound Systems are assembled in Mexico and the United States, with components sourced from both TAA-designated countries, as well as non-TAA-designated countries. Mexico is a TAA-designated country.

In order to determine whether a substantial transformation occurs when components of various origins are assembled into completed products, CBP considers the totality of the circumstances and makes such determinations on a case-by-case basis. The country of origin of the item's components, extent of the processing that occurs within a country, and whether such processing renders a product with a new name, character, and use are primary considerations in such cases. Additionally, factors such as the resources expended on product design and development, the extent and nature of post-assembly inspection and testing procedures, and worker skill required during the actual manufacturing process will be considered when determining whether a substantial transformation has occurred. No one factor is determinative.

In *Data General* v. *United States,* 4 C.I.T. 182 (1982), the court determined that the programming of a foreign PROM (''Programmable Read-Only Memory'' chip) in the United States substantially transformed the PROM into a U.S. article. In the United States, the programming bestowed upon each integrated circuit its electronic function, that is, its ''memory,'' which could be retrieved. The court concluded that the programming altered the character of the PROM and that altering the non-functioning circuitry comprising the PROM through technological expertise in order to produce a functioning read only memory device, possessing a desired distinctive circuit pattern, was no less a ''substantial transformation'' than the manual interconnection of transistors, resistors and diodes upon a circuit board creating a similar pattern. The programming established the ''essence'' of the PROM, its pattern of interconnections, or stored memory.

In Headquarters Ruling Letter (''HQ'') H219597, dated April 3, 2013, two ultrasound systems, identified as the S2000 and Antares ultrasound systems, were engineered, designed and subject to final assembly in the United States from U.S. and foreign components. CBP noted that substantial manufacturing operations were performed in China, the United States, Korea, and Italy. The electronics module, which was partially assembled in China, was imported into the United States, where it was assembled with other core components, including Korean-origin transducers that sent and received acoustic signals, an Italian-origin monitor that displayed images, and a U.S.-origin control panel that served as the user interface. The completely assembled ultrasound systems were then uploaded with U.S. designed, developed, and written operating system software and application software. The information provided indicated that the software was necessary for the ultrasound systems to perform their intended function of providing diagnostic information (an observable image with related data). It took approximately 23–24 hours to produce the finished S2000 ultrasound system of which 13–14 hours took place in the United States. Approximately 24–25 hours of time were expended to produce the finished Antares ultrasound system of which 14–15 hours took place in the United States. In addition, the assembly, integration, and testing in the United States were conducted by specialized technicians. All of the research and development, product engineering, and design investment occurred in the United States. Based on the totality of the circumstances, CBP found that the last substantial transformation occurred in the United States, the location where the final assembly and installation of the operating system software and application software occurred. Prior to the assembly and programming in the United States, the products were unable to carry out the functions of the ultrasound systems. However, the assembly and programming in the United States created a new product that was capable of providing diagnostic information. Consequently, CBP found that the country of origin of the ultrasound systems was the United States.

HQ H203555, dated April 23, 2012, concerned the country of origin of certain oscilloscopes. CBP considered five manufacturing scenarios. In the various scenarios, the motherboard and the power controller of either Malaysian or Singaporean origin were assembled in Singapore with subassemblies of Singaporean origin into oscilloscopes. CBP found that under the various scenarios, there were three countries under consideration where programming and/or assembly operations took place, the last of which was Singapore. CBP noted that no one country's operations dominated the manufacturing operations of the oscilloscopes. As a result, while the boards assembled in Malaysia were important to the function of the oscilloscopes, and the U.S. firmware and software were used to program the oscilloscopes in Singapore, the final programming and assembly of the oscilloscopes was in Singapore; hence, Singapore imparted the last substantial transformation, and the country of origin of the oscilloscopes was Singapore.

In the instant matter, the ultrasound system is comprised of various components and subassemblies from several countries, including the United States, Mexico, and other TAA-designated and non-TAA-designated countries. For example, the E-box and cart subassemblies are assembled in Mexico. The display monitor is sourced from a TAA-designated country while the control panel is manufactured in the United States. Also in the United States, the components of the transducer subassembly are assembled together in a relatively minor operation. While the essential function of the transducer subassembly is imparted by the sensor sourced from a non-TAA-designated country, the transducer subassembly is further integrated and assembled together in the United States with various subassemblies sourced either from TAA-designated countries or manufactured in the United States, including the E-box and cart subassemblies, the display monitor, control panel, and other components and accessories to produce the ultrasound system in the United States. The completely assembled ultrasound systems are then programmed with a final, updated version of the proprietary system software in the United States. As previously noted, the processing in Mexico takes approximately 450 minutes while the processing in the United States takes approximately 410 minutes. We further note that along with a combined 860 minutes of processing that occurs in the United States or Mexico (a TAA-designated country), approximately 53% to 56% of the material cost of the subject merchandise are costs of subcomponents that are manufactured in the United States or a TAA-designated country. You state that prior to the final assembly, programming, and testing operations performed in the United States, none of the subassemblies is able to carry out the functions of an ultrasound system. Thus, the subject ultrasound system is capable of producing diagnostic images only after these subassemblies are assembled together and programmed with software in the United States.

As in HQ H219597, the loading of the proprietary software in the United States, which was partially developed in the United States where the object code was also compiled, is necessary to ''translate'' the signals from the transducer into images to be displayed on the monitor. In addition, both in HQ H219597 and in the instant manufacturing scenario, the core subassemblies are manufactured or sourced from various countries but are unable to carry out the functions of an ultrasound system until they are assembled together and programmed in the United States. Unlike in HQ H219597, a greater and more equivalent amount of manufacturing operations occurs across two countries, the United States and Mexico, compared to manufacturing operations occurring in non-TAA-designated countries. Nevertheless, the ultrasound system is not functional until final assembly and programming in the United States that occurs after manufacturing operations in Mexico are complete. Therefore, based on the totality of the circumstances, we find that the last substantial transformation occurs in the United States, the location where the final assembly and proprietary software programming occur. Prior to these operations in the United States, the products are unable to carry out the functions of ultrasound systems. Thus, the assembly and programming in the United States create a new product that is capable of providing diagnostic information. Consequently, we find that the last substantial transformation occurs in the United States, and therefore, the Philips Ultrasound System is not a product of a foreign country or instrumentality designated pursuant to 25 U.S.C. 2511(b). As to whether the Philips Ultrasound System produced in the United States qualifies as a ''U.S.-made end product,'' you may wish to consult the relevant government procuring agency and review *Acetris Health, LLC* v. *United States,* 949 F.3d 719 (Fed. Cir. 2020).

Holding

Based on the facts and analysis set forth above, the country of origin of the Philips Ultrasound System will be considered the United States for purposes of U.S. Government procurement.

Notice of this final determination will be given in the **Federal Register**, as required by 19 CFR 177.29. Any party-at-interest other than the party which requested this final determination may request, pursuant to 19 CFR 177.31, that CBP reexamine the matter anew and issue a new final determination. Pursuant to 19 CFR 177.30, any party-at-interest may, within 30 days of publication of the **Federal Register** Notice referenced above, seek judicial review of this final determination before the U.S. Court of International Trade.

Sincerely,

Alice A. Kipel,

Executive Director, Regulations and Rulings, Office of Trade.

[FR Doc. 2026–14310 Filed 7–15–26; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0012]

Agency Information Collection Activities; Revision of a Currently Approved Collection: Petition for Alien Relative

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed revision of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until September 14, 2026.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0012 in the body of the letter, the agency name and Docket ID USCIS–2007–0037. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2007–0037.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, John R Pfirrmann-Powell, Acting Deputy Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2007–0037 in the search box. Comments must be submitted in English, or an English translation must be provided. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Petition for Alien Relative.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* I–130; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary* Individuals or households. Form I–130 allows U.S. citizens, U.S. nationals (who are not U.S. citizens), or lawful permanent residents of the United States to petition on behalf of certain alien relatives (beneficiaries) who wish to immigrate to the United States. Form I–130A is for the beneficiary of Form I–130 to certify certain information contained on Form I–130.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection I–130 is 472,753 and the estimated hour burden per response is 2.3 hours; the estimated total number of respondents for the information collection I–130A is 438,179 and the estimated hour burden per response is 0.4 hours; the estimated total number of respondents for the information collection I–130 E-filing is 472,753 and the estimated hour burden per response is 1.6 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 2,019,008 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $378,202,400.

Dated: July 13, 2026.

John R. Pfirrmann-Powell,

Acting Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2026–14384 Filed 7–15–26; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–R7–NWRS–2026–1156; FXRS12630700000–267–FF07R08000; OMB Control Number 1018–0141]

Agency Information Collection Activities; Alaska Big Game Guide Use Survey

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the U.S. Fish and Wildlife Service (Service), are proposing to renew an information collection with revisions.

DATES: Comments will be accepted on or before September 14, 2026. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date. To ensure your comment is received and considered, you must submit it using one of the methods identified in the **ADDRESSES** section of this document. Comments submitted through any method not authorized in this document, or sent to an address not listed here, will not be considered.

ADDRESSES:

Comment submission: All submissions must include the docket number [FWS–R7–NWRS–2026–1156] for this document. You must submit comments using one of the following methods:

- *Electronic submission:* Federal eRulemaking Portal at: *https://www.regulations.gov.* In the Search box, enter FWS–R7–NWRS–2026–1156, which is the docket number for this action. Then click the Search button. On the resulting page, you may submit a comment by clicking on ''Comment.'' Please ensure that you have found the correct document before submitting your comments.
- *U.S. mail:* Service Information Collection Clearance Officer, Attn: Docket No. FWS–R7–NWRS–2026–

1156, U.S. Fish and Wildlife Service, MS: PRB (JAO/3W), 5275 Leesburg Pike, Falls Church, VA 22041–3803.

Comments submitted through any method not authorized in this document, or sent to an address not listed here, will not be considered. We will not accept comments via email, fax, or hand delivery. We are not required to consider comments that are submitted after the comment period ends or that are submitted via a method outside of these instructions. Comments containing profanity, vulgarity, threats, or other inappropriate content will not be considered. We will post all comments at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Madonna Baucum, Service Information Collection Clearance Officer, by email at *Info_Coll@fws.gov,* or by telephone at (703) 358–2503. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance. You may also view the information collection request (ICR) at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we provide the general public and other Federal agencies with an opportunity to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again soliciting comments from the public and other Federal agencies on the proposed information collection request (ICR) described below. We are especially interested in public comments addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility;

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How might the agency minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personally identifiable information (PII) in your comment, you should be aware that your entire comment—including your PII—may be made publicly available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee that we will be able to do so.

Abstract: The National Wildlife Refuge Administration Act of 1966, as amended (16 U.S.C. 668dd–ee), authorizes the Service to permit uses—including commercial visitor services—on national wildlife refuges when such activities are determined to be compatible with the purposes for which each refuge was established. To support the provision of high-quality visitor services for wildlife-dependent recreation across the National Wildlife Refuge System, the Service issues permits for commercial guide services, including big game hunting, sport fishing, wildlife viewing, river trips, and other guided activities.

The Service uses Form 3–2538, ''Alaska Guide Service Evaluation,'' to collect information necessary to evaluate commercial guide services operating on national wildlife refuges in Alaska. This information assists refuge managers in assessing service quality, monitoring compliance with permit conditions, and ensuring that commercial activities align with refuge purposes and visitor experience objectives. Information gathered via Form 3–2538 allows the Service to:

- Monitor the quality of services provided by commercial guides.
- Gauge client satisfaction with the services.
- Assess the impacts of the activity on refuge resources.

We collect the following information from participants in the Alaska guide program via Form 3–2538:

- Details regarding the guided trip—name of the person(s) or outfitters guiding the trip and top three purposes for visiting the refuge.
- Experiences with guided trip.
- Level of satisfaction with guided trip and details regarding purpose of visit to refuge.
- Suggestions for improvements.
- Details about visitor—gender; State and/or country of residence; year of birth; race or ethnicity; details regarding formal schooling; and approximate household income.
- Contact information for follow-up questions (optional).

We collect this information to better understand visitor satisfaction and to effectively adapt visitor services programming in the Alaska Region. Form 3–2538 provides refuges with a quantitative, standardized tool that reflects social science survey design best practices and can be used consistently across the region. Individual refuge programs use the collected information to establish baseline conditions for guide-supported visitor experiences and to adjust management over time to ensure they continue to provide the desired opportunities on Alaska's refuges.

Proposed Revisions

With this submission, we will propose the following changes to this information collection:

1. Change the title of the collection from ''Alaska Guide Service Evaluation'' to ''Alaska Big Game Guide Use Survey.''

2. Remove the following questions from Form 3–2538:

a. Question 3: What was the name of the outfitter(s) for your guided trip? Outfitter name(s).

b. Question 4: What was the name(s) of the person(s) who guided you? Guide Name(s).

c. Removal of all questions in Section 5—A little about you.

3. Add a field at the end of Section 3 for respondents to explain their responses (optional).

4. Renumber Section 6 to be Section 5.

5. Add a point-of-contact at the end of the new Section 6 for respondents to contact any questions or concerns they would like to share or discuss.

6. Correct minor grammatical and formatting errors.

The public may request a copy of updated draft Form 3–2538 contained in this information collection by sending a request to the Service Information Collection Clearance Officer (see **ADDRESSES**).

Title of Collection: Alaska Big Game Guide Use Survey.

OMB Control Number: 1018–0141.

Form Number: Form 3–2538.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: Clients of permitted commercial guide service providers.

Total Estimated Number of Annual Respondents: 300.

Total Estimated Number of Annual Responses: 300.

Estimated Completion Time per Response: 20 minutes.

Total Estimated Number of Annual Burden Hours: 100.

Respondent's Obligation: Voluntary.

Frequency of Collection: One time, following use of commercial guide services.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Madonna Baucum,

Information Collection Clearance Officer, U.S. Fish and Wildlife Service.

[FR Doc. 2026–14256 Filed 7–15–26; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[A2407–014–004–065516, #O2509–014–004–125222; 267.LLHQ220000.L10200000.PK0000]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Grazing Management: Range Improvement Agreements and Permits Materials

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Land Management (BLM) is requesting to extend an approved information collection.

DATES: Interested persons are invited to submit comments on or before August 17, 2026.

ADDRESSES: Written comments and recommendations for this information collection request (ICR) should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Jessica Phillips by email at *jmphillips@blm.gov,* or by telephone at (406) 490–5654. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA and 5 CFR 1320.8(d)(1), we invite the public and other Federal agencies to comment on new, proposed, revised and continuing collections of information. This helps the BLM assess impacts of its information collection requirements and minimize the public's reporting burden. It also helps the public understand BLM information collection requirements and ensure requested data is provided in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on March 19, 2026 (91 FR 13324). No comments were received in response to that notice.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again inviting the public and other Federal agencies to comment on the proposed ICR described below. The BLM is especially interested in public comments addressing the following:

(1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How the agency could minimize the burden of the information collection on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. Before including your address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so.

Abstract: OMB Control Number 1004–0019 covers the information collections concerning range improvements to improve livestock grazing management, improve watershed conditions, enhance wildlife habitat on BLM lands, or serve similar purposes. Under 43 CFR 4120.3–1(b), the BLM requires that an operator enter into a Cooperative Range Improvement Agreement, or obtain a Range Improvement Permit, before installing, using, maintaining, and/or modifying a range improvement. The BLM uses Form 4120–6, Cooperative Range Improvement Agreement, to document cooperative range improvement construction arrangements with grazing operators. This OMB control number is currently scheduled to expire on August 31, 2026. The BLM request that OMB renew this OMB control number for an additional three (3) years.

Title of Collection: Grazing Management: Range Improvements Agreements and Permits (43 CFR Subpart 4120).

OMB Control Number: 1004–0019.

Form Numbers: 4120–6, Cooperative Range Improvement Agreement; and 4120–7, Range Improvement Permit.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Holders of BLM grazing permits or grazing leases.

Total Estimated Number of Annual Respondents: 530.

Total Estimated Number of Annual Responses: 530.

Estimated Completion Time per Response: Varies from 1 to 2 hours per response.

Total Estimated Number of Annual Burden Hours: 1,060.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Annual Non-hour Burden Cost: $0.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Darrin King,

Information Collection Clearance Officer.

[FR Doc. 2026–14349 Filed 7–15–26; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[A2407–014–004–065516, #O2509–014–004–125222; LLAK980200 L14100000.HM0000 234]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Alaska Native Vietnam-Era Veterans Allotments

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of Information Collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Bureau of Land Management (BLM) proposes extending an information collection.

DATES: Interested persons are invited to submit comments on or before August 17, 2026.

ADDRESSES: Written comments and recommendations for this information collection request (ICR) should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request additional information about this Information Collection Request (ICR), contact Michael Everett, by email at *meverett@blm.gov,* or by telephone at (907) 271–3786. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States. You may also view the ICR at *http://www.reginfo.gov/public/do/PRAMain.*

SUPPLEMENTARY INFORMATION: In accordance with the PRA (44 U.S.C. 3501 *et seq.*) and 5 CFR 1320.8(d)(1), we invite the public and other Federal agencies to comment on new, proposed, revised and continuing collections of information. This helps the BLM assess impacts of its information collection requirements and minimize the public's reporting burden. It also helps the public understand BLM information collection requirements and ensure requested data are provided in the desired format.

A **Federal Register** notice with a 60-day public comment period soliciting comments on this collection of information was published on March 27, 2026 (91 FR 14866). No comments were received in response to that notice.

As part of our continuing effort to reduce paperwork and respondent burdens, we are again inviting the public and other Federal agencies to comment on the proposed ICR described below. The BLM is especially interested in public comments addressing the following:

(1) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility.

(2) The accuracy of our estimate of the burden for this collection of information, including the validity of the methodology and assumptions used.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) How the agency could minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of response.

Comments submitted in response to this notice are a matter of public record. Before including your address, phone number, email address, or other personally identifying information in your comment, you should be aware that your entire comment—including your personally identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifying information from public review, we cannot guarantee that we will be able to do so.

Abstract: Under OMB Control Number 1004–0216 the BLM collects information related to Native veteran land allotment applications. The authority for this Program is section 1119 of the John D. Dingell, Jr. Conservation, Management, and Recreation Act of March 12, 2019, Public Law 116–9, codified at 43 U.S.C. 1629g–1. This OMB control number is currently scheduled to expire on July 31, 2026. The BLM request that OMB renew this OMB control number for an additional three (3) years.

Title of Collection: Alaska Native Vietnam-Era Veterans Allotments (43 CFR 2569).

OMB Control Number: 1004–0216.

Form Numbers: Alaska Native Vietnam-Era Veterans Allotments Application, AK 2569–10.

Type of Review: Extension of a currently approved collection.

Respondents/Affected Public: Individuals and State/Local/Tribal governments.

Total Estimated Number of Annual Respondents: 1,265.

Total Estimated Number of Annual Responses: 1,265.

Estimated Completion Time per Response: Varies from 4.5 hours to 30 minutes per response.

Respondent's Obligation: Required to obtain or retain a benefit.

Frequency of Collection: On occasion.

Total Estimated Number of Annual Hours: 3,828.

Total Estimated Annual Non-hour Burden Cost: $55,000.

An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

The authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Darrin King,

Information Collection Clearance Officer.

[FR Doc. 2026–14342 Filed 7–15–26; 8:45 am]

BILLING CODE 4310–84–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRNHL–DTS#-43244;PPWOCRADI0, PCU00RP14.R50000]

National Register of Historic Places; Notification of Pending Nominations and Related Actions

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: The National Park Service is soliciting electronic comments on the significance of properties nominated before July 4, 2026, for listing or related actions in the National Register of Historic Places.

DATES: Comments should be submitted by July 31, 2026.

ADDRESSES: Comments are encouraged to be submitted electronically to *National_Register_Submissions@nps.gov* with the subject line ''Public Comment on <property or proposed district name, (County) State≤.'' If you have no access to email, you may send them via U.S. Postal Service and all other carriers to the National Register of Historic Places, National Park Service, 1849 C Street NW, MS 2013, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Sherry A. Frear, Chief, National Register of Historic Places/National Historic Landmarks Program, 1849 C Street NW, MS 2013, Washington, DC 20240, *sherry_frear@nps.gov,* 202–913–3763.

SUPPLEMENTARY INFORMATION: The properties listed in this notice are being considered for listing or related actions in the National Register of Historic Places. Nominations for their consideration were received by the National Park Service before July 4, 2026. Pursuant to 36 CFR 60.13, comments are being accepted concerning the significance of the nominated properties under the National Register criteria for evaluation.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Nominations submitted by State or Tribal Historic Preservation Officers.

Key: State, County, Property Name, Multiple Name(if applicable), Address/Boundary, City, Vicinity, Reference Number.

COLORADO

Conejos County

Ruybal Homestead, Address Restricted, Antonito, SG100013296

Denver County

Cullen-Thompson Motor Company, (Jules Jacques Benois Benedict Architecture in Colorado MPS), 1000 Broadway, Denver, MP100013295

Wat Buddhawararam, 4801 Julian Street, Denver, SG100013307

INDIANA

Marion County

Belmont Beach, 1300 N. White River Parkway West Drive; bounded by White River Parkway West Drive on the south, and the White River on the north east of Belmont Ave., Indianapolis, SG100013298

MONTANA

Fergus County

Bear Gulch, 2649 Fairview Road, Forest Grove, SG100013304

Prairie County, State Bank of Terry, 101 S. Logan Avenue, Terry, SG100013305

PENNSYLVANIA

Bucks County

Maxo Vanka Property, 3080 Wilkinson Road, Jamison, SG100013294

Chester County

Mendenhall Valentine Edge House, 931 Bondsville Road, Caln Township, SG100013303

TEXAS

Denton County

Little Chapel in the Woods, 415 Chapel Dr., Denton, SG100013299

Harris County

Olivewood Cemetery, 1300 Court Street, Houston, SG100013306

Tarrant County

Binyon-O'Keefe Storage Company Building, 210 E. 7th Street, Fort Worth, SG100013301

An owner objection was received for the following resource(s):

WISCONSIN

Milwaukee County

St. Benedict the Moor Roman Catholic Church, 924 West State Street, Milwaukee, SG100013302

A request for removal has been made for the following resource(s):

GEORGIA

Houston County

New Perry Hotel, 800 Main St., Perry, OT04000241

Nomination(s) submitted by Federal Preservation Officers:

The State Historic Preservation Officer reviewed the following nomination(s) and responded to the Federal Preservation Officer within 45 days of receipt of the nomination(s) and supports listing the properties in the National Register of Historic Places.

TEXAS

Lubbock County

Federal Building and U.S. Courthouse, 1205 Texas Avenue, Lubbock, SG100013293

Authority: 36 CFR 60.13

Sherry A. Frear,

Chief, National Register of Historic Places/National Historic Landmarks Program.

[FR Doc. 2026–14332 Filed 7–15–26; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1510]

Certain Convertible Child Highchairs; Notice of Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 12, 2026, under section 337 of the Tariff Act of 1930, as amended, on behalf of Kids2, LLC of Atlanta, Georgia. A letter supplementing the complaint was filed on June 30, 2026. The complaint, as supplemented, alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain convertible child highchairs by reason of the infringement of certain claims of U.S. Patent No. 9,101,225 (''the '225 patent''); U.S. Patent No. 9,883,749 (''the '749 patent''); U.S. Patent No. 10,278,513 (''the '513 patent''); U.S. Patent No. 10,835,053 (''the '053 patent''); and U.S. Patent No. 11,534,006 (''the '006 patent''). The complaint, as supplemented, further alleges that an industry in the United States exists as required by the applicable Federal Statute.

The complainant requests that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: Susan Orndoff, The Office of the Secretary, Docket Services Division, U.S. International Trade Commission, telephone (202) 205–1802.

SUPPLEMENTARY INFORMATION:

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2025).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on July 14, 2026, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted

to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain products identified in paragraph (2) by reason of infringement of one or more of claims 6, 7, and 9–14 of the '225 patent; claims 3–8 of the '749 patent; claims 3–25 of the '513 patent; claims 3, 6, 7, 9–13, 17–20, and 22–34 of the '053 patent; and claims 3, 4, 6, 7, 10, 11, 13, 14, and 18–23 of the '006 patent, and whether an industry in the United States exists as required by subsection (a)(2) of section 337;

(2) Pursuant to section 210.10(b)(1) of the Commission's Rules of Practice and Procedure, 19 CFR 210.10(b)(1), the plain language description of the accused products or category of accused products, which defines the scope of the investigation, is ''[c]onvertible children's highchairs with a second child seat that nests a first child seat in a highchair configuration and that is removable from the first child seat to be used independently as a booster seat when securely placed on another support surface such as a dining chair'';

(3) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) *The complainant is:* Kids2, LLC, 3333 Piedmont Rd., Suite 1800, Atlanta, Georgia 30305.

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

Graco Children's Products Inc., 5 Concourse Parkway, 8th Floor, Atlanta, Georgia 30328

Newell Brands Distribution LLC, 3419 Ritner Highway, Newville, PA, 17241

Newell Brands Inc., 5 Concourse Parkway, Atlanta, GA 30328

Newell Brands Canada ULC, 6 Manchester Court, Unit 1, Bolton, ON L7E 2J3 Canada

Baby Trend, Inc., 13048 Valley Boulevard, Fontana, California 92335

(4) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

The Office of Unfair Import Investigations will not participate as a party in this investigation.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: July 14, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–14355 Filed 7–15–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation 731–TA–1740 (Final)]

Multifunctional Acrylate and Methacrylate Monomers and Oligomers From South Korea; Determination

On the basis of the record [1] developed in the subject investigation, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of multifunctional acrylate and methacrylate monomers and oligomers (''MAMMOs'') from South Korea, provided for in subheadings 2916.12.50, 2916.14.20, 3824.99.29, 3907.29.00, and 3907.30.00 of the Harmonized Tariff Schedule of the United States, that have been found by the U.S. Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV'').[2] [3]

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 91 FR 31415, May 27, 2026.

Background

The Commission instituted these investigations effective March 27, 2025, following receipt of petitions filed with the Commission and Commerce by Arkema, Inc., King of Prussia, Pennsylvania, alleging that an industry in the United States is materially injured and threatened with material injury by reason of subsidized imports of MAMMOs from Taiwan and LTFV imports of MAMMOs from South Korea and Taiwan. The Commission scheduled the final phase of the investigations following notification of preliminary determinations by Commerce that imports of MAMMOs from Taiwan were being sold at LTFV within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)) and subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on September 5, 2025 (90 FR 42984).[4] All persons who requested the opportunity were permitted to participate.

The investigation schedules became staggered when Commerce did not align its antidumping duty investigation with respect to MAMMOs from South Korea with its antidumping and countervailing duty investigations with respect to MAMMOs from Taiwan and reached earlier final determinations on imports of MAMMOs from Taiwan. On March 4, 2026, the Commission issued final affirmative determinations in its antidumping and countervailing duty investigations of MAMMOs from Taiwan (91 FR 11337, March 9, 2026). Following notification of a final determination by Commerce that imports of MAMMOs from South Korea were being sold at LTFV within the meaning of section 735(a) of the Act (19 U.S.C. 1673d(a)), notice of the supplemental scheduling of the final phase of the Commission's antidumping duty investigation with respect to

[3] The Commission also finds that imports subject to Commerce's affirmative critical circumstances determination are not likely to undermine seriously the remedial effect of the antidumping duty order on South Korea.

[4] Due to the lapse in appropriations and ensuing cessation of Commission operations, the Commission tolled its schedule for this proceeding. The schedule was revised in subsequent notices published in the **Federal Register** on December 1, 2025 (90 FR 55175) and December 16, 2025 (90 FR 58307).

MAMMOs from South Korea was given by posting copies of the notices in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of June 5, 2026 (91 FR 34250).

The Commission made this determination pursuant to § 735(b) of the Act (19 U.S.C. 1673d(b)). It completed and filed its determination in this investigation on July 13, 2026. The views of the Commission are contained in USITC Publication 5761 (July 2026), entitled *Multifunctional Acrylate and Methacrylate Monomers and Oligomers from South Korea: Investigation 731–TA–1740 (Final).*

By order of the Commission.

Issued: July 13, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–14301 Filed 7–15–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–646 and 731–TA–1502–1516 (Review)]

Prestressed Concrete Steel Wire Strand From Argentina, Colombia, Egypt, Indonesia, Italy, Malaysia, Netherlands, Saudi Arabia, South Africa, Spain, Taiwan, Tunisia, Turkey, Ukraine, and United Arab Emirates; Scheduling of Full Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of full reviews pursuant to the Tariff Act of 1930 to determine whether revocation of the countervailing duty order on prestressed concrete steel wire strand (''PC strand'') from Turkey and the revocation of the antidumping duty orders on PC strand from Argentina, Colombia, Egypt, Indonesia, Italy, Malaysia, Netherlands, Saudi Arabia, South Africa, Spain, Taiwan, Tunisia, Turkey, Ukraine, and United Arab Emirates would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: July 9, 2026.

FOR FURTHER INFORMATION CONTACT: Lawrence Jones (202–205–3358), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On April 7, 2026, the Commission determined that responses to its notice of institution of the subject five-year review were such that a full review should proceed (91 FR 41660, July 7, 2026); accordingly, a full review is being scheduled pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)). A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements are available from the Office of the Secretary and at the Commission's website.

Participation in the review and public service list.—Persons, including industrial users of the subject merchandise and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in this review as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, by 45 days after publication of this notice. A party that filed a notice of appearance following publication of the Commission's notice of institution of the review need not file an additional notice of appearance. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the review.

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to section 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in this review available to authorized applicants under the APO issued in the review, provided that the application is made by 45 days after publication of this notice. Authorized applicants must represent interested parties, as defined by 19 U.S.C. 1677(9), who are parties to the review. A party granted access to BPI following publication of the Commission's notice of institution of the review need not reapply for such access. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Staff report.—The prehearing staff report in the review will be placed in the nonpublic record on October 28, 2026, and a public version will be issued thereafter, pursuant to section 207.64 of the Commission's rules.

Hearing.—The Commission will hold an in-person hearing in connection with the review beginning at 9:30 a.m. on Thursday, November 19, 2026. Requests to appear at the hearing should be filed in writing with the Secretary to the Commission on or before 5:15 p.m. on Tuesday, November 10, 2026. Any requests to appear as a witness via videoconference must be included with your request to appear. Requests to appear via videoconference must include a statement explaining why the witness cannot appear in person; the Chairman, or other person designated to conduct the review, may in their discretion for good cause shown, grant such a request. Requests to appear as remote witness due to illness or a positive COVID–19 test result may be submitted by 3 p.m. the business day prior to the hearing. Further information about participation in the hearing will be posted on the Commission's website at *https://www.usitc.gov/calendarpad/calendar.html.*

A nonparty who has testimony that may aid the Commission's deliberations may request permission to present a short statement at the hearing. All parties and nonparties desiring to appear at the hearing and make oral presentations should attend a prehearing conference, if deemed necessary, to be held at 9:30 a.m. on Friday, November 13, 2026. Parties shall file and serve written testimony and presentation slides in connection with their presentation at the hearing by no later than noon on November 18, 2026. Oral testimony and written materials to be submitted at the public hearing are governed by sections 201.6(b)(2), 201.13(f), and 207.24 of the Commission's rules. Parties must submit

any request to present a portion of their hearing testimony *in camera* no later than 7 business days prior to the date of the hearing.

Written submissions.—Each party to the review may submit a prehearing brief to the Commission. Prehearing briefs must conform with the provisions of section 207.65 of the Commission's rules; the deadline for filing is 5:15 p.m. on November 6, 2026. Parties shall also file written testimony in connection with their presentation at the hearing, and posthearing briefs, which must conform with the provisions of section 207.67 of the Commission's rules. The deadline for filing posthearing briefs is 5:15 p.m. on December 1, 2026. In addition, any person who has not entered an appearance as a party to the review may submit a written statement of information pertinent to the subject of the review on or before 5:15 p.m. on December 1, 2026. On December 21, 2026, the Commission will make available to parties all information on which they have not had an opportunity to comment. Parties may submit final comments on this information on or before 5:15 p.m. on January 5, 2027, but such final comments must not contain new factual information and must otherwise comply with section 207.68 of the Commission's rules. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of sections 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

The Commission has determined that these reviews are extraordinarily complicated and therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C.1675(c)(5)(B).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: July 13, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–14287 Filed 7–15–26; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1782–1785 (Preliminary)]

Polytetramethylene Ether Glycol from China, South Korea, Taiwan, and Vietnam; Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports of polytetramethylene ether glycol (''PTMEG'') from China, South Korea, Taiwan, and Vietnam, provided for in subheadings 3907.29.00 and 2932.11.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value (''LTFV'').[2]

Commencement of Final Phase Investigation

Pursuant to section 207.18 of the Commission's rules, the Commission also gives notice of the commencement of the final phase of its investigations. The Commission will issue a final phase notice of scheduling, which will be published in the **Federal Register** as provided in section 207.21 of the Commission's rules, upon notice from the U.S. Department of Commerce (''Commerce'') of an affirmative preliminary determinations in the investigations under § 733(b) of the Act, or, if the preliminary determinations are negative, upon notice of an affirmative final determinations in those investigations under § 735(a) of the Act. Parties that filed entries of appearance in the preliminary phase of the investigations need not enter a separate appearance for the final phase of the investigations. Any other party may file an entry of appearance for the final phase of the investigations after publication of the final phase notice of scheduling. Industrial users, and, if the merchandise under investigation is sold at the retail level, representative consumer organizations have the right to appear as parties in Commission antidumping investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to the investigations. As provided in section 207.20 of the Commission's rules, the Director of the Office of Investigations will circulate draft questionnaires for the final phase of the investigations to parties to the investigations, placing copies on the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*), for comment.

Background

On April 8, 2026, BASF Corporation, Florham Park, New Jersey, filed petitions with the Commission and Commerce, alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV imports of PTMEG from China, South Korea, Taiwan, and Vietnam. Accordingly, effective April 8, 2026, the Commission instituted antidumping duty investigation Nos. 731–TA–1782–1785 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of April 13, 2026 (91 FR 18879). The Commission conducted its conference on April 29, 2026. All persons who requested the opportunity were permitted to participate.

The Commission made these determinations pursuant to § 733(a) of the Act (19 U.S.C. 1673b(a)). It completed and filed its determinations in these investigations on May 26, 2026. The views of the Commission are contained in USITC Publication 5746 (June 2026), entitled *Polytetramethylene Ether Glycol from China, South Korea, Taiwan, and Vietnam: Investigation Nos. 731–TA–1782–1785 (Preliminary).*

By order of the Commission.

Issued: July 14, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–14351 Filed 7–15–26; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] 91 FR 24162 (May 5, 2026).

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–767 and 731–TA–1750 (Final)]

L-Lysine from China; Cancellation of Hearing for Antidumping and Countervailing Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: July 10, 2026.

FOR FURTHER INFORMATION CONTACT: Caitlyn Costello (202–205–2058), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On March 6, 2026, the Commission established a schedule for the final phase of the subject antidumping and countervailing duty investigations (91 FR 16967, April 3, 2026). On May 29, 2025, counsel for Lysine Fair Trade Coalition and its individual members (collectively, ''Petitioners'') filed a request to appear at the hearing. No other parties submitted a request to appear at the hearing. On July 9, 2026, counsel for the Petitioners withdrew their request to appear at the hearing, filed a request that the Commission cancel the scheduled hearing for this proceeding and indicated a willingness to respond to any Commission questions in lieu of an actual hearing. The Commission considers Petitioners' letter to be a request under 19 CFR 201.12 to take action with respect to these investigations, and that cancellation is appropriate because a public hearing is not necessary to address the legal and factual issues these investigations present. Consequently, the Commission has cancelled the public hearing in connection with this proceeding, scheduled to begin at 9:30 a.m. on July 14, 2026. Parties to this proceeding should respond to any written questions posed by the Commission in their posthearing briefs, which are due to be filed on July 22, 2026.

For further information concerning this proceeding, see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.21 of the Commission's rules.

By order of the Commission.

Issued: July 13, 2026.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2026–14277 Filed 7–15–26; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1741]

Importer of Controlled Substances Application: Catalent Greenville, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Catalent Greenville, Inc. has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before August 17, 2026. Such persons may also file a written request for a hearing on the application on or before August 17, 2026.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on June 4, 2026, Catalent Greenville, Inc., 1240 Sugg Parkway, Greenville, North Carolina 27834–9006, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Lysergic acid diethylamide	7315	I
3,4-Methylenedioxymethamphetamine	7405	I
Psilocybin	7437	I

The company plans to import the listed controlled substances for dosage formulations development for research, clinical trial studies and analytical purposes. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Thomas Prevoznik,

Deputy Assistant Administrator.

[FR Doc. 2026–14286 Filed 7–15–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1739]

Bulk Manufacturer of Controlled Substances Application: AMPAC Fine Chemicals LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: AMPAC Fine Chemicals LLC has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to **SUPPLEMENTARY INFORMATION** listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on or objections to the issuance of the proposed registration on or before September 14, 2026. Such persons may also file a written request for a hearing on the application on or before September 14, 2026.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on May 7, 2026, AMPAC Fine Chemicals LLC, Highway 50 and Hazel Avenue, Rancho Cordova, California 95670, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Norlevorphanol	9634	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Methylphenidate	1724	II
Levomethorphan	9210	II
Levorphanol	9220	II
Thebaine	9333	II
Remifentanil	9739	II
Tapentadol	9780	II

The company plans to bulk manufacture the listed controlled substances for use as intermediates, impurity testing, and distribution to its customers. No other activities for these drug codes are authorized for this registration.

Thomas Prevoznik,

Deputy Assistant Administrator.

[FR Doc. 2026–14284 Filed 7–15–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1740]

Importer of Controlled Substances Application: Unither Manufacturing LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Unither Manufacturing LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit electronic comments on, or objections to the issuance of the proposed registration on or before August 17, 2026. Such persons may also file a written request for a hearing on the application on or before August 17, 2026.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on May 7, 2026, Unither Manufacturing LLC, 331 Clay Road, Rochester, New York 14623–3226, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Methylphenidate	1724	II

The company plans to import the listed controlled substance as bulk solely for purposes of updating their analytical testing procedures to meet European Union requirements for their exported finished dosage form product. No other activity for this drug code is authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Thomas Prevoznik,

Deputy Assistant Administrator.

[FR Doc. 2026–14285 Filed 7–15–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–1738]

Importer of Controlled Substances Application: Catalent CTS, LLC

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: Catalent CTS, LLC has applied to be registered as an importer of basic class(es) of controlled substance(s). Refer to Supplementary Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants, therefore, may submit

electronic comments on or objections to the issuance of the proposed registration on or before August 17, 2026. Such persons may also file a written request for a hearing on the application on or before August 17, 2026.

ADDRESSES: The Drug Enforcement Administration requires that all comments be submitted electronically through the Federal eRulemaking Portal, which provides the ability to type short comments directly into the comment field on the web page or attach a file for lengthier comments. Please go to *https://www.regulations.gov* and follow the online instructions at that site for submitting comments. Upon submission of your comment, you will receive a Comment Tracking Number. Please be aware that submitted comments are not instantaneously available for public view on *https://www.regulations.gov.* If you have received a Comment Tracking Number, your comment has been successfully submitted and there is no need to resubmit the same comment. All requests for a hearing must be sent to: (1) Drug Enforcement Administration, Attn: Hearing Clerk/OALJ, 8701 Morrissette Drive, Springfield, Virginia 22152; and (2) Drug Enforcement Administration, Attn: DEA Federal Register Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing should also be sent to: Drug Enforcement Administration, Attn: Administrator, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.34(a), this is notice that on June 4, 2026, Catalent CTS, LLC, 10245 Hickman Mills Drive, Kansas City, Missouri 64137–14180, applied to be registered as an importer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Gamma Hydroxybutyric Acid.	2010	I
Marihuana Extract	7350	I
Marihuana	7360	I
Tetrahydrocannabinols	7370	I

The company plans to import the listed controlled substances as bulk and dosage unit products for distribution to support customers' clinical trials. In reference to drug code 7370 (Tetrahydrocannabinols), the company plans to import a synthetic tetrahydrocannabinol. No other activities for these drug codes are authorized for this registration.

Approval of permit applications will occur only when the registrant's business activity is consistent with what is authorized under 21 U.S.C. 952(a)(2). Authorization will not extend to the import of Food and Drug Administration-approved or non-approved finished dosage forms for commercial sale.

Thomas Prevoznik,

Deputy Assistant Administrator.

[FR Doc. 2026–14280 Filed 7–15–26; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0017]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Title—Semi-Annual Progress Report for the Technical Assistance Program

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Office on Violence Against Women (OVW), Department of Justice (DOJ, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until August 17, 2026.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Tiffany Watson, Office on Violence Against Women, at 202–307–6026 or *Tiffany.Watson@usdoj.gov.*

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register** on May 14, 2026, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

— Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
— Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
— Enhance the quality, utility, and clarity of the information to be collected; and/or
— Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1122–0017. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a currently approved collection.

2. *Title of the Form/Collection:* Semi-annual Progress Report for the Technical Assistance Program.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0017. U.S. Department of Justice, Office on Violence Against Women.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the 53 programs providing technical assistance as recipients under the Technical Assistance Program.

The primary purpose of the OVW Technical Assistance Program is to provide assistance to grantees and their subgrantees to enhance the success of local projects they are implementing

with VAWA grant funds. In addition, OVW is focused on building the capacity of criminal justice and victim services organizations to respond effectively to sexual assault, domestic violence, dating violence, and stalking and to foster partnerships between organizations that have not traditionally worked together to address violence against women, such as faith-and community-based organizations.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the 53 respondents (Technical Assistance Providers) approximately one hour to complete a semi-annual progress report twice a year. The Semi-annual Progress Report for the Technical Assistance Program is divided into sections that pertain to the different types of activities in which Technical Assistance Providers are engaged.

6. *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the semi-annual progress report form is 106 hours. It will take approximately one hour for the grantees to complete the form twice a year.

7. An estimate of the total annual cost burden associated with the collection, if applicable: The annualized costs to the Federal Government resulting from the OVW staff review of the progress reports submitted by grantees are estimated to be $6,144.89.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Enterprise Portfolio Management, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: July 14, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–14385 Filed 7–15–26; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0024]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Title—Semi-Annual Progress Report for Grantees From the Tribal Sexual Assault Services Program

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Office on Violence Against Women (OVW), Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until August 17, 2026.

FOR FURTHER INFORMATION CONTACT: If you have comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact: Tiffany Watson, Office on Violence Against Women, at 202–307–6026 or *Tiffany.Watson@usdoj.gov*.

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register** on May 14, 2026, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so, how the quality, utility, and clarity of the information to be collected can be enhanced; and—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number 1122–0024. This information collection request may be viewed at *www.reginfo.gov*. Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Overview of This Information Collection

1. *Type of Information Collection:* Extension of a Currently Approved Collection.

2. *Title of the Form/Collection:* Semi-Annual Progress Report for the Tribal Sexual Assault Services Program.

3. *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection: Form Number:* 1122–0024. U.S. Department of Justice, Office on Violence Against Women.

4. *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 17 grantees of the Tribal Sexual Assault Services Program. The Sexual Assault Services Program (SASP), created by the Violence Against Women Act of 2005 (VAWA 2005), is the first federal funding stream solely dedicated to the provision of direct intervention and related assistance for victims of sexual assault. The SASP encompasses four different funding streams for States and Territories, Tribes, State Sexual Assault Coalitions, Tribal Coalitions, and culturally specific organizations. Overall, the purpose of SASP is to provide intervention, advocacy, accompaniment, support services, and related assistance for adult, youth, and child victims of sexual assault, family and household members of victims, and those collaterally affected by the sexual assault.

The Tribal SASP supports efforts to help survivors heal from sexual assault trauma through direct intervention and related assistance including 24-hour sexual assault hotlines, crisis intervention, and medical and criminal justice accompaniment. The Tribal SASP will support such services through the establishment, maintenance, and expansion of programs and projects to assist those victimized by sexual assault.

5. *An estimate of the total number of respondents and the amount of time*

estimated for an average respondent to respond/reply: It is estimated that it will take the approximately 17 respondents (grantees from the Tribal Sexual Assault Services Program) approximately one hour to complete a semi-annual progress report. The semi-annual progress report is divided into sections that pertain to the different types of activities in which grantees may engage. A Tribal SASP grantee will only be required to complete the sections of the form that pertain to its own specific activities.

6. *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 34 hours, that is 17 grantees completing a form twice a year with an estimated completion time for the form being one hour.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* The annualized costs to the Federal Government resulting from the OVW staff review of the progress reports submitted by grantees are estimated to be $1,971.00.

If additional information is required, contact: Darwin Arceo, Department Clearance Officer, Enterprise Portfolio Management, Justice Management Division, United States Department of Justice, Two Constitution Square, 145 N Street NE, 4W–218 Washington, DC 20530.

Dated: July 14, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–14386 Filed 7–15–26; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0030]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Previously Approved Collection; Title—Electronic Applications for the Attorney General's Honors Program and the Summer Law Intern Program (HP/SLIP)

AGENCY: Office of Adjudication, Recruitment, and Management, Justice Management Division, Department of Justice.

ACTION: 30-Day notice.

SUMMARY: The Office of Adjudication, Recruitment and Management, Department of Justice (DOJ), will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 30 days until August 17, 2026.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Deana Willis, Assistant Director, Office of Adjudication, Recruitment, and Management, c/o Deana Willis, 450 5th Street NW, Suite 10200, Washington, DC, 20530, 202–514–8900, *Deana.Willis@usdoj.gov.*

SUPPLEMENTARY INFORMATION: The proposed information collection was previously published in the **Federal Register** on May 15, 2026, allowing a 60-day comment period. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Written comments and recommendations for this information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/*PRAMain. Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function and entering either the title of the information collection or the OMB Control Number [1105–0030]. This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view Department of Justice, information collections currently under review by OMB.

DOJ seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOJ notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Abstract: Candidates enter information pertinent to legal employment on a series of electronic screens (the number of screens varies by Program; hiring organizations vary by year). The data is then certified and submitted into a database for OARM review and transmission to the components that consider the candidates for legal employment. The candidate is automatically notified by email that his/her application has been received when he/she certifies and submits his/her electronic application, and provided other hiring status updates throughout the hiring cycle.

The Department of Justice developed an in-house electronic application managed by the Office of Chief Information Office (OCIO) Service Delivery Staff (SDS) Application Services Branch (ASB) to replace one previously managed by contract with an outside vendor. There is no impact on the public burden.

The questions presented to applicants are unchanged except for the following deletions:

- Questions relating to geographic preference;
- A checklist of practice area interests;
- Two ''check the box'' questions about undergraduate awards;
- A ''yes/no'' question presented only to SLIP-Pathways applicants asking whether the law school transcript listed failing grades;

The estimate of annualized cost to the federal government is $71,429.00.

Overview of This Information Collection

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *The Title of the Form/Collection:* Electronic Applications for the Attorney General's Honors Program and the Summer Law Intern Program.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* N/A.

4. *Affected public who will be asked or required to respond, as well as the obligation to respond:* Affected Public-Individuals. The obligation to respond is voluntary.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 1900 candidates apply to the HP & SLIP annually. It is estimated that the electronic application takes approximately one hour to complete and submit. It is further estimated that it takes an average of an additional 45 minutes to review the instructions, search existing data sources, gather and maintain the data needed, and complete and review the information collected. In addition, approximately 600 HP applicants will complete a Virtual Interview Scheduling form. Each Interview Scheduling Form will take approximately 10 minutes to complete. Thus, the annual burden would be 3425 hours based on 1900 applicants (the average number of applications received in the last several years) x 1.75 response hours (estimated time to collect the appropriate information and complete the Program application) plus 100 hours (time for 600 HP candidates to complete the Virtual Interview Scheduling Form).

6. *An estimate of the total annual burden (in hours) associated with the collection:* The total annual burden hours for this collection is 3425 hours.

7. *An estimate of the total annual cost burden associated with the collection, if applicable:* $71,492.

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response (minutes)	Total annual burden (hours)
Electronic application (individuals).	1900	1/annually	1900	105	3325
Virtual Interview Scheduling Form (Individuals).	600	1/annually	600	10	100
Unduplicated Totals.	2500	.....	2500	.....	3425

If additional information is required contact: Darwin Arceo, Department Clearance Officer, United States Department of Justice, Justice Management Division, Enterprise Portfolio Management, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC.

Dated: July 13, 2026.

Darwin Arceo,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2026–14251 Filed 7–15–26; 8:45 am]

BILLING CODE 4410–PB–P

NATIONAL CREDIT UNION ADMINISTRATION

Renewal of Agency Information Collections for Comments Request: Proposed Collections

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comments.

SUMMARY: The National Credit Union Administration (NCUA) will submit the following information collection requests to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, on or after the date of publication of this notice.

DATES: Written comments should be received on or before September 14, 2026 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Dacia Rogers, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314, Suite 6070; Fax No. (703) 519–8161; or email at *PRAComments@NCUA.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by contacting Dacia Rogers at (703) 518–6547.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–0098.

Title: Advertising of Excess Insurance, 12 CFR 740.3.

Type of Review: Extension of a previously approved collection.

Abstract: Federally insured credit unions which offer or provide excess insurance coverage for their accounts must indicate the type and amount of such insurance, the name of the carrier and a statement that the carrier is not affiliated with the NCUSIF or the Federal government in all advertising that mentions account insurance.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 297.

OMB Number: 3133–0117.

Title: Designation of Low-Income Status, 12 CFR 701.34(a).

Type of Review: Extension of a previously approved collection.

Abstract: The Federal Credit Union Act (12 U.S.C. 1752(5)) authorizes the NCUA Board to define low-income members so that credit unions with a membership serving predominantly low-income members can benefit from certain statutory relief and receive assistance from the Community Development Revolving Loan Fund (CDRLF). Under the authority of 12 CFR 701.34(a), NCUA must obtain certain data to determine if a credit union qualifies for the designation. NCUA uses the information from credit unions to determine whether they meet the criteria for the low-income designation.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 356.

OMB Number: 3133–0134.

Title: Truth in Savings (TISA), 12 CFR part 707.

Type of Review: Extension of a previously approved collection.

Abstract: NCUA's TISA regulation requires credit unions to provide specific disclosures when an account is opened, when a disclosed term changes or a term account is close to renewal, on periodic statements of account activity, in advertisements, and upon a member's

or potential member's request. 12 CFR 707.4, 707.5, 707.6, 707.8. Credit unions that provide periodic statements are required to include information about fees imposed, the annual percentage yield earned during those statement periods, and other account terms. The requirements for creating and disseminating account disclosures, change in terms notices, term share renewal notices, statement disclosures, and advertising disclosures are necessary to implement TISA's purpose of providing the public with information that will permit informed comparisons of accounts at depository institutions.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 298,563.

OMB Number: 3133–0154.

Title: Prompt Corrective Action, 12 CFR 702 (Subparts A–D).

Type of Review: Extension of a previously approved collection.

Abstract: Section 216 of the Federal Credit Union Act (12 U.S.C. 1790d) mandates prompt corrective action requirements for federally insured credit unions (FICUs) that become less than well capitalized. The NCUA Board is required to (1) adopt, by regulation, a system of prompt corrective action to restore the net worth of inadequately capitalized FICUs; and (2) develop an alternative system of prompt corrective action for new credit unions that carries out the purpose of prompt corrective actions while allowing an FICU reasonable time to build its net worth to an adequately capitalized level. Part 702 implements the statutory requirements and, to achieve this, various information collections to meet the purpose of prompt corrective action as circumstances require.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 2,433.

OMB Number: 3133–0166.

Title: Home Mortgage Disclosure Act (HMDA), 12 CFR 1003 (Regulation C).

Type of Review: Extension of a previously approved collection.

Abstract: The collection of this data is required under the Home Mortgage Disclosure Act. The information collection is intended to provide the public with loan data that can be used—(i) to help determine whether financial institutions are serving the housing needs of their communities; Reg C 203.1(b)(1)(ii); (ii) to assist public officials in distributing public-sector investments so as to attract private investment to areas where it is needed; Reg CC 203.1(b)(1)(iii) and (iii) to assist in identifying possible discriminatory lending patterns and enforcing anti-discrimination statutes. Reg C 203.1(b)(2).

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 145,886.

OMB Number: 3133–0167.

Title: Foreign Branching, 12 CFR 741.11.

Type of Review: Extension of a previously approved collection.

Abstract: This collection covers the additional information a credit union must provide to establish a branch office outside the United States (except for U.S. embassies and military installations). This is a three step process (1) The credit union must receive written approval from the host country to establish a branch, (2) The credit union must develop a detailed business plan, and (3) The credit union must submit documentation showing host country approval, state regulatory approval (if applicable), and the business plan to NCUA and receive NCUA approval before establishing the branch office.

Affected Public: Private Sector: Not-for-profit institutions.

Estimated Total Annual Burden Hours: 33.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) whether the collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By the National Credit Union Administration Board.

Melane Conyers-Ausbrooks,

Secretary of the Board.

[FR Doc. 2026–14302 Filed 7–15–26; 8:45 am]

BILLING CODE 7535–01–P

NUCLEAR REGULATORY COMMISSION

[Project No. 99902077; NRC–2026–2641]

Eden Radioisotopes, LLC; Construction Permit Application

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice; receipt, acceptance for docketing, opportunity to request a hearing and petition for leave to intervene; order imposing procedures.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC, the Commission) is providing public notice of receipt and availability of, and has accepted for review and docketed, an application from Eden Radioisotopes, LLC (Eden) for a construction permit for a medical isotope production complex to be built near Eunice, Lea County, New Mexico. The construction permit application is dated May 5, 2026. This notice also provides the public an opportunity to request a hearing and petition for leave to intervene with respect to that application. The NRC staff will conduct safety and environmental reviews of the construction permit application. If the NRC issues a construction permit, the applicant, Eden, would be authorized to construct its proposed complex in accordance with the provisions of the construction permit. Because the application contains Sensitive Unclassified Non-Safeguards Information (SUNSI), this notice includes an order that imposes procedures to obtain access to SUNSI for contention preparation.

DATES: The application was docketed on June 15, 2026. A request for a hearing or petition for leave to intervene must be filed by September 14, 2026. Any potential party as defined in section 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR) who believes access to SUNSI is necessary to respond to this notice must request document access by July 27, 2026.

ADDRESSES: Please refer to Docket ID NRC–2026–2641 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2026–2641. Address questions about Docket IDs in *Regulations.gov* to Bridget Curran; telephone: 301–415–1003; email: *Bridget.Curran@nrc.gov.* For technical questions, contact the individual(s) listed in the ''For Further Information Contact'' section of this document.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin ADAMS Public Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Andrew Miller, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–1080; email: *Andrew.Miller@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Discussion

By letter dated May 5, 2026, Eden filed, pursuant to Section 104c. of the Atomic Energy Act of 1954, as amended, and 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities,'' an application for a construction permit for a medical isotope production complex consisting of a non-power, open-pool reactor facility, a separation processing hot cell facility, a target fabrication facility, and a waste packaging, handling, and storage facility. This complex would be located near Eunice, Lea County, New Mexico. The reactor facility would use light water as the moderator and coolant and individual annular low-enriched uranium fueled targets.

The publicly available version of the construction permit application is available in ADAMS under Package Accession No. ML26125A060. Along with other documents, the ADAMS package includes the transmittal letter (ADAMS Accession No. ML26125A061), the preliminary safety analysis report and environmental report (ADAMS Accession No. ML26125A141), and the quality assurance program description (ADAMS Accession No. ML26125A071). The information submitted by Eden includes certain general information such as financial qualifications submitted pursuant to 10 CFR 50.33, ''Contents of applications; general information,'' certain technical information submitted pursuant to 10 CFR 50.34, ''Contents of applications; technical information,'' and an environmental report submitted pursuant to 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.''

The NRC staff determined that the construction permit application is complete and acceptable for docketing in accordance with 10 CFR 2.101(a) and 10 CFR part 50 and assigned it Docket No. 99902077. The NRC staff provided Eden notice of the acceptance and docketing determination by letter dated June 15, 2026 (ADAMS Accession No. ML26146A213).

The NRC staff will perform a detailed technical review of the construction permit application and document its safety findings in a safety evaluation report. Also, in accordance with 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions,'' the NRC staff will complete an environmental review of the application.

Docketing of the construction permit application does not preclude the NRC staff from requesting additional information from the applicant as the review proceeds, nor does it predict whether the Commission will grant or deny the application. If the Commission finds that the construction permit application meets the applicable standards of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, and that any required notifications to other agencies and bodies have been made, the Commission will issue a construction permit, in the form and containing conditions and limitations that the Commission finds appropriate and necessary.

II. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person (petitioner) whose interest may be affected by this action may file a request for a hearing and petition for leave to intervene (petition) with respect to the action. Petitions shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested persons should consult 10 CFR 2.309. If a petition is filed, the presiding officer will rule on the petition and, if appropriate, a notice of a hearing will be issued.

Petitions must be filed no later than 60 days from the date of publication of this notice in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document. Petitions and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i) through (iii).

A State, local government body, Federally recognized Indian Tribe, or designated agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h) no later than 60 days from the date of publication of this notice. Alternatively, a State, local government body, Federally recognized Indian Tribe, or agency thereof may participate as a non-party under 10 CFR 2.315(c).

For information about filing a petition and about participation by a person not a party under 10 CFR 2.315, see ADAMS Accession No. ML20340A053 (*https://adamswebsearch2.nrc.gov/webSearch2/main.jsp?AccessionNumber=ML20340A053*) and on the NRC's public website (*https://www.nrc.gov/about-nrc/regulatory/adjudicatory/hearing.html#participate*).

III. Electronic Submittals (E-Filing)

All documents filed in NRC adjudicatory proceedings, including documents filed by an interested State, local government body, Federally recognized Indian Tribe, or designated agency thereof that requests to participate under 10 CFR 2.315(c), must be filed in accordance with 10 CFR 2.302. The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases, to mail copies on electronic storage media, unless an exemption permitting an alternative filing method, as further discussed, is granted. Detailed guidance on electronic submissions is located in the ''Guidance for Electronic Submissions to the NRC'' (ADAMS Accession No. ML13031A056) and on the NRC's public website (*https://www.nrc.gov/site-help/e-submittals.html*).

To comply with the procedural requirements of E-Filing, at least 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *Hearing.Docket@nrc.gov,* or by telephone at 301–415–1677, to: (1) request a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign submissions and access

the E-Filing system for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a petition or other adjudicatory document (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public website (*https://www.nrc.gov/site-help/e-submittals/getting-started.html*). After a digital ID certificate is obtained and a docket created, the participant must submit adjudicatory documents in Portable Document Format. Guidance on submissions is available on the NRC's public website (*https://www.nrc.gov/site-help/electronic-sub-ref-mat.html*). A filing is considered complete at the time the document is submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. ET on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email confirming receipt of the document. The E-Filing system also distributes an email that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the document on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before adjudicatory documents are filed to obtain access to the documents via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC's Electronic Filing Help Desk through the ''Contact Us'' link located on the NRC's public website (*https://www.nrc.gov/site-help/e-submittals.html*), by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Electronic Filing Help Desk is available between 9 a.m. and 6 p.m., ET, Monday through Friday, excluding government holidays.

Participants who believe that they have good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing stating why there is good cause for not filing electronically and requesting authorization to continue to submit documents in paper format. Such filings must be submitted in accordance with 10 CFR 2.302(b)–(d). Participants filing adjudicatory documents in this manner are responsible for serving their documents on all other participants. Participants granted an exemption under 10 CFR 2.302(g)(2) must still meet the electronic formatting requirement in 10 CFR 2.302(g)(1), unless the participant also seeks and is granted an exemption from 10 CFR 2.302(g)(1).

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket, which is publicly available at *https://ehd.nrc.gov/home,* unless excluded pursuant to an order of the presiding officer. If you do not have an NRC-issued digital ID certificate as described above, click ''cancel'' when the link requests certificates and you will be automatically directed to the NRC's electronic hearing dockets where you will be able to access any publicly available documents in a particular hearing docket. Participants are requested not to include personal privacy information such as social security numbers, home addresses, or personal phone numbers in their filings unless an NRC regulation or other law requires submission of such information. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants should not include copyrighted materials in their submission.

IV. Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing Sensitive Unclassified Non-Safeguards Information (SUNSI).

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request access to SUNSI. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requestor shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Deputy General Counsel for Licensing, Hearings, and Enforcement, Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email addresses for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *RidsOgcMailCenter.Resource@nrc.gov,*[1] respectively. The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requestor's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C, the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2), the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order,[2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after receipt of (or access to) that information. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and requisite need, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requestor may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if this individual is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) if another officer has been designated to rule on information access issues, with that officer.

(3) Further appeals of decisions under this paragraph must be made pursuant to 10 CFR 2.311.

H. Review of Grants of Access. A party other than the requestor may challenge a NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed within 5 days of the notification by the NRC staff of its grant of access and must be filed with: (a) the presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an Administrative Law Judge with jurisdiction pursuant to 10 CFR 2.318(a) if another officer has been designated to rule on information access issues, with that officer.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. The attachment to this Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Authority: 42 U.S.C. 2011 *et seq.*

Dated: July 14, 2026.

For the Nuclear Regulatory Commission.

Jody Martin,

Secretary of the Commission.

Attachment 1—General Target Schedule for Processing and Resolving Requests for Access to Sensitive Unclassified Non-Safeguards Information in This Proceeding

Day	Event/activity
0	Publication of **Federal Register** notice of hearing or opportunity for hearing, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) which contains information: (i) supporting the standing of a potential party identified by name and address; and (ii) describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention which contains: (i) demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requestor of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and demonstrates the need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (*i.e.,* preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requestor to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff's reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Agreement or Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement or Affidavit for SUNSI.
A	If access is granted: issuance of presiding officer or other designated officer decision on motion for protective order for access to SUNSI (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Agreements or Affidavits. Access provided to SUNSI consistent with decision issuing the Protective Order.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requestors should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007, as amended at 77 FR 46562; August 3, 2012) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

Day	Event/activity
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or notice of opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60	Decision on contention admission.

[FR Doc. 2026–14314 Filed 7–15–26; 8:45 am]
BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket Nos. K2026–125; MC2026–299 and K2026–296; MC2026–302 and K2026–298; MC2026–303 and K2026–299; MC2026–304 and K2026–300]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 21, 2026.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *https://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

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I. Introduction
II. Public Proceeding(s)
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I. Introduction

Pursuant to 39 CFR 3041.405, the Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to Competitive negotiated service agreement(s). The request(s) may propose the addition of a negotiated service agreement from the Competitive product list or the modification of an existing product currently appearing on the Competitive product list.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

Section II identifies the docket number(s) associated with each Postal Service request, if any, that will be reviewed in a public proceeding as defined by 39 CFR 3010.101(p), the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each such request, the Commission appoints an officer of the Commission to represent the interests of the general public in the proceeding, pursuant to 39 U.S.C. 505 and 39 CFR 3000.114 (Public Representative). The Public Representative does not represent any individual person, entity or particular point of view, and, when Commission attorneys are appointed, no attorney-client relationship is established. Section II also establishes comment deadline(s) pertaining to each such request.

The Commission invites comments on whether the Postal Service's request(s) identified in Section II, if any, are consistent with the policies of title 39. Applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3041. Comment deadline(s) for each such request, if any, appear in Section II.

Section III identifies the docket number(s) associated with each Postal Service request, if any, to add a standardized distinct product to the Competitive product list or to amend a standardized distinct product, the title of each such request, the request's acceptance date, and the authority cited by the Postal Service for each request. Standardized distinct products are negotiated service agreements that are variations of one or more Competitive products, and for which financial models, minimum rates, and classification criteria have undergone advance Commission review. *See* 39 CFR 3041.110(n); 39 CFR 3041.205(a). Such requests are reviewed in summary proceedings pursuant to 39 CFR 3041.325(c)(2) and 39 CFR 3041.505(f)(1). Pursuant to 39 CFR 3041.405(c)–(d), the Commission does not appoint a Public Representative or request public comment in proceedings to review such requests.

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

II. Public Proceeding(s)

1. *Docket No(s).:* K2026–125; *Filing Title:* USPS Request Concerning Amendment One to Priority Mail & USPS Ground Advantage Contract 935, with Material Filed Under Seal; *Filing Acceptance Date:* July13, 2026; *Filing Authority:* 39 CFR. 3035.105 and 39 CFR 3041.505; *Public Representative:* Kenneth Moeller; *Comments Due:* July 21, 2026.

2. *Docket No(s).:* MC2026–299 and K2026–296; *Filing Title:* USPS Request to Add Priority Mail Express International, Priority Mail International & First-Class Package International Service Contract 117 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 3, 2026; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3035.105, and 39 CFR 3041.310; *Public Representative:* Maxine Bradley; *Comments Due:* July 21, 2026.

III. Summary Proceeding(s)

1. *Docket No(s).:* MC2026–292 and K2026–289; *Filing Title:* USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 1029, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 2, 2026; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

2. *Docket No(s).:* MC2026–294 and K2026–291; *Filing Title:* USPS Request to Add New Mid-Market Standardized Distinct Product, PM–GA Contract 1030, and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 2, 2026; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

3. *Docket No(s).:* MC2026–295 and K2026–292; *Filing Title:* USPS Request to Add New Fulfillment Standardized Distinct Product, PM–GA Contract 1031,

and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* July 2, 2026; *Filing Authority:* 39 U.S.C. 3642 and 3633, 39 CFR 3035.105, and 39 CFR 3041.325.

This Notice will be published in the **Federal Register**.

Danielle LeFlore,

Legal Assistant.

[FR Doc. 2026–14352 Filed 7–15–26; 8:45 am]

BILLING CODE 7710–FW–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105885; File No. SR–FINRA–2026–014]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend FINRA Rule 1210 (Registration Requirements)

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 29, 2026, the Financial Industry Regulatory Authority, Inc. (''FINRA'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. FINRA has designated the proposed rule change as constituting a ''non-controversial'' rule change under paragraph (f)(6) of Rule 19b–4 under the Act,[3] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 1210 (Registration Requirements) to reduce the waiting periods for retaking FINRA qualification examinations.

The text of the proposed rule change is available on FINRA's website at *http://www.finra.org* and at the principal office of FINRA.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 17 CFR 240.19b–4(f)(6).

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

FINRA Rule 1210 requires each person engaged in the investment banking or securities business of a member to be registered with FINRA as a representative or principal in each category of registration appropriate to his or her functions and responsibilities as specified in FINRA Rule 1220 (Registration Categories), unless exempt from registration pursuant to FINRA Rule 1230 (Associated Persons Exempt from Registration). Under FINRA Rule 1210.03 (Qualification Examinations and Waivers of Examinations), before a person can be registered with FINRA he or she must pass the appropriate qualification examinations or obtain a waiver of the qualification examination requirement.

If a person fails a FINRA qualification examination, FINRA Rule 1210.06 (Waiting Periods for Retaking a Failed Examination) sets forth the time the person must wait before he or she can retake that qualification examination. For the first and second failed attempts, the person must wait 30 calendar days to retake the qualification examination. A person who fails a qualification examination three or more times within a two-year period must wait 180 calendar days before he or she can retake that examination.[4] These waiting periods apply to all FINRA qualification examinations, including the Securities Industry Essentials (''SIE'') qualification examination.[5]

[4] For the 180-day waiting period calculation, failed qualification examination attempts from more than two years ago are not included in determining the total number of times an individual has failed the qualification examination.

[5] The waiting period applies to the specific qualification examination that the person fails. For example, if a person fails the SIE examination, he or she would not be required to wait 30 days to take the Series 7 (General Securities Representative) qualification examination.

The current qualification examination waiting periods were implemented in 1989 because extensive automation of the registration and qualification process had made it possible for applicants to make multiple attempts to pass qualification examinations in rapid succession, often within very brief periods.[6] The waiting periods were adopted to address three main purposes. The first was to encourage candidates who did not pass the qualification examination to study and learn more about the job functions of the registration category rather than just focusing on the recently seen test questions. The second was to protect the integrity of the qualification examinations. Allowing an individual to retest multiple times in a short period of time increases the risk that test content could be compromised because the individual may share questions with others. The third purpose was to give FINRA time to investigate and address potential breaches of the FINRA Qualification Examination Rules of Conduct (''Rules of Conduct'').[7]

Since the implementation of the current retake waiting periods, the FINRA qualification program has undergone changes that have shifted the principal risks discussed above that originally informed the rule. Today's high-volume FINRA qualification examinations use extensive question banks that contain thousands of questions, with each test taker receiving only a small subset of questions per attempt. This approach reduces both the likelihood that repeat test takers will depend on memorized questions from prior attempts and the risk of content being disseminated to others. Additionally, FINRA employs data forensics and advanced technology to identify misconduct and compromised examination content, taking appropriate corrective action when such incidents occur. Moreover, these enhanced detection capabilities help to ensure that the shortened waiting periods would not compromise FINRA's ability to conduct timely investigations into possible cheating or other violations of the Rules of Conduct.

Over the past several years, FINRA has received input from various industry channels about the burden that the current qualification examination waiting periods place on individuals seeking to enter the securities industry. Similar feedback regarding these

[6] *See* Securities Exchange Act Release No. 26909 (June 8, 1989), 54 FR 25652 (June 16, 1989) (Order Approving File No. SR–NASD–89–14).

[7] The Rules of Conduct are available at *https://www.finra.org/registration-exams-ce/qualification-exams/exam-day/finra-rules-conduct.*

challenges was received by FINRA in response to its request for comment on modernizing FINRA rules, guidance, and processes for the organization and operation of member workplaces.[8] Given this consistent input and FINRA's current efforts to modernize its requirements to make sure that they remain relevant and effective, FINRA is proposing to shorten the required qualification examination retake waiting periods to 15 days after the first and second failed attempts, and 60 days after the third and all subsequent failed attempts that occur within a two-year period. FINRA believes that as a result of the changes to the qualification program that have occurred since the implementation of the current retake waiting periods, shortening the waiting periods in this manner would lessen the burden on individuals who are trying to register to begin their employment in the securities industry while also continuing to protect investors by maintaining appropriate program integrity.

The proposed rule change would apply only to FINRA qualification examinations (including the SIE qualification examination) and would not impact the waiting periods for other qualification examinations that FINRA administers on behalf of the Municipal Securities Rulemaking Board (''MSRB''), the National Futures Association (''NFA'') or the North American Securities Administrators Association (''NASAA'').[9] To reduce confusion regarding which waiting periods apply to which qualification examinations and in the interest of harmonizing the waiting periods across all qualification examinations should the proposal become effective, FINRA has engaged in discussions with the MSRB, the NFA and NASAA to communicate its intention to change the waiting periods.[10] If an agreement cannot be reached to harmonize the waiting periods for all qualification examinations, FINRA would work with other SROs and NASAA to address the operational implications of the proposal to mitigate any potential confusion for the securities industry.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,[11] which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

FINRA believes that the proposed rule change would lessen the burden on individuals who are trying to register to begin their employment in the securities industry in a manner that would continue to protect investors and the public interest. Specifically, as discussed above, the proposed rule change would allow FINRA to maintain the appropriate integrity of its qualification examinations. In this regard, changes to FINRA's qualifications program have reduced the risk that repeat test takers will depend on memorized questions from prior attempts and the risk of content being disseminated to others. In addition, under the proposed waiting periods, FINRA would continue to have sufficient time to conduct timely investigations into possible cheating or other misconduct.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change modifies FINRA qualification examination waiting periods in recognition of changes to the FINRA qualification program, consistent with the purposes of the waiting periods as described above.

Economic Impact Assessment

FINRA has undertaken an economic impact assessment, as set forth below, to analyze the economic baseline for the proposed amendment and its potentially significant economic impacts, including anticipated costs and benefits, relative to the baseline, and the alternatives considered in assessing how best to meet FINRA's regulatory objectives.

Regulatory Need

In light of changes to the FINRA qualification program, shorter examination retake waiting periods may offer a better balance between the benefits of promoting learning and facilitating examination security and the costs to individuals seeking registration and the firms that employ or would employ them.

Economic Baseline

The economic baseline includes the current qualification examination retake waiting period structure, the limitations on individual job functions and responsibilities during waiting periods, and the associated costs to individuals and firms. The economic baseline also includes incentives to learn, risks to qualification examination integrity and risks of qualification examination material harvesting as these risks relate to waiting periods.

We analyzed data from candidates with first attempts in 2024 for FINRA's three most popular qualification examinations: the SIE, the Series 7, and the Series 24 (General Securities Principal). Over 70 percent of individuals pass these qualification examinations on the first attempt. Retake rates vary across these qualification examinations: 65 percent of individuals who fail the SIE take the qualification examination a second time, compared to 85 percent for the Series 7 and 78 percent for the Series 24.

Economic Impacts

Under the proposed retake waiting period structure of 15–15–60 days, the cumulative mandatory waiting period until the fourth attempt for candidates who fail three consecutive attempts will fall by 150 days, to 90 days. Only some individuals, however, would make use of the opportunity under the proposed structure to proceed more quickly. For the SIE, 23 percent of individuals currently make a second attempt as quickly as possible (within 30 to 34 days). For the Series 7 and the Series 24, the figures are, respectively, 21 percent and 14 percent. These individuals may want to proceed even more quickly. However, 40 percent of individuals who take the SIE a second time currently wait over 60 days to do so. The figures for the Series 7 and the Series 24 are 32 percent and 52 percent, respectively.

[8] *See Regulatory Notice 25–07* (April 2025). All commenters addressing this topic recommended either reducing or removing the qualification examination retake waiting periods. Those who commented on the 30-day waiting periods proposed shortening them to 15 days. *See, e.g.,* letter from Roseann Viscardi, President, Association of Registration Management, Inc., to Jennifer Piorko Mitchell, Office of the Corporate Secretary, FINRA, dated July 14, 2025 (''ARM''). Concerning the 180-day waiting period, commenters proposed reducing it to either 30 or 60 days. *See, e.g.,* ARM; letter from Bernard V. Canepa, Managing Director and Associate General Counsel, and Alyssa Pompei, Vice President and Assistant General Counsel, Securities Industry and Financial Markets Association, to Jennifer Piorko Mitchell, Office of the Corporate Secretary, FINRA, dated July 14, 2025.

[9] More information on the qualification examinations that FINRA administers on behalf of the MSRB, the NFA and NASAA is available on FINRA's website at *https://www.finra.org/registration-exams-ce/qualification-exams.*

[10] FINRA also has communicated its intention to change the qualification waiting periods to other self-regulatory organizations (''SROs'') because some SROs would need to engage in rulemaking to harmonize their rules with the proposed changes as they have codified their qualification examination waiting periods under their respective rules.

[11] 15 U.S.C. 78o–3(b)(6).

Whether shortened waiting periods would affect pass rates is uncertain.

For high-volume examinations, FINRA does not expect this change would reduce the incentive to learn the material that will be tested on a qualification examination. Given large examination banks, the likelihood of seeing the same question again on an attempt is likely not much greater under the proposed rule change than currently under the baseline. For many lower-volume examinations, candidates are generally employed and looking to advance and are incentivized to study and pass.

Anticipated Benefits

Under the proposed rule change, individuals who retake and pass FINRA qualification examinations more quickly may be better positioned to advance in their careers more quickly. Members benefit from being able to give advanced job functions and responsibilities more quickly to individuals who under the baseline would retake and ultimately pass FINRA examinations. Members also benefit from being able to more quickly terminate individuals who would retake and not ultimately pass FINRA examinations. Accordingly, members spend less in salary and other expenses on individuals who do not meet their workforce needs and more on individuals who do meet such needs.[12]

Anticipated Costs

Reducing waiting periods might lead some candidates to attempt to retake a qualification examination quickly without making necessary adjustments, potentially resulting in additional failures and extending overall time to qualification. Where members can influence retake timing, they will need to determine if there are risks of additional failure and turnover from less time between retakes of qualification examinations and whether those risks are offset by other benefits.

Any reduction in waiting periods may have a nominal cost related to FINRA's ability to respond to test security concerns in a timely manner and the associated potential risks to investors and members. FINRA believes this risk is mitigated by changes to the FINRA qualification program discussed above.

Alternatives Considered

Other changes to the qualification examination waiting times were considered, including 15–30–90 days. FINRA believes that a retake waiting period structure of 15–15–60 days provides an appropriate balance between potential benefits to individuals and members and potential costs and risks described above.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[13] and Rule 19b–4(f)(6) thereunder.[14]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–FINRA–2026–014 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–FINRA–2026–014. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of FINRA. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–FINRA–2026–014 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Sherry R. Haywood,

Assistant Secretary.

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BILLING CODE 8011–01–P

[12] The assessment of the anticipated benefits of the proposed rule change assumes that the waiting periods for all qualification examinations are the same. The full potential benefits of the proposal may not be realized otherwise.

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105887; File No. SR–PEARL–2026–33]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Options Regulatory Fee (ORF)

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Pearl Options Exchange Fee Schedule (''Fee Schedule'') regarding the Options Regulatory Fee (''ORF'').

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/pearl-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange previously filed to amend its ORF assessment and collection methodology,[3] with the rate to be set closer to the implementation date of the amended ORF collection methodology. At this time, the Exchange proposes to set the ORF rate effective July 1, 2026 to $0.0240 per contract side. Additionally, the Exchange proposes to amend the rule text that describes the ORF collection methodology to provide greater clarity to the ORF collection methodology.

July 1, 2026 ORF

As of July 1, 2026, the Exchange will assess ORF for options transactions that clear in the ''customer'' range at The Options Clearing Corporation (''OCC''), however ORF will be assessed to each Members [4] for executions that occur on the Exchange. Specifically, the ORF will be collected on behalf of the Exchange from Members and non-members for all customer transactions executed on the Exchange. ORF would be assessed and collected on all ultimately cleared customer contracts, taking into account adjustments for CMTA that were provided to the Exchange the same day as the trade.[5] Further, the Exchange would bill ORF according to the clearing instructions provided on the execution. More specifically, the Exchange proposes to assess ORF based on the clearing instruction provided on the execution on trade date and would not take into consideration CMTA changes or transfers that occur at OCC.[6]

Based on the Exchange's review of regulatory costs, ORF revenue, and options transaction volume, the Exchange proposes to set the ORF rate effective July 1, 2026 to $0.0240 per contract side. On June 2, 2026, the Exchange notified Members of the proposed ORF rate effective July 1, 2026 via a Regulatory Circular.[7] The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. More specifically, the Exchange will endeavor to ensure that the amount of revenue collected from the ORF will not exceed 80% of the Exchange's regulatory costs. The Exchange will monitor its regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs in a given year, the Exchange will adjust the ORF by submitting a fee change filing to the Securities and Exchange Commission (the ''Commission''). The Exchange will notify Members of adjustments to the ORF via a Regulatory Circular in advance of any change.

As is the case today, the Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange will continue to review all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary matter will continue to offset regulatory costs.

Revenue generated from ORF, when combined with all of the Exchange's other regulatory fees and fines, is designed to cover a material portion of the regulatory costs to the Exchange of the supervision and regulation of Members' customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. Regulatory costs include direct regulatory expenses and certain indirect expenses in support of the regulatory function. The direct expenses include in-house and third party service provider costs to support the day-to-day regulatory work such as surveillances, investigations and examinations. The indirect expenses are only those expenses that are in support of the regulatory functions, such areas include Office of the General Counsel, technology, finance, and internal audit.

Rule Text Amendment

The Exchange proposes to delete the last sentence of the rule text ''The ORF is not assessed on outbound linkage trades.'' This revision more accurately describes the Exchange's collection process as explained in its prior rule proposal.[8] The Exchange proposes this revised rule text because it provides greater clarity to the manner in which ORF is collected.

Additionally, the Exchange proposes to remove obsolete text regarding an ORF rate that is no longer in effect.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [9] in general, and furthers the objectives of Section 6(b)(4) of the Act [10] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [11] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that the proposed fee change is reasonable, equitable and not unfairly discriminatory in that it is charged to all

[3] *See* Securities and Exchange Act Release No. 104711 (January 28, 2026) 91 FR 4771 (February 2, 2026) (SR–PEARL–2026–01)(Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt a New Methodology for Assessment and Collection of the Options Regulatory Fee (ORF)).

[4] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of Exchange Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[5] Adjustments to CMTA that occur at OCC would not be taken into account.

[6] Adjustments that were made the same day as the trade on the Exchange will be taken into account.

[7] *See https://www.miaxglobal.com/alert/2026/06/02/miax-exchange-group-option-markets-options-regulatory-fee-1.*

[8] *See supra* note 3.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78f(b)(5).

Exchange transactions that clear in the ''customer'' range at the OCC. Additionally, the Exchange believes that the proposed fee change ensures fairness by assessing a specific fee to those Members that require more Exchange regulatory services based on the amount of customer options business they conduct. Over recent years, options trading volume has increased with a growing percentage of the volume applicable to customer transactions. Customers trading on the Exchange (through a Member) benefit from the protections of a robust regulatory program including the maintenance of fair and orderly markets and protections against fraud and other manipulation. The Exchange believes it is equitable and not unfairly discriminatory to assess a regulatory fee to transactions that clear in the ''customer'' range to cover regulatory costs, but not to transactions clearing in the ''firm'' or ''market maker'' range because Clearing Members [12] and Market Makers [13] (who clear in the Firm and Market Maker range), as those market participants are generally subject to other Exchange fees, fines and obligations. For example, Clearing Members and Market Makers are required to pay Exchange application fees, permit fees, and connectivity fees, amongst others. In addition, all fines issued by the Exchange for regulatory infractions are assessed only to Members and would be applied to regulatory revenues. The Exchange expects that Clearing Members from whom the ORF is collected will pass through the fee to their customers (as the Exchange understands occurs today). In addition, Market Makers in particular are subject to various quoting and other obligations to ensure that they provide stable and liquid markets, which benefit all market participants including customers. Excluding Market Maker transactions from the ORF collection will allow Market Makers to better manage their costs more effectively thus enabling them to better allocate resources toward technology, risk management, and capacity to ensure continued liquidity provision.

In addition to the overall increase in ''customer'' range volume generally, regulating customer trading activity is more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. For example, there are costs associated with main office and branch office examinations (*e.g.,* staff and travel expenses), as well as investigations into customer complaints and terminations of registered persons. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* Clearing Member proprietary transactions) of its regulatory program.[14] While the Exchange notes that it has broad regulatory responsibilities with respect to its Member's activities, irrespective of where their transactions take place, the Exchange believes it is reasonable to assess the proposed fee to only those transactions occurring on the Exchange. The proposed change more narrowly tailors the fee to products and transactions with a direct connection to the Exchange. With this proposal, transactions that would clear in the ''customer'' range occurring on other exchanges would no longer be subject to an ORF assessed by the Exchange.

The Exchange further believes that the proposed change fee is reasonable because it would help ensure that revenue collected from the ORF, in combination with other regulatory fees and fines, would cover a material portion of the Exchange's regulatory costs.

As noted above, the Exchange will also continue to monitor on at least a semiannual basis the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, would cover a material portion of the Exchange's regulatory costs and not exceed it.

Additionally, the Exchange proposes to delete the last sentence of the rule text and to remove obsolete text regarding the ORF rate that is no longer in effect. The Exchange believes that the proposal to delete the last sentence of the rule text and to remove obsolete text regarding the ORF rate that is no longer in effect would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed change would provide greater clarity to market participants regarding the Exchange's Fee Schedule. It is in the public interest for the Exchange's Fee Schedule to be accurate so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity on the Exchange, thereby raising regulatory revenue to offset regulatory expenses. It also supplements the regulatory revenue derived from non-customer activity. The Exchange notes, however, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and paragraph (f) of Rule 19b–4 [16] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

[12] Clearing Member means a Member that has been admitted to membership in the Clearing Corporation pursuant to the provisions of the rules of the Clearing Corporation. *See* Exchange Rule 100.

[13] Market Maker means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of the Exchange Rules. *See* Exchange Rule 100.

[14] If the Exchange changes its method of funding regulation or if circumstances otherwise change in the future, the Exchange may decide to modify the ORF or assess a separate regulatory fee on Member proprietary transactions if the Exchange deems it advisable.

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2026–33 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–PEARL–2026–33. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2026–33 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14264 Filed 7–15–26; 8:45 am]

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[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105890; File No. SR–CboeBZX–2026–058]

Self-Regulatory Organizations; Cboe BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change to Amend the Definition of Professional To Require Monthly Reviews of Orders

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe BZX Exchange, Inc. (the ''Exchange'' or ''BZX'') proposes to amend the definition of Professional[3] to require monthly reviews of orders. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/equities/regulation/rule_filings/bzx/*), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Rule 16.1, which defines Professional as any person or entity that (A) is not a broker or dealer in securities; and (B) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). All Professional orders shall be appropriately marked by Options Members.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the definition of Professional to modify the Exchange's quarterly review of Professional orders. This filing is based on a proposal recently submitted by Nasdaq ISE, LLC (''ISE'').[4]

Today, orders for any Public Customer[5] that average more than 390 orders per day during any month of a calendar quarter must be represented as Professional orders for the next calendar quarter.[6] In order to properly represent orders entered on the Exchange, Options Members[7] are required currently to review their Public Customers' activity and, on at least a quarterly basis, designate orders as Public Customer orders or Professional orders.[8] Specifically, Options Members are required to conduct a quarterly review and make any appropriate changes to the way in which they are representing orders within five days after the end of each calendar quarter.[9] While Options Members are required to designate accounts on a quarterly basis, if during a quarter the Exchange identifies a customer for which orders are being represented as Public Customer orders but that has averaged more than 390 orders per day during a month, the Exchange must notify the Options Member and the Options Member is required to change the manner in which it is representing the customer's orders within five days.[10]

[4] *See* Securities Exchange Act Release No. 105218 (April 13, 2026), 91 FR 20542 (April 16, 2026) (SR ISE–2026–16) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Review of Professional Orders.)

[5] *See* Rule 16.1, which defines Public Customer as a person that is not a broker or dealer in securities.

[6] The requirement to review Public Customers' activity on at least a quarterly basis to determine whether orders that are not for the account of a broker-dealer should be represented as Public Customer Orders or Professional Orders is not in the current rule text, however it was described in the adopting proposal. See Securities Exchange Act Release No. 78226 (July 5, 2016), 81 FR 44903 (July 11, 2016) (BatsBZX–2016–31) (Notice of Filing of Proposed Rule Change Relating to Calculation Methodology for Counting Professional Orders) (''SR–BatsBZX–2016–31''). The current proposal seeks to codify the timing for review of Public Customers' activity.

[7] *See* Rule 16.1, which defines Options Member as a firm, or organization that is registered with the Exchange pursuant to Chapter XVII of these Rules for purposes of participating in options trading on BZX Options as an ''Options Order Entry Firm'' or ''Options Market-Maker.''

[8] *See* 81 FR 44903 at 44904.

[9] *See id.*

[10] *See id.*

Proposal

At this time, the Exchange proposes to shorten the quarterly review and designation to a monthly review. The Exchange proposes to amend the definition of Professional in Rule 16.1 to require that orders for any customer that had an average of more than 390 orders per day during any calendar month be represented as Professional orders for the next calendar month.

As noted, currently, each Options Member is required to monitor Public Customer orders to determine if the Public Customer has averaged more than 390 orders per day during a month. Determining whether a Public Customer has executed more than 390 orders per day during a month requires computing a daily average. As such, Options Members should be performing the workflow necessary to designate orders on a daily basis. Therefore, the proposal does not amend the current workflow, rather, the proposal amends the timeframe to change the manner in which the customer's order is being represented from five days after the end of each calendar quarter to five days after the end of each calendar month.

The Exchange does not believe that this amendment is a significant departure from the current rule, nor does it impose any burden on any Options Member because each broker-dealer is required currently to perform the necessary calculation daily to arrive at the requisite average. Further, in addition to the calculation, broker-dealers are subject to know-your-customer and suitability requirements under FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) and would need to consider whether a customer meets the Professional designation for purposes of determining best execution and making appropriate recommendations. The Exchange notes that the trading behavior of a Public Customer can be distinguished from that of a Professional which is the purpose of the separate designations. Finally, some Options Members currently designate a Public Customer that has averaged more than 390 orders per day during a month as a Professional on a more expedited basis, not waiting until five days after the quarter.

The Exchange believes that a calendar month is a sufficient time period to determine whether the activity of a customer meets the criteria for a Professional order. The Exchange believes that the shortened time period will ensure that the spirit of the designation of Professional order is met in that Options Members will make any appropriate changes to the way in which they are representing orders in a 30-day timeframe as opposed to a 90-day timeframe, thereby ensuring the designation is applied in a more expeditious manner.

The Exchange continues to believe that identifying Professional Orders based upon the average number of orders entered in qualified accounts is an appropriate and objective approach to reasonably distinguish such persons and entities from retail investors or market participants.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange's proposal to shorten the quarterly look-back to a monthly look-back is consistent with the Act because it will ensure that the spirit of the designation of Professional order continues to be met, only on a more expedited basis—removing a potential delay of two months before affecting a change in the designation. The Exchange believes that this amendment will remove impediments to and perfect the mechanism of a free and open market and a national market system by promoting the consistent application of its rules and shortening the timeframe to change the designation for all Options Members while continuing to provide a sufficient time period to determine whether the activity of a customer meets the criteria for a Professional order. Further, the Exchange believes that the shortened time period will continue to promote consistency in the treatment of orders as Professional orders while also preventing members with high volume from receiving benefits reserved for Public Customer orders.

As noted, currently, each Options Member is required to monitor Public Customer orders to determine if the Public Customer has averaged more than 390 orders per day during a month. Determining whether a Public Customer has executed more than 390 orders per day during a month requires computing a daily average. As such, Options Members should be performing the workflow necessary to designate orders on a daily basis. Therefore, the proposal does not amend the current workflow, rather, the proposal amends the timeframe to change the manner in which the customer's order is being represented from five days after the end of each calendar quarter to five days after the end of each calendar month.

The Exchange does not believe that this amendment is a significant departure from the current rule, nor does it impose any burden on any Options Member because each broker-dealer is required currently to perform the necessary calculation daily to arrive at the requisite average. Further, in addition to the calculation, broker-dealers are subject to know-your customer and suitability requirements under FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) and would need to consider whether a customer meets the Professional designation for purposes of determining best execution and making appropriate recommendations. Finally, some Options Members currently designate a Public Customer that has averaged more than 390 orders per day during a month as a Professional on a more expedited basis, not waiting until five days after the quarter.

The Exchange notes that the trading behavior of a Public Customer can be distinguished from that of a Professional which is the purpose of the separate designations. The Exchange continues to believe that identifying Professional orders based upon the average number of orders entered in qualified accounts is an appropriately objective approach to reasonably distinguish such persons and entities from retail investors or market participants. Priority is one of the marketplace advantages provided to Public Customer orders on the Exchange. Public Customer orders are given execution priority over non-Customer orders and quotations of market makers at the same price. Another marketplace advantage afforded

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

to Public Customer orders on the Exchange is that members are generally not assessed transaction fees or are assessed lower fees for the execution of Public Customer orders. The purpose of these marketplace advantages is to attract retail order flow to the Exchange by leveling the playing field for retail investors over market Professionals. This proposal will continue to provide Public Customer accounts with marketplace advantages and distinguish those accounts non-Professional retail investors from the Professionals accounts. The Exchange notes that some non-broker-dealer individuals and entities have access to information and technology that enables them to Professionally trade listed options in the same manner as a broker or dealer in securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange does not believe that the proposed rule change will impose any burden on intra-market competition because, today, each Options Member is required to monitor Public Customer orders to determine if the Public Customer has averaged more than 390 orders per day during a month. Determining whether a Public Customer has executed more than 390 orders per day during a month requires computing a daily average. As such, Options Members should be performing the workflow necessary to designate orders on a daily basis. Therefore, the proposal does not amend the current workflow, rather, the proposal amends the timeframe to change the manner in which the customer's order is being represented from five days after the end of each calendar quarter to five days after the end of each calendar month.

The Exchange does not believe that this amendment is a significant departure from the current rule, nor does it impose any burden on any Options Member because each broker-dealer is required currently to perform the necessary calculation daily to arrive at the requisite average. Further, in addition to the calculation, broker-dealers are subject to know-your-customer and suitability requirements under FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) and would need to consider whether a customer meets the Professional designation for purposes of determining best execution and making appropriate recommendations. Finally, some Options Members currently designate a Public Customer that has averaged more than 390 orders per day during a month as a Professional on a more expedited basis, not waiting until five days after the quarter.

The Exchange notes that the trading behavior of a Public Customer can be distinguished from that of a Professional which is the purpose of the separate designations.

Further, the designation of Professional orders would not result in any different treatment of such orders for purposes of compliance with the Exchange's Rules. Public Customers have been granted certain priority over other non-broker-dealer individuals and entities that have access to information and technology that enables them to Professionally trade listed options in the same manner as a broker or dealer in securities. Further, the Public Customer designation allows the Exchange to attract order flow or create more competitive markets.

Also, the Exchange does not believe that the proposed rule change will impose any burden on inter-market competition because other exchanges are expected to adopt similar rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6)[15] thereunder.[16]

A proposed rule change filed under Rule 19b–4(f)(6)[17] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[18] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the proposed rule change will ensure fair competition among the exchanges by allowing the Exchange to shorten the quarterly review and designation to a monthly review of Options Members to determine whether the activity of a customer meets the criteria for a Professional order. For these reasons, and because the proposed rule change raises no new or novel legal or regulatory issues, the Commission finds that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.[19]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CboeBZX–2026–058 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 240.19b–4(f)(6)(iii).

[19] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CboeBZX–2026–058. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CboeBZX–2026–058 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14266 Filed 7–15–26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105892; File No. SR–EMERALD–2026–18]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Options Regulatory Fee (ORF)

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Emerald Options Exchange Fee Schedule (''Fee Schedule'') regarding the Options Regulatory Fee (''ORF'').

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/emerald-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange previously filed to amend its ORF assessment and collection methodology,[3] with the rate to be set closer to the implementation date of the amended ORF collection methodology. At this time, the Exchange proposes to set the ORF rate effective July 1, 2026 to $0.0220 per contract side. Additionally, the Exchange proposes to amend the rule text that describes the ORF collection methodology to provide greater clarity to the ORF collection methodology.

July 1, 2026 ORF

As of July 1, 2026, the Exchange will assess ORF for options transactions that clear in the ''customer'' range at The Options Clearing Corporation (''OCC''), however ORF will be assessed to each Members [4] for executions that occur on the Exchange. Specifically, the ORF will be collected on behalf of the Exchange from Members and non-members for all customer transactions executed on the Exchange. ORF would be assessed and collected on all ultimately cleared customer contracts, taking into account adjustments for CMTA that were provided to the Exchange the same day as the trade.[5] Further, the Exchange would bill ORF according to the clearing instructions provided on the execution. More specifically, the Exchange proposes to assess ORF based on the clearing instruction provided on the execution on trade date and would not take into consideration CMTA changes or transfers that occur at OCC.[6]

Based on the Exchange's review of regulatory costs, ORF revenue, and options transaction volume, the Exchange proposes to set the ORF rate effective July 1, 2026 to $0.0220 per contract side. On June 2, 2026, the Exchange notified Members of the proposed ORF rate effective July 1, 2026 via a Regulatory Circular.[7] The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. More specifically, the Exchange will endeavor to ensure that the amount of revenue collected from the ORF will not exceed 80% of the Exchange's regulatory costs. The Exchange will monitor its regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs in a given year, the Exchange will adjust the ORF by submitting a fee change filing to the Securities and Exchange Commission (the ''Commission''). The Exchange will notify Members of adjustments to the ORF via a Regulatory Circular in advance of any change.

As is the case today, the Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange will continue to review all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines

[20] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities and Exchange Act Release No. 104709 (January 28, 2026) 91 FR 4653 (February 2, 2026) (SR–EMERALD–2026–01)(Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt a New Methodology for Assessment and Collection of the Options Regulatory Fee (ORF)).

[4] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[5] Adjustments to CMTA that occur at OCC would not be taken into account.

[6] Adjustments that were made the same day as the trade on the Exchange will be taken into account.

[7] *See https://www.miaxglobal.com/alert/2026/06/02/miax-exchange-group-option-markets-options-regulatory-fee-1.*

collected by the Exchange in connection with a disciplinary matter will continue to offset regulatory costs.

Revenue generated from ORF, when combined with all of the Exchange's other regulatory fees and fines, is designed to cover a material portion of the regulatory costs to the Exchange of the supervision and regulation of Members' customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. Regulatory costs include direct regulatory expenses and certain indirect expenses in support of the regulatory function. The direct expenses include in-house and third party service provider costs to support the day-to-day regulatory work such as surveillances, investigations and examinations. The indirect expenses are only those expenses that are in support of the regulatory functions, such areas include Office of the General Counsel, technology, finance, and internal audit.

Rule Text Amendment

The Exchange proposes to delete the last sentence of the rule text ''The ORF is not assessed on outbound linkage trades.'' This revision more accurately describes the Exchange's collection process as explained in its prior rule proposal.[8] The Exchange proposes this revised rule text because it provides greater clarity to the manner in which ORF is collected.

Additionally, the Exchange proposes to remove obsolete text regarding an ORF rate that is no longer in effect.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[9] in general, and furthers the objectives of Section 6(b)(4) of the Act[10] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act[11] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that the proposed fee change is reasonable, equitable and not unfairly discriminatory in that it is charged to all Exchange transactions that clear in the ''customer'' range at the OCC. Additionally, the Exchange believes that the proposed fee change ensures fairness by assessing a specific fee to those Members that require more Exchange regulatory services based on the amount of customer options business they conduct. Over recent years, options trading volume has increased with a growing percentage of the volume applicable to customer transactions. Customers trading on the Exchange (through a Member) benefit from the protections of a robust regulatory program including the maintenance of fair and orderly markets and protections against fraud and other manipulation. The Exchange believes it is equitable and not unfairly discriminatory to assess a regulatory fee to transactions that clear in the ''customer'' range to cover regulatory costs, but not to transactions clearing in the ''firm'' or ''market maker'' range because Clearing Members[12] and Market Makers[13] (who clear in the Firm and Market Maker range), as those market participants are generally subject to other Exchange fees, fines and obligations. For example, Clearing Members and Market Makers are required to pay Exchange application fees, permit fees, and connectivity fees, amongst others. In addition, all fines issued by the Exchange for regulatory infractions are assessed only to Members and would be applied to regulatory revenues. The Exchange expects that Clearing Members from whom the ORF is collected will pass through the fee to their customers (as the Exchange understands occurs today). In addition, Market Makers in particular are subject to various quoting and other obligations to ensure that they provide stable and liquid markets, which benefit all market participants including customers. Excluding Market Maker transactions from the ORF collection will allow Market Makers to better manage their costs more effectively thus enabling them to better allocate resources toward technology, risk management, and capacity to ensure continued liquidity provision.

In addition to the overall increase in ''customer'' range volume generally, regulating customer trading activity is more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. For example, there are costs associated with main office and branch office examinations (*e.g.,* staff and travel expenses), as well as investigations into customer complaints and terminations of registered persons. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* Clearing Member proprietary transactions) of its regulatory program.[14] While the Exchange notes that it has broad regulatory responsibilities with respect to its Member's activities, irrespective of where their transactions take place, the Exchange believes it is reasonable to assess the proposed fee to only those transactions occurring on the Exchange. The proposed change more narrowly tailors the fee to products and transactions with a direct connection to the Exchange. With this proposal, transactions that would clear in the ''customer'' range occurring on other exchanges would no longer be subject to an ORF assessed by the Exchange.

The Exchange further believes that the proposed change fee is reasonable because it would help ensure that revenue collected from the ORF, in combination with other regulatory fees and fines, would cover a material portion of the Exchange's regulatory costs.

As noted above, the Exchange will also continue to monitor on at least a semiannual basis the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory

[8] *See supra* note 3.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78f(b)(5).

[12] Clearing Member means a Member that has been admitted to membership in the Clearing Corporation pursuant to the provisions of the rules of the Clearing Corporation. *See* Exchange Rule 100.

[13] Market Makers refers to ''Lead Market Makers,'' ''Primary Lead Market Makers,'' and ''Registered Market Makers'' collectively. Lead Market Maker means a Member registered with the Exchange for the purpose of making markets in securities traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of these Rules with respect to Lead Market Makers. Primary Lead Market Maker means a Lead Market Maker appointed by the Exchange to act as the Primary Lead Market Maker for the purpose of making markets in securities traded on the Exchange. Registered Market Maker means a Member registered with the Exchange for the purpose of making markets in securities traded on the Exchange, who is not a Lead Market Maker and is vested with the rights and responsibilities specified in Chapter VI of these Rules with respect to Registered Market Makers. *See* Exchange Rule 100.

[14] If the Exchange changes its method of funding regulation or if circumstances otherwise change in the future, the Exchange may decide to modify the ORF or assess a separate regulatory fee on Member proprietary transactions if the Exchange deems it advisable.

fees and fines, would cover a material portion of the Exchange's regulatory costs and not exceed it.

Additionally, the Exchange proposes to delete the last sentence of the rule text and to remove obsolete text regarding the ORF rate that is no longer in effect. The Exchange believes that the proposal to delete the last sentence of the rule text and to remove obsolete text regarding the ORF rate that is no longer in effect would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed change would provide greater clarity to market participants regarding the Exchange's Fee Schedule. It is in the public interest for the Exchange's Fee Schedule to be accurate so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity on the Exchange, thereby raising regulatory revenue to offset regulatory expenses. It also supplements the regulatory revenue derived from non-customer activity. The Exchange notes, however, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and paragraph (f) of Rule 19b–4 [16] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–EMERALD–2026–18 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–EMERALD–2026–18. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–EMERALD–2026–18 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14268 Filed 7–15–26; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105891; File No. SR–CBOE–2026–060]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Definition of Professional To Require Monthly Reviews of Orders

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to amend the definition of Professional [3] to require monthly reviews of orders. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/options/regulation/rule_filings/cone/*), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Rule 1.1, which defines Professional as any person or entity that (a) is not a broker or dealer in securities, and (b) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).

the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the definition of Professional to modify the Exchange's quarterly review of Professional orders. This filing is based on a proposal recently submitted by Nasdaq ISE, LLC (''ISE'').[4]

Today, orders for any Public Customer[5] that average more than 390 orders per day during any month of a calendar quarter must be represented as Professional orders for the next calendar quarter.[6] In order to properly represent orders entered on the Exchange, Trading Permit Holder Organizations (''TPH organizations'')[7] are required currently to review their Public Customers' activity and, on at least a quarterly basis, designate orders as Public Customer orders or Professional orders.[8] Specifically, TPH organizations are required to conduct a quarterly review and make any appropriate changes to the way in which they are representing orders within five days after the end of each calendar quarter.[9] While TPH organizations are required to designate accounts on a quarterly basis, if during a quarter the Exchange identifies a customer for which orders are being represented as Public Customer orders but that has averaged more than 390 orders per day during a month, the Exchange must notify the TPH organization and the TPH organization is required to change the manner in which it is representing the customer's orders within five days.[10]

Proposal

At this time, the Exchange proposes to shorten the quarterly review and designation to a monthly review. The Exchange proposes to amend the definition of Professional in Rule 1.1 to require that orders for any customer that had an average of more than 390 orders per day during any calendar month be represented as Professional orders for the next calendar month.

As noted, currently, each TPH organization is required to monitor Public Customer orders to determine if the Public Customer has averaged more than 390 orders per day during a month. Determining whether a Public Customer has executed more than 390 orders per day during a month requires computing a daily average. As such, TPH organizations should be performing the workflow necessary to designate orders on a daily basis. Therefore, the proposal does not amend the current workflow, rather, the proposal amends the timeframe to change the manner in which the customer's order is being represented from five days after the end of each calendar quarter to five days after the end of each calendar month.

The Exchange does not believe that this amendment is a significant departure from the current rule, nor does it impose any burden on any TPH organization because each broker-dealer is required currently to perform the necessary calculation daily to arrive at the requisite average. Further, in addition to the calculation, broker-dealers are subject to know-your-customer and suitability requirements under FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) and would need to consider whether a customer meets the Professional designation for purposes of determining best execution and making appropriate recommendations. The Exchange notes that the trading behavior of a Public Customer can be distinguished from that of a Professional which is the purpose of the separate designations. Finally, some TPH organizations currently designate a Public Customer that has averaged more than 390 orders per day during a month as a Professional on a more expedited basis, not waiting until five days after the quarter.

The Exchange believes that a calendar month is a sufficient time period to determine whether the activity of a customer meets the criteria for a Professional order. The Exchange believes that the shortened time period will ensure that the spirit of the designation of Professional order is met in that TPH organizations will make any appropriate changes to the way in which they are representing orders in a 30-day timeframe as opposed to a 90-day timeframe, thereby ensuring the designation is applied in a more expeditious manner. The Exchange continues to believe that identifying Professional Orders based upon the average number of orders entered in qualified accounts is an appropriate and objective approach to reasonably distinguish such persons and entities from retail investors or market participants.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange's proposal to shorten the quarterly look-back to a monthly look-back is consistent with the Act because it will ensure that the spirit of the designation of Professional

[4] *See* Securities Exchange Act Release No. 105218 (April 13, 2026), 91 FR 20542 (April 16, 2026) (SR ISE–2026–16) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Review of Professional Orders).

[5] *See* Rule 1.1, which defines Public Customer as a person that is not a Broker-Dealer.

[6] The requirement to review Public Customers' activity on at least a quarterly basis to determine whether orders that are not for the account of a broker-dealer should be represented as Public Customer Orders or Professional Orders is not in the current rule text, however it was described in the adopting proposal. See Securities Exchange Act Release No. 77049 (February 4, 2016), 81 FR 7173 (February 10, 2016) (CBOE–2016–005) (Notice of Filing of Proposed Rule Change Relating to Professionals Order Counting) (''SR–CBOE–2016–005''). The current proposal seeks to codify the timing for review of Public Customers' activity.

[7] *See* Cboe By-Laws, which defines ''Trading Permit Holder'' as any individual, corporation, partnership, limited liability company or other entity authorized by the Rules that holds a Trading Permit. If a Trading Permit Holder is an individual, the Trading Permit Holder may also be referred to as an ''individual Trading Permit Holder.'' If a Trading Permit Holder is not an individual, the Trading Permit Holder may also be referred to as a ''TPH organization.'' A Trading Permit Holder is a ''member'' solely for purposes of the Act; however, one's status as a Trading Permit Holder does not confer on that Person any ownership interest in the Exchange

[8] *See* 81 FR 7173 at 7178

[9] *See id.*

[10] *See id.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

order continues to be met, only on a more expedited basis—removing a potential delay of two months before affecting a change in the designation. The Exchange believes that this amendment will remove impediments to and perfect the mechanism of a free and open market and a national market system by promoting the consistent application of its rules and shortening the timeframe to change the designation for all TPH organizations while continuing to provide a sufficient time period to determine whether the activity of a customer meets the criteria for a Professional order. Further, the Exchange believes that the shortened time period will continue to promote consistency in the treatment of orders as Professional orders while also preventing members with high volume from receiving benefits reserved for Public Customer orders.

As noted, currently, each TPH organization is required to monitor Public Customer orders to determine if the Public Customer has averaged more than 390 orders per day during a month. Determining whether a Public Customer has executed more than 390 orders per day during a month requires computing a daily average. As such, TPH Organizations should be performing the workflow necessary to designate orders on a daily basis. Therefore, the proposal does not amend the current workflow, rather, the proposal amends the timeframe to change the manner in which the customer's order is being represented from five days after the end of each calendar quarter to five days after the end of each calendar month.

The Exchange does not believe that this amendment is a significant departure from the current rule, nor does it impose any burden on any TPH organization because each broker-dealer is required currently to perform the necessary calculation daily to arrive at the requisite average. Further, in addition to the calculation, broker-dealers are subject to know-your customer and suitability requirements under FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) and would need to consider whether a customer meets the Professional designation for purposes of determining best execution and making appropriate recommendations. Finally, some TPH organizations currently designate a Public Customer that has averaged more than 390 orders per day during a month as a Professional on a more expedited basis, not waiting until five days after the quarter.

The Exchange notes that the trading behavior of a Public Customer can be distinguished from that of a Professional which is the purpose of the separate designations. The Exchange continues to believe that identifying Professional orders based upon the average number of orders entered in qualified accounts is an appropriately objective approach to reasonably distinguish such persons and entities from retail investors or market participants. Priority is one of the marketplace advantages provided to Public Customer orders on the Exchange. Public Customer orders are given execution priority over non-Customer orders and quotations of market makers at the same price. Another marketplace advantage afforded to Public Customer orders on the Exchange is that members are generally not assessed transaction fees or are assessed lower fees for the execution of Public Customer orders. The purpose of these marketplace advantages is to attract retail order flow to the Exchange by leveling the playing field for retail investors over market Professionals. This proposal will continue to provide Public Customer accounts with marketplace advantages and distinguish those accounts non-Professional retail investors from the Professionals accounts. The Exchange notes that some non-broker-dealer individuals and entities have access to information and technology that enables them to Professionally trade listed options in the same manner as a broker or dealer in securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange does not believe that the proposed rule change will impose any burden on intra-market competition because, today, each TPH organization is required to monitor Public Customer orders to determine if the Public Customer has averaged more than 390 orders per day during a month. Determining whether a Public Customer has executed more than 390 orders per day during a month requires computing a daily average. As such, TPH organizations should be performing the workflow necessary to designate orders on a daily basis. Therefore, the proposal does not amend the current workflow, rather, the proposal amends the timeframe to change the manner in which the customer's order is being represented from five days after the end of each calendar quarter to five days after the end of each calendar month.

The Exchange does not believe that this amendment is a significant departure from the current rule, nor does it impose any burden on any TPH organization because each broker-dealer is required currently to perform the necessary calculation daily to arrive at the requisite average. Further, in addition to the calculation, broker-dealers are subject to know-your-customer and suitability requirements under FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) and would need to consider whether a customer meets the Professional designation for purposes of determining best execution and making appropriate recommendations. Finally, some TPH organizations currently designate a Public Customer that has averaged more than 390 orders per day during a month as a Professional on a more expedited basis, not waiting until five days after the quarter.

The Exchange notes that the trading behavior of a Public Customer can be distinguished from that of a Professional which is the purpose of the separate designations. Further, the designation of Professional orders would not result in any different treatment of such orders for purposes of compliance with the Exchange's Rules. Public Customers have been granted certain priority over other non-broker-dealer individuals and entities that have access to information and technology that enables them to Professionally trade listed options in the same manner as a broker or dealer in securities. Further, the Public Customer designation allows the Exchange to attract order flow or create more competitive markets.

Also, the Exchange does not believe that the proposed rule change will impose any burden on inter-market competition because other exchanges are expected to adopt similar rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the

Act[14] and Rule 19b–4(f)(6)[15] thereunder.[16]

A proposed rule change filed under Rule 19b–4(f)(6)[17] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[18] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the proposed rule change will ensure fair competition among the exchanges by allowing the Exchange to shorten the quarterly review and designation to a monthly review of TPH organizations to determine whether the activity of a customer meets the criteria for a Professional order. For these reasons, and because the proposed rule change raises no new or novel legal or regulatory issues, the Commission finds that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and designates the proposed rule change to be operative upon filing.[19]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act.

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 240.19b–4(f)(6)(iii).

[19] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–CBOE–2026–060 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–CBOE–2026–060. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–CBOE–2026–060 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14267 Filed 7–15–26; 8:45 am]

BILLING CODE 8011–01–P

[20] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105896; File No. SR–EMERALD–2026–17]

Self-Regulatory Organizations; MIAX Emerald, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Emerald Options Exchange Fee Schedule To Extend the Temporary Discount Program for Historical Requests of Certain Open-Close Report Data Until December 31, 2026

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'')[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, MIAX Emerald, LLC (''MIAX Emerald'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Emerald Options Exchange Fee Schedule (''Fee Schedule'') to extend the temporary discount program for historical requests of certain Open-Close Report (described below) data.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/emerald-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 6)e) of the Fee Schedule to extend the temporary discount program for historical requests of certain Open-Close Report data until December 31, 2026. In general, the Exchange currently provides a temporary 20% discount on fees assessed to Open-Close Report subscribers that purchase $20,000 or more in a single order of historical Open-Close Report data (with one exception, described below), which

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

discount is set to expire on June 30, 2026.[3]

By way of background, the Exchange offers an end-of-day summary and two intra-day versions of the Open-Close Report (described in more detail below).[4] The End-of-Day Open-Close Report (referred to herein as the ''End-of-Day Report'') is a volume summary of trading activity on the Exchange at the option level by origin (Priority Customer,[5] Non-Priority Customer, Firm, Broker-Dealer, and Market Maker[6]), side of the market (buy or sell), contract volume, and transaction type (opening or closing). All volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts).

The Intra-Day Open-Close Report provides similar information to that of the End-of-Day Report but is produced and updated at two different intervals during the trading day: 1 minute (referred to herein as the ''1-Minute Report'') and 10 minutes (referred to herein as the ''10-Minute Report''). For the 1-Minute Report and 10-Minute Report, data is captured in ''snapshots'' taken every 1 minute or 10 minutes, respectively, throughout the trading day and is available to subscribers within five minutes of the conclusion of each 1 minute or 10 minute period. Each update represents the aggregate data captured from the current ''snapshot'' and all previous ''snapshots.'' The 1-Minute and 10-Minute Reports provides a volume summary of trading activity on the Exchange at the option level by origin (Priority Customer, Non-Priority Customer, Firm, Broker-Dealer, and Market Maker), side of the market (buy or sell), and transaction type (opening or closing). All volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts).

Each version of the Open-Close Report contains proprietary Exchange trade data and does not include trade data from any other exchange. The Intra-Day and End-of-Day Open-Close Report data products are completely voluntary products, in that the Exchange is not required by any rule or regulation to make this data available and that potential customers may purchase it on an ad-hoc basis only if they voluntarily choose to do so. The Open-Close Report is also a historical data product and not a real-time data feed.

The Exchange makes the Open-Close Report available for purchase to Members[7] and non-Members.[8] Customers may currently purchase the Open-Close Report on a subscription basis (monthly) or by ad-hoc request for a specified month or number of months. The Exchange assesses the following fees for active subscriptions: $600 per month for subscribing to the End-of-Day Report; $2,000 per month for subscribing to the 10-Minute Report; and $6,000 per month for subscribing to the 1-Minute Report.[9] The Exchange also assesses the following fees for ad-hoc historical requests: $500 per request per month for ad-hoc requests for historical End-of-Day Report data;[10] $1,000 per request per month for ad-hoc requests for historical 10-Minute Report data;[11] and $2,500 per request per month for ad-hoc requests for historical 1-Minute Report data.[12] The Exchange also provides discounts or free data for customers who request multiple subscriptions, make ad-hoc requests for historical data for multiple types of the Open-Close Report, or who are Qualifying Academic Purchasers.[13]

Open-Close Report data is subject to direct competition from similar end-of-day and intra-day options trading summaries offered by several other options exchanges.[14] All of these exchanges offer essentially the same end-of-day and intra-day options trading summary information for trading activity on those exchanges.

Currently, the Exchange provides a temporary pricing incentive program in which subscribers that make ad-hoc requests for historical Open-Close Report data receive a percentage fee discount when a specific purchase threshold is met. Footnote ''e.'' below the table of fees in Section 6)e) of the Fee Schedule provides that from January 1, 2026 through June 30, 2026, any single ad-hoc purchase of historical End-of-Day Report data and/or historical 10-Minute Report data by an existing End-of-Day Report or 10-Minute Report subscriber totaling $20,000 or more, will receive a 20% discount when the subscriber purchases the same category of historical data for which they have a monthly subscription.[15] Section 6)e) of the Fee Schedule further provides that this discount cannot be combined with any other discount offered by the Exchange, including the academic discount provided to Qualifying Academic Purchasers of historical Open-Close Report data. To encourage the purchase of monthly subscriptions to Open-Close Report data, the temporary discount program is provided only to existing monthly subscribers who purchase the same category of historical data for which they have a monthly End-of-Day Report or 10-Minute Report subscription. The temporary discount program is currently set to expire on June 30, 2026.

The Exchange now proposes to extend the temporary discount program until December 31, 2026.[16] The purpose of this extension is to continue attracting subscribers of historical Open-Close Report data and making such data more widely accessible. The Exchange notes that the proposed discount will continue to not apply to ad-hoc historical requests for the 1-Minute Report.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Section 6(b)(5)

[3] *See* Securities Exchange Act Release No. 104605 (January 14, 2026), 91 FR 2410 (January 20, 2026) (SR–EMERALD–2025–24).

[4] *See, generally,* Exchange Rule 531(e)(1).

[5] *See* Exchange Rule 100.

[6] *Id.* The Exchange notes that certain terms are not specifically defined in the Rulebook, including Non-Priority Customer, Firm, Broker-Dealer.

[7] *See* Exchange Rule 100.

[8] *See* Fee Schedule, Section 6)e).

[9] *Id.*

[10] An ad-hoc request for historical End-of-Day Report data can be for any number of months beginning with June 2021 for which the data is available. *Id.*

[11] An ad-hoc request for historical 10-Minute Report data can be for any number of months beginning with March 2019 for which the data is available. *Id.*

[12] An ad-hoc request for historical 1-Minute Report data can be for any number of months beginning with March 2019 for which the data is available. *Id.*

[13] In order to qualify for the academic pricing, an academic purchaser must: (1) be an accredited academic institution or member of the faculty or staff of such an institution, and (2) use the data in independent academic research, academic journals and other publications, teaching and classroom use, or for other bona fide educational purposes (*i.e.* academic use). *See* Securities Exchange Act Release No. 97307 (April 13, 2024), 88 FR 24217 (April 19, 2023) (SR–EMERALD–2023–09).

[14] *See, e.g.,* Cboe DataShop, Open-Close Volume Summary products offered by Cboe Exchange, Inc. (''Cboe''), Cboe C2 Exchange, Inc. (''C2''), Cboe EDGX Exchange, Inc. (''EDGX''), and Cboe BZX Exchange, Inc. (''BZX''), *available at https://datashop.cboe.com/cboe-options-open-close-volume-summary* (last visited June 8, 2026).

[15] The discount applies on an order-by-order basis. To qualify for the discount, an order must contain an ad-hoc request for historical End-of-Day Report data and/or historical 10-Minute Report data and must total $20,000 or more. The Exchange does not aggregate purchases made throughout a billing cycle for purposes of this incentive program. The discount applies to the total purchase price once the $20,000 minimum purchase is satisfied (for example, a qualifying order of $25,000 would be discounted to $20,000, *i.e.* receiving a 20% discount of $5,000).

[16] The Exchange notes that at the end of this period, the temporary discount program will expire unless the Exchange files another 19b–4 Rule Filing with the Securities and Exchange Commission (the ''Commission'') to amend the terms or extend the discount program.

[17] 15 U.S.C. 78f(b).

of the Act,[18] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposed changes to its Fee Schedule concerning fees for the Open-Close Report is consistent with Section 6(b) of the Act [19] in general, and furthers the objectives of Section 6(b)(4) of the Act [20] in particular, in that it is an equitable allocation of dues, fees and other charges among its members and other recipients of Exchange data.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. Particularly, the Open-Close Report further broadens the availability of U.S. options market data to investors consistent with the principles of Regulation NMS. The data product also promotes increased transparency through the dissemination of the Open-Close Report. Particularly, information regarding opening and closing activity across different option series during the trading day may indicate investor sentiment, which may allow market participants to make better informed trading decisions throughout the day. Subscribers to the data may also be able to enhance their ability to analyze option trade and volume data and create and test trading models and analytical strategies. The Exchange believes that the Open-Close Report provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading and completely optional. Moreover, several other exchanges offer similar data products which offer the same type of data content through end-of-day or intra-day reports.[21]

The Exchange operates in a highly competitive environment. Indeed, there are currently 18 registered options exchanges that trade options. Based on publicly available information, no single options exchange had more than approximately 11–12% of the equity options market share for the month of May 2026 and the Exchange represented only approximately 3.13% of the equity options market share for that month.[22] The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Particularly, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [23] Making similar data products available to market participants fosters competition in the marketplace, and constrains the ability of exchanges to charge supra-competitive fees. In the event that a market participant views one exchange's data product as more or less attractive than the competition they can, and do, switch between similar products. The extension of the fee discount for historical Open-Close Report data is a result of this competitive environment, as the Exchange seeks to continue attracting subscribers of historical Open-Close Report data and making such data more widely accessible.

The Exchange believes that extending the temporary discount program for any Member or non-Member who purchases historical End-of-Day Report or historical 10-Minute Report data is reasonable because such purchasers will continue to receive a 20% discount for purchasing $20,000 or more worth of such historical Open-Close Report data. The Exchange believes the extended discount is reasonable as it gives purchasers additional time to use and test the historical Open-Close Report data at a discounted rate and therefore should continue to encourage and promote users to purchase the historical Open-Close Report data. Further, the extension of the temporary discount is intended to continue promoting increased use of the Exchange's historical Open-Close Report data by defraying some of the costs a purchaser would ordinarily have to expend. Further, continuing to provide the discount only to existing subscribers of a monthly End-of-Day Report or 10-Minute Report subscription is designed to encourage the purchase of monthly subscriptions to Open-Close Report data.

The Exchange believes that the extension of the temporary discount program is equitable and not unfairly discriminatory because it applies equally to all Members and non-Members who are existing subscribers of the End-of-Day Report or 10-Minute Report and choose to also purchase historical Open-Close Report data for the same category of products. Providing the discount only to existing subscribers is not unfairly discriminatory because it is a reasonable means to encourage the purchase of monthly subscriptions to Open-Close Report data.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to exclude ad-hoc requests for historical 1-Minute Report data from the discount program because a participant who subscribes to the 1-Minute Report (or requests historical 1-Minute Reports) receives ten times the data points that they would receive in comparison to the 10-Minute Report, which is more beneficial since they are receiving additional data based on shorter intervals. The increased frequency of data intervals in the 1-Minute Report provides more current information and more data reporting intervals. As such, the Exchange believes it reasonable, equitable and not unfairly discriminatory to exclude ad-hoc requests for historical 1-Minute Report data from the discount program because of the enhanced value of the 1-Minute Report, which is 10 times the amount of data. In addition, the Exchange offers free historical data for any current subscriber to the 1-Minute Report who makes an ad-hoc request for historical 1-Minute Report data. In particular, a current 1-Minute Report subscriber who purchases historical 1-Minute Report data may submit an ad-hoc request for historical End-of-Day Report data and/or historical 10-Minute Report data for the same date or date range for no additional charge.[24]

Lastly, the purchase of this data product is discretionary and not compulsory. Indeed, no market participant is required to purchase the historical Open-Close Report data, and the Exchange is not required to make the historical Open-Close Report data available to all investors. Potential purchasers may request the data at any

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(4).

[21] *See supra* note 14.

[22] *See* the ''Market Share'' section of the Exchange's website, *available at https://www.miaxglobal.com/.*

[23] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[24] *See* Fee Schedule, Section 6)e), note b.

time if they believe it to be valuable or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment in which the Exchange must continually adjust its fees to remain competitive. Because competitors are free to modify their own fees in response, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As discussed above, Open-Close Report data is subject to direct competition from several other options exchanges that offer substantively similar substitutes to the Exchange's Open-Close Report, albeit for trading data on those exchanges.[25] Moreover, purchase of historical Open-Close Report data is entirely optional. It is designed to help investors understand underlying market trends to improve the quality of investment decisions, but is not necessary to execute a trade.

The rule change is grounded in the Exchange's efforts to compete more effectively. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Further, the Exchange believes that the proposed change will not cause any unnecessary or inappropriate burden on intermarket competition, as the extension of the temporary discount program applies uniformly to any purchaser of historical Open-Close Report data.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[26] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors, or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–EMERALD–2026–17 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–EMERALD–2026–17. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–EMERALD–2026–17 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14272 Filed 7–15–26; 8:45 am]

BILLING CODE 8011–01–P

[25] *See supra* note 14.

[26] 15 U.S.C. 78s(b)(3)(A)(ii).

[27] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105894; File No. SR–PEARL–2026–34]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Options Exchange Fee Schedule To Amend Certain Fees and Rebates Applicable to Transactions in Non-Penny Classes for All Origins

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Pearl Options Exchange Fee Schedule (the ''Fee Schedule'') to amend certain fees and rebates applicable to transactions in non-Penny Classes (defined below) for all origins.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/pearl-options/rule-filings* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 1)a) of the Fee Schedule to: (1) amend the Priority Customer [3] origin table to increase Maker (described below) rebates [4] in all tiers in non-Penny Classes; (2) amend the MIAX Pearl Market Maker [5] origin table to amend Maker rebates in all tiers in non-Penny Classes and increase Taker fees in all tiers in non-Penny Classes; and (3) amend the Non-Priority Customer, Firm, BD, and Non-MIAX Pearl Market Maker origin (collectively referred to herein as the ''Professional origin'') [6] table to amend Maker rebates in all tiers in non-Penny Classes and increase Taker fees in all tiers in non-Penny Classes.

Background

The Exchange currently assesses transaction rebates and fees to all market participants which are based upon the total monthly volume executed by the Member [7] on MIAX Pearl in the relevant, respective origin type (not including Excluded Contracts) [8] (as the numerator) expressed as a percentage of (divided by) TCV [9] (as the denominator). In addition, the per contract transaction rebates and fees are applied retroactively to all eligible volume for that origin type once the respective threshold tier has been reached by the Member. The Exchange aggregates the volume of Members and their Affiliates.[10] Members that place resting liquidity, *i.e.,* orders resting on the Book [11] of the MIAX Pearl System,[12] are paid the specified ''maker'' rebate (each a ''Maker''), and Members that execute against resting liquidity are assessed the specified ''taker'' fee (each a ''Taker''). For opening transactions and ABBO [13] uncrossing transactions, per contract transaction rebates and fees are waived for all market participants. Finally, Members are assessed lower transaction fees and receive lower rebates for order executions in standard option classes in the Penny Interval Program [14] (''Penny Classes'') than for order executions in standard option classes which are not in the Penny Interval Program (''non-Penny Classes''), where Members are assessed higher transaction fees and receive higher rebates.

Proposal To Amend the Priority Customer Origin Table To Increase Maker Rebates in Non-Penny Classes

First, the Exchange proposes to amend the Priority Customer origin table to increase the Maker rebates in all tiers for Priority Customer orders in non-Penny Classes that trade against all origins. Currently, the Priority Customer origin table provides certain volume criteria thresholds for all tiers that are based upon the total monthly volume executed in all option classes by a Priority Customer on MIAX Pearl as a percentage of TCV. Pursuant to the Priority Customer origin table, Priority Customers qualify for Maker rebates of ($1.06) per contract for all tiers when Priority Customer orders in non-Penny Classes trade against all origins.

The Exchange now proposes to amend the Priority Customer origin table to increase the Maker rebates from ($1.06) to ($1.19) per contract for all tiers for Priority Customer orders in non-Penny Classes that trade against all origins. The Exchange does not propose to amend any of the volume threshold criteria or the Taker fee for Priority Customers in non-Penny Classes.

The purpose of this proposed change is for business and competitive reasons in order to attract additional non-Penny Class volume from Members by increasing the Maker rebates for options

[3] The term ''Priority Customer'' means a person or entity that (i) is not a broker or dealer in securities, and (ii) does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial accounts(s). The number of orders shall be counted in accordance with Interpretation and Policy .01 of Exchange Rule 100. *See* the Definitions section of the Fee Schedule and Exchange Rule 100, including Interpretation and Policy .01.

[4] Rebates are denoted in parentheses in the Fee Schedule.

[5] The term ''Market Maker'' means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of Exchange Rules. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[6] The Exchange notes that certain terms are not specifically defined in the Rulebook, including away Non-Priority Customer, Firm, BD, and Non-MIAX Pearl Market Make.

[7] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of Exchange Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[8] The term ''Excluded Contracts'' means any contracts routed to an away market for execution. *See* the Definitions section of the Fee Schedule.

[9] The term ''TCV'' means total consolidated volume calculated as the total national volume in those classes listed on MIAX Pearl for the month for which the fees apply, excluding consolidated volume executed during the period time in which the Exchange experiences an ''Exchange System Disruption'' (solely in the option classes of the affected Matching Engine (as defined below)). *See* the Definitions section of the Fee Schedule. The term ''Exchange System Disruption'' means an outage of a Matching Engine or collective Matching Engines for a period of two consecutive hours or more, during trading hours. *Id.* A ''Matching Engine'' is a part of the MIAX Pearl electronic system that processes options orders and trades on a symbol-by-symbol basis. Some Matching Engines will process option classes with multiple root symbols, and other Matching Engines may be dedicated to one single option root symbol (for example, options on SPY may be processed by one single Matching Engine that is dedicated only to SPY). A particular root symbol may only be assigned to a single designated Matching Engine. A particular root symbol may not be assigned to multiple Matching Engines. *Id.* The Exchange believes that it is reasonable and appropriate to select two consecutive hours as the amount of time necessary to constitute an Exchange System Disruption, as two hours equates to approximately 1.4% of available trading time per month. The Exchange notes that the term ''Exchange System Disruption'' and its meaning have no applicability outside of the Fee Schedule, as it is used solely for purposes of calculating volume for the threshold tiers in the Fee Schedule.

[10] The term ''Affiliate'' means (i) an affiliate of a Member of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, or (ii) the Appointed Market Maker of an Appointed EEM (or, conversely, the Appointed EEM of an Appointed Market Maker). An ''Appointed Market Maker'' is a MIAX Pearl Market Maker (who does not otherwise have a corporate affiliation based upon common ownership with an EEM) that has been appointed by an EEM and an ''Appointed EEM'' is an EEM (who does not otherwise have a corporate affiliation based upon common ownership with a MIAX Pearl Market Maker) that has been appointed by a MIAX Pearl Market Maker, pursuant to the following process. A MIAX Pearl Market Maker appoints an EEM and an EEM appoints a MIAX Pearl Market Maker, for the purposes of the Fee Schedule, by each completing and sending an executed Volume Aggregation Request Form by email to *membership@miaxoptions.com* no later than 2 business days prior to the first business day of the month in which the designation is to become effective. Transmittal of a validly completed and executed form to the Exchange along with the Exchange's acknowledgement of the effective designation to each of the Market Maker and EEM will be viewed as acceptance of the appointment. The Exchange will only recognize one designation per Member. A Member may make a designation not more than once every 12 months (from the date of its most recent designation), which designation shall remain in effect unless or until the Exchange receives written notice submitted 2 business days prior to the first business day of the month from either Member indicating that the appointment has been terminated. Designations will become operative on the first business day of the effective month and may not be terminated prior to the end of the month. Execution data and reports will be provided to both parties. *See* the Definitions section of the Fee Schedule.

[11] The term ''Book'' means the electronic book of buy and sell orders and quotes maintained by the System. *See* Exchange Rule 100.

[12] The term ''System'' means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[13] The term ''ABBO'' means the best bid(s) or offer(s) disseminated by other Eligible Exchanges (defined in Exchange Rule 1400(g)) and calculated by the Exchange based on market information received by the Exchange from OPRA. *See* the Definitions section of the Fee Schedule and Exchange Rule 100.

[14] *See* Securities Exchange Act Release No. 88992 (June 2, 2020), 85 FR 35142 (June 8, 2020) (SR–PEARL–2020–06).

transactions in non-Penny Classes in all tiers for Priority Customer orders. The Exchange believes that this may, in turn, encourage Members to submit more Priority Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads.

Proposal To Amend the Market Maker Origin Table To Amend Maker Rebates in all Tiers and Increase Taker Fees in all Tiers in Non-Penny Classes

The Exchange proposes to amend the Market Maker origin table to amend the Maker rebates in all tiers and increase the Taker fees in all tiers for Market Maker orders in non-Penny Classes that trade against all origins. Currently, pursuant to the Market Maker origin table, Market Makers qualify for the Maker rebate of ($0.55) per contract or Taker fee of $1.20 per contract in tier 1 for non-Penny Classes if the Market Maker executes above 0.00% to at least 0.20% of TCV. Market Makers can qualify for the Maker rebate of ($0.55) per contract or Taker fee of $1.20 per contract in tier 2 for non-Penny Classes by achieving at least one of the following three volume calculations: (i) if the Market Maker executes above 0.20% to at least 0.50% of TCV; or (ii) if the Market Maker executes above 0.55% in SPY/QQQ/IWM classes; or (iii) if the Market Maker executes above 0.30% in SPY/QQQ/IWM classes when adding liquidity to the Exchange.[15] Market Makers can qualify for the Maker rebate of ($0.60) per contract or Taker fee of $1.20 per contract in tier 3 for non-Penny Classes by achieving at least one of the following two volume calculations: (i) if the Market Maker executes above 0.50% to at least 0.85% of TCV; or (ii) if the Market Maker executes above 1.10% in SPY when adding liquidity.[16] Market Makers can qualify for the Maker rebate of ($0.65) per contract or Taker fee of $1.20 per contract in tier 4 for non-Penny Classes by achieving at least one of the following two volume calculations: (i) if the Market Maker executes above 0.85% to at least 1.25% of TCV; or (ii) if the Market Maker executes above 2.50% in SPY.[17] Market Makers can qualify for the Maker rebate of ($0.70) per contract or Taker fee of $1.20 per contract in tier 5 for non-Penny Classes if the Market Maker executes above 1.25% to at least 1.40% of TCV. Finally, Market Makers can qualify for the Maker rebate of ($0.85) per contract or Taker fee of $1.20 per contract in tier 6 if the Market Maker executes above 1.40% of TCV.

The Exchange now proposes to amend the Market Maker origin table to (i) increase the Maker rebates to ($0.80) per contract for tiers 1, 2, 3, 4, and 5 for Market Maker orders in non-Penny Classes that trade against all origins; and (ii) reduce the Maker rebate from ($0.85) to ($0.80) per contract for tier 6 for Market Maker orders in non-Penny Classes that trade against all origins. The Exchange also proposes to increase the Taker fees from $1.20 to $1.21 per contract for all tiers for Market Maker orders in non-Penny Classes that trade against all origins. The Exchange does not propose to amend any of the volume threshold criteria.

The purpose of the proposed changes to the Maker rebates is for business and competitive reasons in order to attract additional non-Penny Class volume from Members by increasing the Maker rebates for options transactions in non-Penny Classes in tiers 1, 2, 3, 4, and 5 for Market Maker orders. The Exchange believes that this may, in turn, encourage Members to submit more Market Maker orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads. Additionally, the Exchange believes that even with the proposed decrease to the Maker rebate for Marker Maker orders in non-Penny Classes in tier 6 and the proposed increase to the Taker fees for Market Maker orders in non-Penny Classes in all tiers, the Exchange's Maker rebates and Taker fees will remain competitive with the rebates offered and fees assessed by other exchanges for similar transactions.[18]

Proposal To Amend the Professional Origin Table To Amend Maker Rebates in Certain Tiers and Increase Taker Fees in all Tiers in Non-Penny Classes

The Exchange proposes to amend the Professional origin table to increase the Maker rebates in tiers 1, 2, 3, 4, and 5 for Professional orders in non-Penny Classes that trade against all origins, reduce the Marker rebate in tier 6 for Professional orders in non-Penny Classes that trade against all origins, and increase the Taker fees in all tiers for Professional orders in non-Penny Classes that trade against all origins. The Professional origin table provides certain volume criteria thresholds for all tiers that are based upon the total monthly volume executed in all option classes by a Professional on MIAX Pearl as a percentage of TCV. Currently, Professionals can qualify for the following rebates and fees for transactions in non-Penny Classes: (i) Maker rebate of ($0.55) per contract or Taker fee of $1.20 per contract in tier 1 if the Professional executes above 0.00% to at least 0.20% of TCV; (ii) Maker rebate of ($0.55) per contract or Taker fee of $1.20 per contract in tier 2 if the Professional executes above 0.20% to at least 0.50% of TCV; (iii) Maker rebate of ($0.60) per contract or Taker fee of $1.20 per contract in tier 3 if the Professional executes above 0.50% to at least 0.85% of TCV; (iv) Maker rebate of ($0.65) per contract or Taker fee of $1.20 per contract in tier 4 if the Professional executes above 0.85% to at least 1.25% of TCV; (v) Maker rebate of ($0.70) per contract or Taker fee of $1.20 per contract in tier 5 if the Professional executes above 1.25% to at least 1.50% of TCV; and (vi) Maker rebate of ($0.85) per contract or Taker fee of $1.20 per

[15] In tier 2 for the Market Maker origin, the alternative volume criteria (above 0.55% in SPY/QQQ/IWM) is calculated based on the total monthly volume executed by the Market Maker collectively in SPY, QQQ, and IWM options on MIAX Pearl in the relevant origin type, not including Excluded Contracts, (as the numerator) expressed as a percentage of (divided by) SPY/QQQ/IWM TCV (as the denominator). In Tier 2 for the Market Maker origin, the alternative volume criteria (above 0.30% in SPY/QQQ/IWM when adding liquidity) is calculated based on the total monthly volume that added liquidity executed by the Market Maker collectivity in SPY, QQQ, and IWM options on MIAX Pearl in the relevant origin type, not including Excluded Contracts, (as the numerator) expressed as a percentage of (divided by) SPY/QQQ/IWM TCV (as the denominator). *See* Fee Schedule, Section 1)a) (explanatory notes section below the tables).

[16] In tier 3 for the Market Maker origin, the alternative volume criteria (above 1.10% in SPY when adding liquidity) is calculated based on the total monthly volume that added liquidity executed by the Market Maker solely in SPY options on MIAX Pearl, not including Excluded Contracts, (as the numerator) expressed as a percentage of (divided by) SPY TCV (as the denominator). Market Makers that do not qualify for the alternative volume criteria in tier 3 will receive the tier 3 rates in the Market Maker origin table in Penny Classes and non-Penny Classes. Members will receive the highest tier based on the thresholds achieved. *See* Fee Schedule, Section 1)a), footnote ✦.

[17] In tier 4 for the Market Maker origin, the alternative volume criteria (above 2.50% in SPY) is calculated based on the total monthly volume executed by the Market Maker solely in SPY options on MIAX Pearl in the relevant origin type, not including Excluded Contracts, (as the numerator) expressed as a percentage of (divided by) SPY TCV (as the denominator). *See* Fee Schedule, Section 1)a) (explanatory notes section below the tables).

[18] *See* The Nasdaq Stock Market LLC (''Nasdaq''), Options 7: Pricing Schedule, Section 2, Nasdaq Options Market—Fees and Rebates (providing NOM Market Makers a rebate up to ($0,40) per contract for adding liquidity to Nasdaq in non-penny classes and assessing NOM Market Makers a fee of $1.25 per contract for removing liquidity from Nasdaq in non-penny classes); *see also* MEMX LLC (''MEMX'') Options Fee Schedule, Transaction Fees section (providing market makers a rebate of ($0.80) per contract for adding liquidity to MEMX in non-penny classes and assessing market makers a fee of $1.21 per contract for removing liquidity from MEMX in non-penny classes).

contract in tier 6 if the Professional executes above 1.50%.

The Exchange now proposes to amend the Professional origin table to increase the Maker rebates to ($0.80) per contract for tiers 1, 2, 3, 4, and 5 for Professional orders in non-Penny Classes that trade against all origins and reduce the Maker rebates from ($0.85) to ($0.80) per contract for tier 6 for Professional orders in non-Penny Classes that trade against all origins. The Exchange also proposes to increase the Taker fees from $1.20 to $1.21 per contract for all tiers for Professional orders in non-Penny Classes that trade against all origins. The Exchange does not propose to amend any of the volume threshold criteria.

The purpose of the proposed changes to the Maker rebates is for business and competitive reasons in order to attract additional non-Penny Class volume from Members by increasing the Maker rebates for options transactions in non-Penny Classes in tiers 1, 2, 3, 4, and 5 for Professional orders. The Exchange believes that this may, in turn, encourage Members to submit more Professional orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads. Additionally, the Exchange believes that even with the proposed decrease to the Maker rebates for Professional orders in non-Penny Classes in tier 6 and proposed increase to the Taker fees for Professional orders in non-Penny Classes in all tiers that the Exchange's Maker rebates and Taker fees will remain competitive with the rebates offered and fees assessed by at least one other exchange for similar transactions.[19]

Implementation

The proposed changes are effective beginning July 1, 2026.

2. Statutory Basis

The Exchange believes that its proposal to amend the Fee Schedule is consistent with Section 6(b) of the Act [20] in general, and furthers the objectives of Section 6(b)(4) of the Act,[21] in that it is an equitable allocation of reasonable dues, fees and other charges among Exchange Members and issuers and other persons using its facilities, and 6(b)(5) of the Act,[22] in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [23]

There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based and singly-listed options, no single exchange had more than approximately 11–12% of the multiply-listed equity options market share for the month of May 2026.[24] Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 1.69% of executed volume of multiply-listed equity options for the month of May 2026.[25]

Proposal To Amend the Priority Customer Origin Table To Increase All Maker Rebates in Non-Penny Classes

The Exchange believes its proposal to amend the Priority Customer origin to increase the Maker rebates in all tiers to ($1.19) per contract for Priority Customer orders in non-Penny Classes that trade against all origins is reasonable, equitable and not unfairly discriminatory because it would further incentivize Priority Customer orders to the Exchange. The Exchange believes that this may, in turn, encourage Members to submit more Priority Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads. The Exchange believes the proposed increased Maker rebates in all tiers for Priority Customer orders in non-Penny Classes is equitable and not unfairly discriminatory because it will apply equally to all market participants who provide Priority Customer orders in such classes.

Proposals To Amend the Market Maker and Professional Origins To Amend Maker Rebates in all Tiers and Increase Taker Fees in all Tiers in Non-Penny Classes

The Exchange believes its proposal to amend the Market Maker and Professional origins to increase the Maker rebates in tiers 1, 2, 3, 4, and 5 to ($0.80) per contract for Market Maker and Professional orders in non-Penny Classes that trade against all origins is reasonable, equitable and not unfairly discriminatory because it would further incentivize Market Maker and Professional orders to the Exchange. The Exchange believes that this may, in turn, encourage Members to submit more Market Maker and Professional orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads. The Exchange believes the proposed increased Maker rebates in tiers 1, 2, 3, 4, and 5 for Market Maker and Professional orders in non-Penny Classes is equitable and not unfairly discriminatory because it will apply equally to all market participants who provide Market Maker and Professional orders in such classes.

The Exchange believes the proposal to amend the Market Maker and Professional origins to reduce the Maker rebates from ($0.85) to ($0.80) per contract in tier 6 in non-Penny Classes is reasonable, equitably allocated, and not unfairly discriminatory because, even with the proposed decrease, the Exchange believes the proposed Maker rebates will not discourage Market Maker and Professional order flow. The Exchange notes that despite the changes proposed herein, the Exchange's proposed Maker rebate of ($0.80) per contract for the Market Maker and Professional origin for respective tier 6 in non-Penny Classes remains competitive with the Maker rebates for similar executions that are charged by other equity options exchanges.[26]

The Exchange believes the proposal to amend the Market Maker and Professional origins to increase Taker fees to $1.21 per contract in all tiers in non-Penny Classes is reasonable, equitably allocated, and not unfairly discriminatory because, even with the

[19] *See* MEMX Options Fee Schedule, Transaction Fees section (providing professional a rebate of ($0.72) for adding liquidity to MEMX in non-penny classes and assessing professional a fee of $1.21 per contract for removing liquidity from MEMX in non-penny classes).

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(4).

[22] 15 U.S.C. 78f(b)(1) and (b)(5).

[23] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496 (June 29, 2005).

[24] *See* the ''Market Share'' section of the Exchange's website, *available at https://www.miaxglobal.com/* (last visited June 29, 2026).

[25] *See id.*

[26] *See supra* notes 18 and 19.

proposed increase, the Exchange believes the proposed Taker fees will not discourage Market Maker and Professional order flow. The Exchange notes that despite the changes proposed herein, the Exchange's proposed Taker fee of $1.21 per contract for the Market Maker and Professional origin for all tiers in non-Penny Classes remains competitive with (and lower than) the Taker fees for similar executions that are charged by other equity options exchanges.[27]

The Exchange believes that even with the proposed decrease to the Maker rebates for Market Maker and Professional orders in non-Penny Classes in tier 6 and proposed increase to the Taker fees for Market Maker and Professional orders in non-Penny Classes in all tiers, the Exchange's Maker rebates and Taker fees for Market Maker and Professional transactions in non-Penny Classes will continue to encourage such market participants to trade on the Exchange. In turn, this should continue to contribute to a deep and liquid market to the benefit of all market participants and allow the Exchange to maintain its attractiveness as a trading venue. The Exchange further believes the proposed decreased rebates and increased Taker fees are equitable and not unfairly discriminatory because the proposed decreased rebates and increased fees will apply to all Market Maker and Professional origin orders in non-Penny Classes, regardless of volume.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act.

Intra-Market Competition

The Exchange does not believe that any of the proposed changes will impose any burden on intra-market competition. The Exchange believes its proposal to amend the Priority Customer origin to increase the Maker rebates in all tiers for Priority Customer orders in non-Penny Classes that trade against all origins will not impose any burden on intra-market competition. Instead, the Exchange believes this proposed change will promote competition because it will further incentivize Priority Customer orders to the Exchange. The Exchange believes that this may, in turn, encourage Members to submit more Priority Customer orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads.

Similarly, the Exchange believes its proposal to amend the Market Maker and Professional origins to increase the Maker rebates in tiers 1, 2, 3, 4, and 5 for Market Maker and Professional orders in non-Penny Classes that trade against all origins will not impose any burden on intra-market competition. Instead, the Exchange believes this proposed change will promote competition because it will further incentivize Market Maker and Professional orders to the Exchange. The Exchange believes that this may, in turn, encourage Members to submit more Market Maker and Professional orders, leading to increased liquidity on the Exchange to the benefit of all market participants by providing more trading opportunities and tighter spreads.

The Exchange believes that its proposal to reduce Maker rebates in tier 6 and increase Taker fees for Market Maker and Professional transactions in non-Penny Classes will not impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because these changes are for business and competitive reasons. The Exchange notes that despite the changes proposed herein, the Exchange's rebates and fees remain competitive with the maker rebates offered and the taker fees assessed by at least one other exchanges for similar executions in non-penny classes by those exchanges market makers and professional customers.[28]

Inter-Market Competition

The Exchange does not believe that the proposed changes will impose any burden on inter-market competition and the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive, or rebate opportunities available at other venues to be more favorable. There are currently 18 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange had more than approximately 11–12% of the multiply-listed equity options market share for the month of May 2026.[29] Therefore, no exchange possesses significant pricing power. More specifically, the Exchange had a market share of approximately 1.69% of executed volume of multiply-listed equity options for the month of May 2026.[30]

In such an environment, the Exchange must continually adjust its rebates and tiers to remain competitive with other options exchanges. Because competitors are free to modify their own fees and tiers in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. The Exchange believes that the proposed rule changes reflect this competitive environment because they modify the Exchange's fees and rebates in a manner that encourages market participants to continue to provide liquidity and to send order flow to the Exchange.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act,[31] and Rule 19b–4(f)(2)[32] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or

[27] *See supra* notes 18 and 19.

[28] *See supra* notes 18 and 19.

[29] *See supra* note 24.

[30] *See id.*

[31] 15 U.S.C. 78s(b)(3)(A)(ii).

[32] 17 CFR 240.19b–4(f)(2).

• Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2026–34 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–PEARL–2026–34. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2026–34 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14270 Filed 7–15–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105899; File No. SR–CME–2026–001]

Self-Regulatory Organizations; Chicago Mercantile Exchange Inc.; Order Approving a Proposed Rule Change Relating to Amendments to Chicago Mercantile Exchange Inc.'s Rules Governing Performance Bond Requirements: Account Holder Level

July 13, 2026.

I. Introduction

On June 1, 2026, the Chicago Mercantile Exchange Inc. (''CME'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend CME Rule 930 in Chapter 9 of the CME Rulebook relating to customer performance bond requirements for security futures contracts that CME intends to list for trading.[3]

The proposed rule change was published for comment in the **Federal Register** on June 8, 2026.[4] The Commission received no comment letters in response to the Notice. This order approves the proposed rule change.

II. Description of the Proposed Rule Change

A. Background

As described more fully in the Notice, on April 10, 2026, CME, in its capacity as a designated contract market, submitted a 1–N notice filing to the Commission to register as a national securities exchange for security futures products pursuant to the notice registration provisions of Section 6(g) of the Exchange Act.[5] On April 29, 2026, the Commission issued a notice acknowledging receipt of such written notice and effectiveness of CME's notice registration as a national securities exchange contemporaneously with CME's submission of the 1–N notice on April 10, 2026.[6]

CME submitted the proposed rule change in connection with its plans to list cash-settled single stock futures, to establish customer-level margin requirements for security futures that are consistent with current Commission (and Commodity Futures Trading Commission (''CFTC'')) requirements.[7]

B. Proposed Rule Change

CME proposes revisions to Rule 930 (Performance Bond Requirements; Account Holder Level) to establish procedures relating to the determination and administration of customer margin requirements for security futures, as well as to exclude qualifying security futures dealers from those requirements and related regulatory requirements. The proposed additions to Rule 930 largely reinstate the margin provisions for security futures that CME previously added to Rule 930, with some modifications to align with the Commission's (and CFTC's) current margin requirements for security futures and some non-substantive clarification changes to the prior text.[8]

1. Performance Bond Rates

CME proposed that proposed Rule 930.B.2.a. would provide that customer performance bond rates shall be established at levels no lower than those prescribed by SEC Rule 242.403 and CFTC Regulation 41.45 or any successor regulations. Proposed Rule 930.B.2.c. elaborates by establishing the requisite performance bond level for each long or short position in a security future at 15% of the current market value of such security futures contract, or such other requirement as may be established by the SEC and CFTC for purposes of SEC Rule 242.403(b)(1) and CFTC Regulation 41.45(b)(1).

Proposed Rule 930.B.2.d. sets out exceptions to that 15% requirement as permitted under SEC Rule 242.403(b)(2) and CFTC Regulation 41.45(b)(2), which establish that a self-regulatory authority may set the required initial or maintenance performance bond level for offsetting positions involving security futures and related positions at a level lower than the level that would apply if performance bond requirements for such positions were calculated separately based on the aforementioned 15% requirement, provided the rules establishing such lower performance bond levels meet the criteria set forth in Section 7(c)(2)(B) of the Act.[9]

Proposed Rule 930.B.2.d. includes a table that sets out in detail the performance bond offsets available with respect to particular combinations of security futures and related positions. CME stated that the offset strategies in the table align with those the SEC and CFTC have acknowledged are permissible, as set forth in their joint 2020 release on customer margin rules relating to security futures.[10]

2. Exclusions From Margin Requirements

Non-customers. Proposed Rule 930.B.2.b. would identify ''exempted persons'' and ''market makers'' as non-

[33] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Act Release No. 105607 (Jun. 3, 2026), 91 FR 34693 (Jun. 8, 2026) (''Notice'').

[4] *See* Notice. The public comment period closed on June 29, 2026.

[5] 15 U.S.C. 78f(g). *See* Notice, 91 FR at 34694.

[6] *See* Acknowledgement of Receipt of Notice of Registration as a National Securities Exchange Pursuant to Section 6(g) of the Securities Exchange Act of 1934 by CME, Exchange Act Release No. 105336 (Apr. 29, 2026). *See* Notice, 91 FR at 34694.

[7] *See* Notice, 91 FR at 34694.

[8] *See* Notice, 91 FR at 34694. *See also* Exhibit 5 to the filing showing the proposed rule text changes.

[9] That section requires that: (I) the margin requirements for a security future product be consistent with the margin requirements for comparable option contracts traded on any exchange registered pursuant to [Section 6(a) of the Act]; and (II) initial and maintenance margin levels for a security future product not be lower than the lowest level of margin, exclusive of premium, required for any comparable option contract traded on any exchange registered pursuant to [Section 6(a) of the Act], other than an option on a security future. *See* Notice, 91 FR at 34694.

[10] *See* Notice, 91 FR at 34694.

customers for the purpose of the rule amendments. Those non-customers would be exempt from the application of the rule's provisions. For the purposes of CME's rulebook, CME stated that the term ''exempted person'' has the definition specifically referenced in applicable SEC and CFTC regulations.[11]

Market Maker Exclusion. SEC Rule 242.400(c)(2)(v) and CFTC Regulation 41.42(c)(2)(v) permit exchanges to adopt rules containing specified requirements for security futures dealers, on the basis of which the financial relations between security futures intermediaries, on the one hand, and qualifying security futures dealers, on the other, are excluded from the customer performance bond requirements for security futures. Rules so adopted by an exchange must meet the criteria set forth in Section 7(c)(2)(B) of the Act. CME proposes a market maker exclusion in its proposed Rule 930.B.2.b. consistent with the requirements of those provisions. To qualify for the market maker exclusion, a person must be a member of CME and registered as a dealer with the SEC under Section 15(b) of the Act.[12]

A proposed market maker must also hold itself out as willing to buy and sell security futures for its own account on a regular or continuous basis. As described more fully in the Notice, the proposed market maker exclusion provides three alternative ways for a person to satisfy this requirement.[13] Under the first alternative CME proposes, the market maker must (1) provide continuous two-sided quotations throughout the trading day for all delivery months of security futures contracts representing a meaningful proportion of the total trading volume of security futures contracts on the Exchange, subject to relaxation during unusual market conditions as determined by CME (such as a fast market in either a security futures contract or a security underlying a security futures contract) at which times the market maker must use its best efforts to quote continuously and competitively; and (2) when providing quotations, quote with a maximum bid/ask spread of no more than the greater of $0.20 or 150% of the bid/ask spread in the primary market for the security underlying each security futures contract. Beginning on the 181st calendar day after the commencement of trading of security futures contracts on the Exchange, a ''meaningful proportion of the total trading volume of security futures contracts on the Exchange from time to time'' shall mean a minimum of 20% of such trading volume.

Under the second alternative, CME proposed that the market maker must (1) respond to at least 75% of the requests for quotation for all delivery months of security futures contracts representing a meaningful proportion of the total trading volume of security futures contracts on the Exchange, subject to relaxation during unusual market conditions as determined by the CME (such as a fast market in either a security futures contract or a security underlying a security futures contract) at which times the Market Maker must use its best efforts to quote competitively; and (2) when responding to requests for quotation, quote within five seconds with a maximum bid/ask spread of no more than the greater of $0.20 or 150% of the bid/ask spread in the primary market for the security underlying each security futures contract. As with the first alternative, beginning on the 181st calendar day after the commencement of trading of security futures contracts on the Exchange, a ''meaningful proportion of the total trading volume of security futures contracts on the Exchange from time to time'' shall mean a minimum of 20% of such trading volume.

Under the third alternative, CME proposes that the market maker is assigned to a group of security futures contracts listed on the Exchange that is either unlimited in nature (''Unlimited Assignment'') or is assigned to no more than 20% of the security futures contracts listed on the Exchange (''Limited Assignment''). In addition, CME states that this alternative provides that: (a) At least 75% of the market maker's total trading activity in Exchange security futures contracts is in its assigned security futures contracts, measured on a quarterly basis; (b) during at least 50% of the trading day, the market maker has bids or offers in the market that are at or near the best market, except in unusual market conditions (such as a fast market in either a security futures contract or a security underlying a security futures contract), with respect to at least 25% (in the case of an Unlimited Assignment) or at least one (in the case of a Limited Assignment) of its assigned security futures contracts; and (c) the first two requirements are satisfied on at least 90% (in the case of an Unlimited Assignment) or 80% (in the case of a Limited Assignment, or in the case of either an Unlimited or Limited Assignment but where the Exchange is listing four or fewer security futures contracts) of the trading days in each calendar quarter.[14]

Under the proposed revisions, market makers are required to maintain books and records including trading statements and other financial records that would evidence compliance with these standards. CME stated that this recordkeeping requirement includes, without limitation, such trading statements and other financial records as may be necessary specifically to verify compliance. CME stated that failure on the part of a market maker to comply with these standards may result in revocation of security futures dealer status or other sanctions provided under CME Rules.[15]

3. Performance Bond Administration

Proposed Rule 930.C.2.a identifies the types of performance bonds that a security futures intermediary may accept from a customer. Consistent with SEC Rule 242.404(b) and CFTC Regulation 41.46(b), CME proposes that acceptable types of performance bonds are limited to: deposits of cash, margin securities (subject to specified restrictions), exempted securities, any other assets permitted under Regulation T of the Board of Governors of the Federal Reserve System (''Federal Reserve Board'') to satisfy a performance bond deficiency in a securities margin account, and any combination of the foregoing. Proposed Rule 930.C.2.a. further provides that the different types of eligible performance bonds are to be valued in accordance with the applicable principles set forth in SEC Rules 242.404(c) and 242.404(e) and CFTC Regulations 41.46(c) and 41.46(e).

CME also proposed Rule 930.C.2.b. which provides that a security futures intermediary shall not accept as performance bond from any customer securities that have been issued by that customer or an affiliate of that customer unless the intermediary files a petition with and receives permission from the Exchange for such purpose. Proposed Rule 930.C.2.c. provides that all assets deposited by a customer to meet performance bond requirements must be and remain unencumbered by third-party claims against that customer.[16]

Proposed Rule 930.K.2. requires a security futures intermediary to take the deduction required with respect to an underfunded account in computing its net capital under applicable SEC and CFTC Regulations if the customer has failed to comply with a required performance bond call within a

[11] 17 CFR 41.43(a)(9); 17 CFR 242.401(a)(9).

[12] *See* Notice, 91 FR at 34694–36945.

[13] *See* Notice, 91 FR at 34695 (describing the three proposed alternatives in detail).

[14] *Id.*

[15] *Id.*

[16] *See* Notice, 91 FR at 34695.

reasonable period of time. CME stated that this requirement is consistent with SEC Rule 242.406(a) and CFTC Regulation 41.48(a). Further, proposed Rule 930.K.2. requires the liquidation of an account where there is a liquidating deficit, in accordance with SEC Rule 242.406(b) and CFTC Regulation 41.48(b).[17]

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.[18] As discussed in more detail below, the Commission finds that the proposed rule change is consistent with, Section 6(b)(5) of the Act [19] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade and, in general, to protect investors and the public interest.

Further, as discussed in more detail below, the Commission finds that the proposed rule change is consistent with Section 7(c)(2)(B) of the Exchange Act.[20] Section 7(c)(2)(B) of the Exchange Act requires, among other things, that the levels of margin (initial and maintenance) for security futures preserve the financial integrity of markets trading security futures, prevent systemic risk, be consistent with the margin requirements for comparable exchange-traded options, and be no lower than the lowest level of margin, exclusive of premium, required for any comparable exchange-traded option.[21] The CFTC and SEC (together the ''Commissions'') have jointly adopted customer margin requirements for security futures pursuant to authority delegated to them by the Federal Reserve Board under Section7(c)(2)(B) of the Exchange Act.[22]

The proposed rule change is consistent with the customer margin rules for security futures that the Commissions jointly adopted.[23] In particular, CME's proposed Rule 930.B.2.c. provides that for a security future held in a futures account, the minimum margin level for each long or short position in a security future shall not be less than 15% of the current market value of the relevant security futures contract.[24] This minimum margin requirement is consistent with the 15% margin requirement the Commissions adopted in the 2020 Security Futures Margin Release.[25] The offsets CME proposed in proposed CME Rule 930.B.2.d. also are consistent with the strategy-based offsets permitted for comparable offset positions involving exchange-traded options and published in the 2020 Security Futures Margin Release.[26]

In addition, CME proposed a market maker exclusion from the scope of the proposed security futures margin rule.[27] The Commissions' joint security futures margin rules do not apply to a member of a national securities exchange or national securities association that is registered with the exchange as a ''security futures dealer'' pursuant to exchange rules that must meet several criteria, including a requirement that a security futures dealer be required ''to hold itself out as being willing to buy and sell security futures for its own account on a regular or continuous basis.'' [28] To meet the market maker exclusion, CME proposed, among other things, that a person must be a member of CME and registered as a dealer with the SEC under Section 15(b) of the Act, and meet one of the three alternatives in proposed Rule 930.B.2.b. to satisfy the requirement it holds itself out as willing to buy and sell security futures for its own account on a regular or continuous basis.[29] These requirements are consistent with joint security future margin rules the Commission adopted [30] in that they require, among other things, that a CME member satisfy of one of the three proposed alternatives [31] to comply with the requirement that a market maker hold itself out as willing to buy and sell security futures for its own account on a regular or continuous basis.[32]

The proposed rule change establishes margin requirements for security futures traded on CME that would not be lower than the requirements under SEC and CFTC regulations or any successor regulations.[33] This requirement will ensure that margin requirements for security futures traded on CME under CME's proposed margin rules remain consistent with the Commissions' joint security futures margin rules and with Section 7(c)(2)(B) under the Exchange Act.[34] In addition, the 15% margin requirement will ensure that margin levels for security futures are set a sufficiently prudent level at the account level for customers of security futures intermediaries that trade security futures on CME.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[35] that the proposed rule change (SR–CME–2026–001) be, and hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[36]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14275 Filed 7–15–26; 8:45 am]

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[17] *Id.*

[18] In approving this rule change, the Commission has considered the rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[19] 15 U.S.C. 78f(b)(5).

[20] 15 U.S.C. 78g(c)(2)(B). This also is a requirement for the listing standards for security futures products under Section 6(h)(3)(L) of the Exchange Act. 15 U.S.C. 78f(h)(3)(L). This section of the Exchange Act requires that the margin requirements for a security futures product comply with the regulations prescribed pursuant to section 7(c)(2)(B) of the Exchange Act. *Id.*

[21] 15 U.S.C. 78g(c)(2)(B).

[22] *See* SEC and CFTC, Customer Margin Rules Relating to Security Futures; Joint Final Rule, Exchange Act Release No. 46292 (Aug. 1, 2002), 67 FR 53146 (Aug. 14, 2002) (''2002 Security Futures Margin Release''); SEC and CFTC, Customer Margin Rules Relating to Security Futures; Joint Final Rule, Exchange Act Release No. 90244 (Oct. 22, 2020), 85 FR 75112 (Nov. 24, 2020) (''2020 Security Futures Margin Release'').

[23] *See* 2020 Security Futures Margin Release.

[24] *See, e.g.,* 17 CFR 242.403(b)(1) and 17 CFR 41.45(b)(1) (prescribing 15% margin requirement for security futures).

[25] *See* 2020 Security Futures Margin Release.

[26] *See* 2020 Security Futures Margin Release, 85 FR at 75123–75125 (publishing offset table) and 17 CFR 242.403(b)(2) and 17 CFR 41.45(b)(2). The strategy-based offset table is designed to permit offsets that are consistent with offsets recognized for comparable exchange-traded options under the securities self-regulatory organization margin rules. 2020 Security Futures Margin Release, 85 FR at 75123.

[27] *See* Notice, 91 FR 34694–35695.

[28] *See* 17 CFR 242.400(c)(2)(v) and 17 CFR 41.42(c)(2)(v).

[29] *See* Notice, 91 FR 34695.

[30] *See* 2020 Security Futures Margin Release and 2002 Security Futures Margin Release.

[31] CME proposed three specific alternatives that a market maker could meet to satisfy the condition that a market maker must hold itself out as willing to buy and sell security futures for its own account on a regular or continuous basis. *See* Notice, 91 FR 34695 (describing the three alternatives).

[32] *See* 2002 Security Futures Margin Release, 67 FR at 53153. In the 2002 Security Futures Margin Release, the Commissions stated that they do not believe that registration with the SEC or CFTC is, by itself, sufficient to show that a market participant is holding itself out as willing to buy and sell security futures. However, the Commissions stated that they believe that there are a number of different ways that an exchange member could satisfy this condition. One alternative the Commissions provided was that the exchange member could be subject to rules that impose on it an affirmative obligation to quote on a regular or continuous basis in security futures. *Id.*

[33] *See* proposed CME Rule 930.B.2.c.

[34] *See* 2020 Security Futures Margin Release and 2002 Security Futures Margin Release. *See also* 15 U.S.C. 78f(h)(3)(L).

[35] 15 U.S.C. 78s(b)(2).

[36] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105886; File No. SR–MIAX–2026–29]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Options Regulatory Fee (ORF)

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, Miami International Securities Exchange, LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Options Exchange Fee Schedule (''Fee Schedule'') regarding the Options Regulatory Fee (''ORF'').

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange previously filed to amend its ORF assessment and collection methodology,[3] with the rate to be set closer to the implementation date of the amended ORF collection methodology. At this time, the Exchange proposes to set the ORF rate effective July 1, 2026 to $0.0170 per contract side. Additionally, the Exchange proposes to amend the rule text that describes the ORF collection methodology to provide greater clarity to the ORF collection methodology.

July 1, 2026 ORF

As of July 1, 2026, the Exchange will assess ORF for options transactions that clear in the ''customer'' range at The Options Clearing Corporation (''OCC''), however ORF will be assessed to each Members [4] for executions that occur on the Exchange. Specifically, the ORF will be collected on behalf of the Exchange from Members and non-members for all customer transactions executed on the Exchange. ORF would be assessed and collected on all ultimately cleared customer contracts, taking into account adjustments for CMTA that were provided to the Exchange the same day as the trade.[5] Further, the Exchange would bill ORF according to the clearing instructions provided on the execution. More specifically, the Exchange proposes to assess ORF based on the clearing instruction provided on the execution on trade date and would not take into consideration CMTA changes or transfers that occur at OCC.[6]

Based on the Exchange's review of regulatory costs, ORF revenue, and options transaction volume, the Exchange proposes to set the ORF rate effective July 1, 2026 to $0.0170 per contract side. On June 2, 2026, the Exchange notified Members of the proposed ORF rate effective July 1, 2026 via a Regulatory Circular.[7] The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. More specifically, the Exchange will endeavor to ensure that the amount of revenue collected from the ORF will not exceed 80% of the Exchange's regulatory costs. The Exchange will monitor its regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs in a given year, the Exchange will adjust the ORF by submitting a fee change filing to the Securities and Exchange Commission (the ''Commission''). The Exchange will notify Members of adjustments to the ORF via a Regulatory Circular in advance of any change.

As is the case today, the Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange will continue to review all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary matter will continue to offset regulatory costs.

Revenue generated from ORF, when combined with all of the Exchange's other regulatory fees and fines, is designed to cover a material portion of the regulatory costs to the Exchange of the supervision and regulation of Members' customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. Regulatory costs include direct regulatory expenses and certain indirect expenses in support of the regulatory function. The direct expenses include in-house and third party service provider costs to support the day-to-day regulatory work such as surveillances, investigations and examinations. The indirect expenses are only those expenses that are in support of the regulatory functions, such areas include Office of the General Counsel, technology, finance, and internal audit.

Rule Text Amendment

The Exchange proposes to delete the last sentence of the rule text ''The ORF is not assessed on outbound linkage trades.'' This revision more accurately describes the Exchange's collection process as explained in its prior rule proposal.[8] The Exchange proposes this revised rule text because it provides

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities and Exchange Act Release No. 104707 (January 28, 2026) 91 FR 4754 (February 2, 2026) (SR–MIAX–2026–01)(Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt a New Methodology for Assessment and Collection of the Options Regulatory Fee (ORF)).

[4] The term ''Member'' means an individual or organization approved to exercise the trading rights associated with a Trading Permit. Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[5] Adjustments to CMTA that occur at OCC would not be taken into account.

[6] Adjustments that were made the same day as the trade on the Exchange will be taken into account.

[7] *See https://www.miaxglobal.com/alert/2026/06/02/miax-exchange-group-option-markets-options-regulatory-fee-1.*

[8] *See supra* note 3.

greater clarity to the manner in which ORF is collected.

Additionally, the Exchange proposes to remove obsolete text regarding an ORF rate that is no longer in effect.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act [9] in general, and furthers the objectives of Section 6(b)(4) of the Act [10] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act [11] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that the proposed fee change is reasonable, equitable and not unfairly discriminatory in that it is charged to all Exchange transactions that clear in the ''customer'' range at the OCC. Additionally, the Exchange believes that the proposed fee change ensures fairness by assessing a specific fee to those Members that require more Exchange regulatory services based on the amount of customer options business they conduct. Over recent years, options trading volume has increased with a growing percentage of the volume applicable to customer transactions. Customers trading on the Exchange (through a Member) benefit from the protections of a robust regulatory program including the maintenance of fair and orderly markets and protections against fraud and other manipulation. The Exchange believes it is equitable and not unfairly discriminatory to assess a regulatory fee to transactions that clear in the ''customer'' range to cover regulatory costs, but not to transactions clearing in the ''firm'' or ''market maker'' range because Clearing Members [12] and Market Makers [13] (who clear in the Firm and Market Maker range), as those market participants are generally subject to other Exchange fees, fines and obligations. For example, Clearing Members and Market Makers are required to pay Exchange application fees, permit fees, and connectivity fees, amongst others. In addition, all fines issued by the Exchange for regulatory infractions are assessed only to Members and would be applied to regulatory revenues. The Exchange expects that Clearing Members from whom the ORF is collected will pass through the fee to their customers (as the Exchange understands occurs today). In addition, Market Makers in particular are subject to various quoting and other obligations to ensure that they provide stable and liquid markets, which benefit all market participants including customers. Excluding Market Maker transactions from the ORF collection will allow Market Makers to better manage their costs more effectively thus enabling them to better allocate resources toward technology, risk management, and capacity to ensure continued liquidity provision.

In addition to the overall increase in ''customer'' range volume generally, regulating customer trading activity is more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. For example, there are costs associated with main office and branch office examinations (*e.g.,* staff and travel expenses), as well as investigations into customer complaints and terminations of registered persons. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* Clearing Member proprietary transactions) of its regulatory program.[14] While the Exchange notes that it has broad regulatory responsibilities with respect to its Member's activities, irrespective of where their transactions take place, the Exchange believes it is reasonable to assess the proposed fee to only those transactions occurring on the Exchange. The proposed change more narrowly tailors the fee to products and transactions with a direct connection to the Exchange. With this proposal, transactions that would clear in the ''customer'' range occurring on other exchanges would no longer be subject to an ORF assessed by the Exchange.

The Exchange further believes that the proposed change fee is reasonable because it would help ensure that revenue collected from the ORF, in combination with other regulatory fees and fines, would cover a material portion of the Exchange's regulatory costs.

As noted above, the Exchange will also continue to monitor on at least a semiannual basis the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, would cover a material portion of the Exchange's regulatory costs and not exceed it.

Additionally, the Exchange proposes to delete the last sentence of the rule text and to remove obsolete text regarding the ORF rate that is no longer in effect. The Exchange believes that the proposal to delete the last sentence of the rule text and to remove obsolete text regarding the ORF rate that is no longer in effect would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed change would provide greater clarity to market participants regarding the Exchange's Fee Schedule. It is in the public interest for the Exchange's Fee Schedule to be accurate so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity on the Exchange, thereby raising regulatory revenue to offset regulatory expenses. It also supplements the regulatory revenue

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78f(b)(5).

[12] Clearing Member means a Member that has been admitted to membership in the Clearing Corporation pursuant to the provisions of the rules of the Clearing Corporation. *See* Exchange Rule 100.

[13] Market Makers refers to ''Lead Market Makers,'' ''Primary Lead Market Makers,'' and ''Registered Market Makers'' collectively. Lead Market Maker means a Member registered with the Exchange for the purpose of making markets in securities traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of these Rules with respect to Lead Market Makers. Primary Lead Market Maker means a Lead Market Maker appointed by the Exchange to act as the Primary Lead Market Maker for the purpose of making markets in securities traded on the Exchange. Registered Market Maker means a Member registered with the Exchange for the purpose of making markets in securities traded on the Exchange, who is not a Lead Market Maker and is vested with the rights and responsibilities specified in Chapter VI of these Rules with respect to Registered Market Makers. *See* Exchange Rule 100.

[14] If the Exchange changes its method of funding regulation or if circumstances otherwise change in the future, the Exchange may decide to modify the ORF or assess a separate regulatory fee on Member proprietary transactions if the Exchange deems it advisable.

derived from non-customer activity. The Exchange notes, however, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and paragraph (f) of Rule 19b–4 [16] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

• Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or SR–MIAX–2026–29 on the subject line.

Paper Comments

• Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MIAX–2026–29. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MIAX–2026–29 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14263 Filed 7–15–26; 8:45 am]

BILLING CODE 8011–01–P

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105888; File No. SR–C2–2026–019]

Self-Regulatory Organizations; Cboe C2 Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Definition of Professional To Require Monthly Reviews of Orders

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Cboe C2 Exchange, Inc. (the ''Exchange'' or ''C2'') proposes to amend the definition of Professional [3] to require monthly reviews of orders. The text of the proposed rule change is provided in Exhibit 5.

The text of the proposed rule change is also available on the Commission's website (*https://www.sec.gov/rules/sro.shtml*), the Exchange's website (*https://www.cboe.com/us/options/regulation/rule_filings/ctwo/*), and at the principal office of the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the definition of Professional to modify the Exchange's quarterly review of Professional orders. This filing is based on a proposal recently submitted by Nasdaq ISE, LLC (''ISE'').[4]

Today, orders for any Public Customer [5] that average more than 390 orders per day during any month of a calendar quarter must be represented as Professional orders for the next calendar quarter.[6] In order to properly represent orders entered on the Exchange, Trading Permit Holder Organizations (''TPH

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Rule 1.1, which defines Professional as any person or entity that (a) is not a broker or dealer in securities, and (b) places more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s).

[4] *See* Securities Exchange Act Release No. 105218 (April 13, 2026), 91 FR 20542 (April 16, 2026) (SR ISE–2026–16) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Review of Professional Orders.)

[5] *See* Rule 1.1, which defines Public Customer as a person that is not a broker or dealer in securities.

[6] The requirement to review Public Customers' activity on at least a quarterly basis to determine whether orders that are not for the account of a broker-dealer should be represented as Public Customer Orders or Professional Orders is not in the current rule text, however it was described in the adopting proposal. See Securities Exchange Act Release No. 78187 (June 28, 2016), 81 FR 43681 (July 5, 2016) (C2–2016–009) (Notice of Filing of Proposed Rule Change Relating to Professionals Order Counting) (''SR–C2–2016–009''). The current proposal seeks to codify the timing for review of Public Customers' activity.

organizations'') [7] are required currently to review their Public Customers' activity and, on at least a quarterly basis, designate orders as Public Customer orders or Professional orders.[8] Specifically, TPH organizations are required to conduct a quarterly review and make any appropriate changes to the way in which they are representing orders within five days after the end of each calendar quarter.[9] While TPH organizations are required to designate accounts on a quarterly basis, if during a quarter the Exchange identifies a customer for which orders are being represented as Public Customer orders but that has averaged more than 390 orders per day during a month, the Exchange must notify the TPH organization and the TPH organization is required to change the manner in which it is representing the customer's orders within five days.[10]

Proposal

At this time, the Exchange proposes to shorten the quarterly review and designation to a monthly review. The Exchange proposes to amend the definition of Professional in Rule 1.1 to require that orders for any customer that had an average of more than 390 orders per day during any calendar month be represented as Professional orders for the next calendar month.

As noted, currently, each TPH organization is required to monitor Public Customer orders to determine if the Public Customer has averaged more than 390 orders per day during a month. Determining whether a Public Customer has executed more than 390 orders per day during a month requires computing a daily average. As such, TPH organizations should be performing the workflow necessary to designate orders on a daily basis. Therefore, the proposal does not amend the current workflow, rather, the proposal amends the timeframe to change the manner in which the customer's order is being represented from five days after the end of each calendar quarter to five days after the end of each calendar month.

The Exchange does not believe that this amendment is a significant departure from the current rule, nor does it impose any burden on any TPH organization because each broker-dealer is required currently to perform the necessary calculation daily to arrive at the requisite average. Further, in addition to the calculation, broker-dealers are subject to know-your-customer and suitability requirements under FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) and would need to consider whether a customer meets the Professional designation for purposes of determining best execution and making appropriate recommendations. The Exchange notes that the trading behavior of a Public Customer can be distinguished from that of a Professional which is the purpose of the separate designations. Finally, some TPH organizations currently designate a Public Customer that has averaged more than 390 orders per day during a month as a Professional on a more expedited basis, not waiting until five days after the quarter.

The Exchange believes that a calendar month is a sufficient time period to determine whether the activity of a customer meets the criteria for a Professional order. The Exchange believes that the shortened time period will ensure that the spirit of the designation of Professional order is met in that TPH organizations will make any appropriate changes to the way in which they are representing orders in a 30-day timeframe as opposed to a 90-day timeframe, thereby ensuring the designation is applied in a more expeditious manner. The Exchange continues to believe that identifying Professional Orders based upon the average number of orders entered in qualified accounts is an appropriate and objective approach to reasonably distinguish such persons and entities from retail investors or market participants.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[11] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [12] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [13] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the Exchange's proposal to shorten the quarterly look-back to a monthly look-back is consistent with the Act because it will ensure that the spirit of the designation of Professional order continues to be met, only on a more expedited basis—removing a potential delay of two months before affecting a change in the designation. The Exchange believes that this amendment will remove impediments to and perfect the mechanism of a free and open market and a national market system by promoting the consistent application of its rules and shortening the timeframe to change the designation for all TPH organizations while continuing to provide a sufficient time period to determine whether the activity of a customer meets the criteria for a Professional order. Further, the Exchange believes that the shortened time period will continue to promote consistency in the treatment of orders as Professional orders while also preventing members with high volume from receiving benefits reserved for Public Customer orders.

As noted, currently, each TPH organization is required to monitor Public Customer orders to determine if the Public Customer has averaged more than 390 orders per day during a month. Determining whether a Public Customer has executed more than 390 orders per day during a month requires computing a daily average. As such, TPH Organizations should be performing the workflow necessary to designate orders on a daily basis. Therefore, the proposal does not amend the current workflow, rather, the proposal amends the timeframe to change the manner in which the customer's order is being represented from five days after the end of each calendar quarter to five days after the end of each calendar month.

The Exchange does not believe that this amendment is a significant departure from the current rule, nor does it impose any burden on any TPH

[7] *See* C2 By-Laws, which defines ''Trading Permit Holder'' as any individual, corporation, partnership, limited liability company or other entity authorized by the Rules that holds a Trading Permit. If a Trading Permit Holder is an individual, the Trading Permit Holder may also be referred to as an ''individual Trading Permit Holder.'' If a Trading Permit Holder is not an individual, the Trading Permit Holder may also be referred to as a ''TPH organization.'' A Trading Permit Holder is a ''member'' solely for purposes of the Act; however, one's status as a Trading Permit Holder does not confer on that Person any ownership interest in the Exchange.

[8] *See* 81 FR 43681 at 43685

[9] *See id.*

[10] *See id.*

[11] 15 U.S.C. 78f(b).

[12] 15 U.S.C. 78f(b)(5).

[13] *Id.*

organization because each broker-dealer is required currently to perform the necessary calculation daily to arrive at the requisite average. Further, in addition to the calculation, broker-dealers are subject to know-your customer and suitability requirements under FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) and would need to consider whether a customer meets the Professional designation for purposes of determining best execution and making appropriate recommendations. Finally, some TPH organizations currently designate a Public Customer that has averaged more than 390 orders per day during a month as a Professional on a more expedited basis, not waiting until five days after the quarter.

The Exchange notes that the trading behavior of a Public Customer can be distinguished from that of a Professional which is the purpose of the separate designations. The Exchange continues to believe that identifying Professional orders based upon the average number of orders entered in qualified accounts is an appropriately objective approach to reasonably distinguish such persons and entities from retail investors or market participants. Priority is one of the marketplace advantages provided to Public Customer orders on the Exchange. Public Customer orders are given execution priority over non-Customer orders and quotations of market makers at the same price. Another marketplace advantage afforded to Public Customer orders on the Exchange is that members are generally not assessed transaction fees or are assessed lower fees for the execution of Public Customer orders. The purpose of these marketplace advantages is to attract retail order flow to the Exchange by leveling the playing field for retail investors over market Professionals. This proposal will continue to provide Public Customer accounts with marketplace advantages and distinguish those accounts non-Professional retail investors from the Professionals accounts. The Exchange notes that some non-broker-dealer individuals and entities have access to information and technology that enables them to Professionally trade listed options in the same manner as a broker or dealer in securities.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange does not believe that the proposed rule change will impose any burden on intra-market competition because, today, each TPH organization is required to monitor Public Customer orders to determine if the Public Customer has averaged more than 390 orders per day during a month. Determining whether a Public Customer has executed more than 390 orders per day during a month requires computing a daily average. As such, TPH organizations should be performing the workflow necessary to designate orders on a daily basis. Therefore, the proposal does not amend the current workflow, rather, the proposal amends the timeframe to change the manner in which the customer's order is being represented from five days after the end of each calendar quarter to five days after the end of each calendar month.

The Exchange does not believe that this amendment is a significant departure from the current rule, nor does it impose any burden on any TPH organization because each broker-dealer is required currently to perform the necessary calculation daily to arrive at the requisite average. Further, in addition to the calculation, broker-dealers are subject to know-your-customer and suitability requirements under FINRA Rules 2090 (Know Your Customer) and 2111 (Suitability) and would need to consider whether a customer meets the Professional designation for purposes of determining best execution and making appropriate recommendations. Finally, some TPH organizations currently designate a Public Customer that has averaged more than 390 orders per day during a month as a Professional on a more expedited basis, not waiting until five days after the quarter.

The Exchange notes that the trading behavior of a Public Customer can be distinguished from that of a Professional which is the purpose of the separate designations.

Further, the designation of Professional orders would not result in any different treatment of such orders for purposes of compliance with the Exchange's Rules. Public Customers have been granted certain priority over other non-broker-dealer individuals and entities that have access to information and technology that enables them to Professionally trade listed options in the same manner as a broker or dealer in securities. Further, the Public Customer designation allows the Exchange to attract order flow or create more competitive markets.

Also, the Exchange does not believe that the proposed rule change will impose any burden on inter-market competition because other exchanges are expected to adopt similar rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not:

A. significantly affect the protection of investors or the public interest;

B. impose any significant burden on competition; and

C. become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6)[15] thereunder.[16]

A proposed rule change filed under Rule 19b–4(f)(6)[17] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[18] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Exchange states that the proposed rule change will ensure fair competition among the exchanges by allowing the Exchange to shorten the quarterly review and designation to a monthly review of TPH organizations to determine whether the activity of a customer meets the criteria for a Professional order. For these reasons, and because the proposed rule change raises no new or novel legal or regulatory issues, the Commission finds that waiver of the operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission waives the 30-day operative delay and

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6).

[16] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[17] 17 CFR 240.19b–4(f)(6).

[18] 17 CFR 240.19b–4(f)(6)(iii).

designates the proposed rule change to be operative upon filing.[19]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–C2–2026–019 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–C2–2026–019. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–C2–2026–019 and should be submitted on or before August 6, 2026.

[19] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14265 Filed 7–15–26; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105897; File No. SR–SAPPHIRE–2026–27]

Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Sapphire Options Exchange Fee Schedule To Extend the Temporary Discount Program for Historical Requests of Certain Open-Close Report Data Until December 31, 2026

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, MIAX Sapphire, LLC (''MIAX Sapphire'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Sapphire Options Exchange Fee Schedule (''Fee Schedule'') to amend the MIAX Sapphire Options Exchange Fee Schedule (''Fee Schedule'') to extend the temporary discount program for historical requests of certain Open-Close Report (described below) data.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 6)c) of the Fee Schedule to extend the temporary discount program for historical requests of certain Open-Close Report data until December 31, 2026. In general, the Exchange currently provides a temporary 20% discount on fees [3] assessed to Open-Close Report subscribers that purchase historical Open-Close Report data (with one exception, described below), which discount is set to expire on June 30, 2026.[4]

By way of background, the Exchange offers an end-of-day summary and two intra-day versions of the Open-Close Report (described in more detail below).[5] The End-of-Day Open-Close Report (referred to herein as the ''End-of-Day Report'') is a volume summary of trading activity on the Exchange at the option level by origin (Priority Customer,[6] Non-Priority Customer, Firm, Broker-Dealer, and Market Maker [7]), side of the market (buy or sell), contract volume, and transaction type (opening or closing). All volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts).

The Intra-Day Open-Close Report provides similar information to that of the End-of-Day Report but is produced and updated at two different intervals during the trading day: 1 minute (referred to herein as the ''1-Minute Report'') and 10 minutes (referred to herein as the ''10-Minute Report''). For

[20] 17 CFR 200.30–3(a)(12), (59).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Unlike the Exchange's affiliates that offer a similar discount for historical purchases of their Open-Close Report data, the Exchange does not require a subscriber to achieve a minimum monetary threshold in order to receive the discount. This is because the Exchange is still a relatively new market, having only launched electronic trading operations less than two years ago.

[4] *See* Securities Exchange Act Release No. 104604 (January 14, 2026), 91 FR 2384 (January 20, 2026) (SR–SAPPHIRE–2025–45).

[5] *See, generally,* Exchange Rule 531(e)(1).

[6] *See* Exchange Rule 100.

[7] *Id.* The Exchange notes that certain terms are not specifically defined in the Rulebook, including Non-Priority Customer, Firm, Broker-Dealer.

the 1-Minute Report and 10-Minute Report, data is captured in ''snapshots'' taken every 1 minute or 10 minutes, respectively, throughout the trading day and is available to subscribers within five minutes of the conclusion of each 1 minute or 10 minute period. Each update represents the aggregate data captured from the current ''snapshot'' and all previous ''snapshots.'' The 1-Minute and 10-Minute Reports provides a volume summary of trading activity on the Exchange at the option level by origin (Priority Customer, Non-Priority Customer, Firm, Broker-Dealer, and Market Maker), side of the market (buy or sell), and transaction type (opening or closing). All volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts).

Each version of the Open-Close Report contains proprietary Exchange trade data and does not include trade data from any other exchange. The Intra-Day and End-of-Day Open-Close Report data products are completely voluntary products, in that the Exchange is not required by any rule or regulation to make this data available and that potential customers may purchase it on an ad-hoc basis only if they voluntarily choose to do so. The Open-Close Report is also a historical data product and not a real-time data feed.

The Exchange makes the Open-Close Report available for purchase to Members [8] and non-Members.[9] Customers may currently purchase the Open-Close Report on a subscription basis (monthly) or by ad-hoc request for a specified month or number of months. The Exchange assesses the following fees for active subscriptions: $600 per month for subscribing to the End-of-Day Report; $2,000 per month for subscribing to the 10-Minute Report; and $6,000 per month for subscribing to the 1-Minute Report.[10] The Exchange also assesses the following fees for ad-hoc historical requests: $500 per request per month for ad-hoc requests for historical End-of-Day Report data; [11] $1,000 per request per month for ad-hoc requests for historical 10-Minute Report data; [12] and $2,500 per request per month for ad-hoc requests for historical 1-Minute Report data.[13] The Exchange also provides discounts or free data for customers who request multiple subscriptions, make ad-hoc requests for historical data for multiple types of the Open-Close Report, or who are Qualifying Academic Purchasers.[14]

Open-Close Report data is subject to direct competition from similar end-of-day and intra-day options trading summaries offered by several other options exchanges.[15] All of these exchanges offer essentially the same end-of-day and intra-day options trading summary information for trading activity on those exchanges.

Currently, the Exchange provides a temporary pricing incentive program in which subscribers that make ad-hoc requests for historical Open-Close Report data receive a percentage fee discount for all purchases. Footnote ''e.'' below the table of fees in Section 6)c) of the Fee Schedule provides that from January 1, 2026 through June 30, 2026, any single ad-hoc purchase of historical End-of-Day Report data and/or historical 10-Minute Report data by an existing End-of-Day Report or 10-Minute Report subscriber will receive a 20% discount when the subscriber purchases the same category of historical data for which they have a monthly subscription.[16] Section 6)c) of the Fee Schedule further provides that this discount cannot be combined with any other discount offered by the Exchange, including the academic discount provided to Qualifying Academic Purchasers of historical Open-Close Report data. To encourage the purchase of monthly subscriptions to Open-Close Report data, the temporary discount program is provided only to existing monthly subscribers who purchase the same category of historical data for which they have a monthly End-of-Day Report or 10-Minute Report subscription. The temporary discount program is currently set to expire on June 30, 2026.

The Exchange now proposes to extend the temporary discount program until December 31, 2026.[17] The purpose of this extension is to continue attracting subscribers of historical Open-Close Report data and making such data more widely accessible. The Exchange notes that the proposed discount will continue to not apply to ad-hoc historical requests for the 1-Minute Report.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[18] in general, and furthers the objectives of Section 6(b)(5) of the Act,[19] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposed changes to its Fee Schedule concerning fees for the Open-Close Report is consistent with Section 6(b) of the Act [20] in general, and furthers the objectives of Section 6(b)(4) of the Act [21] in particular, in that it is an equitable allocation of dues, fees and other charges among its members and other recipients of Exchange data.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. Particularly, the Open-Close Report further broadens the availability of U.S. options market data to investors consistent with the principles of Regulation NMS. The data product also promotes increased transparency through the dissemination

[8] *See* Exchange Rule 100.

[9] *See* Fee Schedule, Section 6)c).

[10] *Id.*

[11] An ad-hoc request for historical End-of-Day Report data can be for any number of months beginning with August 2024 for which the data is available. *Id.*

[12] An ad-hoc request for historical 10-Minute Report data can be for any number of months beginning with August 2024 for which the data is available. *Id.*

[13] An ad-hoc request for historical 1-Minute Report data can be for any number of months beginning with August 2024 for which the data is available. *Id.*

[14] In order to qualify for the academic pricing, an academic purchaser must: (1) be an accredited academic institution or member of the faculty or staff of such an institution, and (2) use the data in independent academic research, academic journals and other publications, teaching and classroom use, or for other bona fide educational purposes (*i.e.* academic use). *See* Securities Exchange Act Release No. 100751 (August 16, 2024), 89 FR 68010 (August 22, 2024) (SR–SAPPHIRE–2024–09).

[15] *See, e.g.,* Cboe DataShop, Open-Close Volume Summary products offered by Cboe Exchange, Inc. (''Cboe''), Cboe C2 Exchange, Inc. (''C2''), Cboe EDGX Exchange, Inc. (''EDGX''), and Cboe BZX Exchange, Inc. (''BZX''), *available at https://datashop.cboe.com/cboe-options-open-close-volume-summary* (last visited June 8, 2026).

[16] The discount applies on an order-by-order basis. To qualify for the discount, an order must contain an ad-hoc request for historical End-of-Day Report data and/or historical 10-Minute Report data.

[17] The Exchange notes that at the end of this period, the temporary discount program will expire unless the Exchange files another 19b–4 Rule Filing with the Securities and Exchange Commission (the ''Commission'') to amend the terms or extend the discount program.

[18] 15 U.S.C. 78f(b).

[19] 15 U.S.C. 78f(b)(5).

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(4).

of the Open-Close Report. Particularly, information regarding opening and closing activity across different option series during the trading day may indicate investor sentiment, which may allow market participants to make better informed trading decisions throughout the day. Subscribers to the data may also be able to enhance their ability to analyze option trade and volume data and create and test trading models and analytical strategies. The Exchange believes that the Open-Close Report provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading and completely optional. Moreover, several other exchanges offer similar data products which offer the same type of data content through end-of-day or intra-day reports.[22]

The Exchange operates in a highly competitive environment. Indeed, there are currently 18 registered options exchanges that trade options. Based on publicly available information, no single options exchange had more than approximately 11–12% of the equity options market share for the month of May 2026 and the Exchange represented only approximately 3.86% of the equity options market share for that month.[23] The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Particularly, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [24] Making similar data products available to market participants fosters competition in the marketplace, and constrains the ability of exchanges to charge supra-competitive fees. In the event that a market participant views one exchange's data product as more or less attractive than the competition they can, and do, switch between similar products. The extension of the fee discount for historical Open-Close Report data is a result of this competitive environment, as the Exchange seeks to continue attracting subscribers of historical Open-Close Report data and making such data more widely accessible.

The Exchange believes that extending the temporary discount program for any Member or non-Member who purchases historical End-of-Day Report or historical 10-Minute Report data is reasonable because such purchasers will continue to receive a 20% discount for purchasing historical Open-Close Report data. The Exchange believes the extended discount is reasonable as it gives purchasers additional time to use and test the historical Open-Close Report data at a discounted rate and therefore should continue to encourage and promote users to purchase the historical Open-Close Report data. Further, the extension of the temporary discount is intended to continue promoting increased use of the Exchange's historical Open-Close Report data by defraying some of the costs a purchaser would ordinarily have to expend. Further, continuing to provide the discount only to existing subscribers of a monthly End-of-Day Report or 10-Minute Report subscription is designed to encourage the purchase of monthly subscriptions to Open-Close Report data.

The Exchange believes that the extension of the temporary discount program is equitable and not unfairly discriminatory because it applies equally to all Members and non-Members who are existing subscribers of the End-of-Day Report or 10-Minute Report and choose to also purchase historical Open-Close Report data for the same category of products. Providing the discount only to existing subscribers is not unfairly discriminatory because it is a reasonable means to encourage the purchase of monthly subscriptions to Open-Close Report data.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to exclude ad-hoc requests for historical 1-Minute Report data from the discount program because a participant who subscribes to the 1-Minute Report (or requests historical 1-Minute Reports) receives ten times the data points that they would receive in comparison to the 10-Minute Report, which is more beneficial since they are receiving additional data based on shorter intervals. The increased frequency of data intervals in the 1-Minute Report provides more current information and more data reporting intervals. As such, the Exchange believes it reasonable, equitable and not unfairly discriminatory to exclude ad-hoc requests for historical 1-Minute Report data from the discount program because of the enhanced value of the 1-Minute Report, which is 10 times the amount of data. In addition, the Exchange offers free historical data for any current subscriber to the 1-Minute Report who makes an ad-hoc request for historical 1-Minute Report data. In particular, a current 1-Minute Report subscriber who purchases historical 1-Minute Report data may submit an ad-hoc request for historical End-of-Day Report data and/or historical 10-Minute Report data for the same date or date range for no additional charge.[25]

Lastly, the purchase of this data product is discretionary and not compulsory. Indeed, no market participant is required to purchase the historical Open-Close Report data, and the Exchange is not required to make the historical Open-Close Report data available to all investors. Potential purchasers may request the data at any time if they believe it to be valuable or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment in which the Exchange must continually adjust its fees to remain competitive. Because competitors are free to modify their own fees in response, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As discussed above, Open-Close Report data is subject to direct competition from several other options exchanges that offer substantively similar substitutes to the Exchange's Open-Close Report, albeit for trading data on those exchanges.[26] Moreover, purchase of historical Open-Close Report data is entirely optional. It is designed to help investors understand underlying market trends to improve the quality of investment decisions, but is not necessary to execute a trade.

The rule change is grounded in the Exchange's efforts to compete more effectively. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Further, the Exchange believes that the proposed

[22] *See supra* note 15.

[23] *See* the ''Market Share'' section of the Exchange's website, *available at https://www.miaxglobal.com/*.

[24] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

[25] *See* Fee Schedule, Section (6)(c), note b.

[26] *See supra* note 15.

change will not cause any unnecessary or inappropriate burden on intermarket competition, as the extension of the temporary discount program applies uniformly to any purchaser of historical Open-Close Report data.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[27] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors, or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–SAPPHIRE–2026–27 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–SAPPHIRE–2026–27. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–SAPPHIRE–2026–27 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[28]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14273 Filed 7–15–26; 8:45 am]

BILLING CODE 8011–01–P

[27] 15 U.S.C. 78s(b)(3)(A)(ii).

[28] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105893; File No. SR–SAPPHIRE–2026–28]

Self-Regulatory Organizations; MIAX Sapphire, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Exchange's Options Regulatory Fee (ORF)

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, 2026, MIAX Sapphire, LLC (''MIAX Sapphire'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Sapphire Options Exchange Fee Schedule (''Fee Schedule'') to amend the MIAX Sapphire Options Exchange Fee Schedule (''Fee Schedule'') regarding the Options Regulatory Fee (''ORF'').

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-sapphire/rule-filings,* and at the Exchange's principal office.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange previously filed to amend its ORF assessment and collection methodology,[3] with the rate to be set closer to the implementation date of the amended ORF collection methodology. At this time, the Exchange proposes to set the ORF rate effective July 1, 2026 to $0.0220 per contract side. Additionally, the Exchange proposes to amend the rule text that describes the ORF collection methodology to provide greater clarity to the ORF collection methodology.

July 1, 2026 ORF

As of July 1, 2026, the Exchange will assess ORF for options transactions that clear in the ''customer'' range at The Options Clearing Corporation (''OCC''), however ORF will be assessed to each Members [4] for executions that occur on the Exchange. Specifically, the ORF will be collected on behalf of the Exchange from Members and non-members for all customer transactions executed on the Exchange. ORF would be assessed and collected on all ultimately cleared customer contracts, taking into account adjustments for CMTA that were provided to the Exchange the same day as the trade.[5] Further, the Exchange

[3] *See* Securities and Exchange Act Release No. 104713 (January 28, 2026) 91 FR 4750 (February 2, 2026) (SR–SAPPHIRE–2026–01) (Self-Regulatory Organizations; MIAX SAPPHIRE, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Adopt a New Methodology for Assessment and Collection of the Options Regulatory Fee (ORF)).

[4] The term ''Member'' means an individual or organization that is registered with the Exchange pursuant to Chapter II of MIAX Sapphire Rules for purposes of trading on the Exchange as an ''Electronic Exchange Member'' or ''Market Maker.'' Members are deemed ''members'' under the Exchange Act. *See* Exchange Rule 100.

[5] Adjustments to CMTA that occur at OCC would not be taken into account.

would bill ORF according to the clearing instructions provided on the execution. More specifically, the Exchange proposes to assess ORF based on the clearing instruction provided on the execution on trade date and would not take into consideration CMTA changes or transfers that occur at OCC.[6]

Based on the Exchange's review of regulatory costs, ORF revenue, and options transaction volume, the Exchange proposes to set the ORF rate effective July 1, 2026 to $0.0220 per contract side. On June 2, 2026, the Exchange notified Members of the proposed ORF rate effective July 1, 2026 via a Regulatory Circular.[7] The Exchange will continue to monitor the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. More specifically, the Exchange will endeavor to ensure that the amount of revenue collected from the ORF will not exceed 80% of the Exchange's regulatory costs. The Exchange will monitor its regulatory costs and revenues at a minimum on a semi-annual basis. If the Exchange determines regulatory revenues exceed or are insufficient to cover a material portion of its regulatory costs in a given year, the Exchange will adjust the ORF by submitting a fee change filing to the Securities and Exchange Commission (the ''Commission''). The Exchange will notify Members of adjustments to the ORF via a Regulatory Circular in advance of any change.

As is the case today, the Exchange will monitor the amount of revenue collected from the ORF to ensure that it, in combination with other regulatory fees and fines, does not exceed regulatory costs. In determining whether an expense is considered a regulatory cost, the Exchange will continue to review all costs and makes determinations if there is a nexus between the expense and a regulatory function. The Exchange notes that fines collected by the Exchange in connection with a disciplinary matter will continue to offset regulatory costs.

Revenue generated from ORF, when combined with all of the Exchange's other regulatory fees and fines, is designed to cover a material portion of the regulatory costs to the Exchange of the supervision and regulation of Members' customer options business including performing routine surveillances, investigations, examinations, financial monitoring, and policy, rulemaking, interpretive, and enforcement activities. Regulatory costs include direct regulatory expenses and certain indirect expenses in support of the regulatory function. The direct expenses include in-house and third party service provider costs to support the day-to-day regulatory work such as surveillances, investigations and examinations. The indirect expenses are only those expenses that are in support of the regulatory functions, such areas include Office of the General Counsel, technology, finance, and internal audit.

Rule Text Amendment

The Exchange proposes to delete the last sentence of the rule text ''The ORF is not assessed on outbound linkage trades.'' This revision more accurately describes the Exchange's collection process as explained in its prior rule proposal.[8] The Exchange proposes this revised rule text because it provides greater clarity to the manner in which ORF is collected.

Additionally, the Exchange proposes to remove obsolete text regarding an ORF rate that is no longer in effect.

2. Statutory Basis

The Exchange believes that its proposal to amend its Fee Schedule is consistent with Section 6(b) of the Act[9] in general, and furthers the objectives of Section 6(b)(4) of the Act[10] in particular, in that it is an equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities. The Exchange also believes the proposal furthers the objectives of Section 6(b)(5) of the Act[11] in that it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest and is not designed to permit unfair discrimination between customers, issuers, brokers and dealers.

The Exchange believes that the proposed fee change is reasonable, equitable and not unfairly discriminatory in that it is charged to all Exchange transactions that clear in the ''customer'' range at the OCC. Additionally, the Exchange believes that the proposed fee change ensures fairness by assessing a specific fee to those Members that require more Exchange regulatory services based on the amount of customer options business they conduct. Over recent years, options trading volume has increased with a growing percentage of the volume applicable to customer transactions. Customers trading on the Exchange (through a Member) benefit from the protections of a robust regulatory program including the maintenance of fair and orderly markets and protections against fraud and other manipulation. The Exchange believes it is equitable and not unfairly discriminatory to assess a regulatory fee to transactions that clear in the ''customer'' range to cover regulatory costs, but not to transactions clearing in the ''firm'' or ''market maker'' range because Clearing Members[12] and Market Makers[13] (who clear in the Firm and Market Maker range), as those market participants are generally subject to other Exchange fees, fines and obligations. For example, Clearing Members and Market Makers are required to pay Exchange application fees, permit fees, and connectivity fees, amongst others. In addition, all fines issued by the Exchange for regulatory infractions are assessed only to Members and would be applied to regulatory revenues. The Exchange expects that Clearing Members from whom the ORF is collected will pass through the fee to their customers (as the Exchange understands occurs today). In addition, Market Makers in particular are subject to various quoting and other obligations to ensure that they provide stable and liquid markets, which benefit all market participants including customers. Excluding Market Maker transactions from the ORF collection will allow Market Makers to better manage their costs more effectively thus enabling them to better allocate resources toward technology, risk management, and capacity to ensure continued liquidity provision.

In addition to the overall increase in ''customer'' range volume generally, regulating customer trading activity is more labor intensive and requires greater expenditure of human and technical resources than regulating non-customer trading activity, which tends to be more automated and less labor-intensive. For example, there are costs

[6] Adjustments that were made the same day as the trade on the Exchange will be taken into account.

[7] *See https://www.miaxglobal.com/alert/2026/06/02/miax-exchange-group-option-markets-options-regulatory-fee-1.*

[8] *See supra* note 3.

[9] 15 U.S.C. 78f(b).

[10] 15 U.S.C. 78f(b)(4).

[11] 15 U.S.C. 78f(b)(5).

[12] Clearing Member means a Member that has been admitted to membership in the Clearing Corporation pursuant to the provisions of the rules of the Clearing Corporation. *See* Exchange Rule 100.

[13] Market Maker means a Member registered with the Exchange for the purpose of making markets in options contracts traded on the Exchange and that is vested with the rights and responsibilities specified in Chapter VI of the Exchange Rules. *See* Exchange Rule 100.

associated with main office and branch office examinations (*e.g.,* staff and travel expenses), as well as investigations into customer complaints and terminations of registered persons. As a result, the costs associated with administering the customer component of the Exchange's overall regulatory program are materially higher than the costs associated with administering the non-customer component (*e.g.,* Clearing Member proprietary transactions) of its regulatory program.[14] While the Exchange notes that it has broad regulatory responsibilities with respect to its Member's activities, irrespective of where their transactions take place, the Exchange believes it is reasonable to assess the proposed fee to only those transactions occurring on the Exchange. The proposed change more narrowly tailors the fee to products and transactions with a direct connection to the Exchange. With this proposal, transactions that would clear in the ''customer'' range occurring on other exchanges would no longer be subject to an ORF assessed by the Exchange.

The Exchange further believes that the proposed change fee is reasonable because it would help ensure that revenue collected from the ORF, in combination with other regulatory fees and fines, would cover a material portion of the Exchange's regulatory costs.

As noted above, the Exchange will also continue to monitor on at least a semiannual basis the amount of revenue collected from the ORF to ensure that it, in combination with its other regulatory fees and fines, would cover a material portion of the Exchange's regulatory costs and not exceed it.

Additionally, the Exchange proposes to delete the last sentence of the rule text and to remove obsolete text regarding the ORF rate that is no longer in effect. The Exchange believes that the proposal to delete the last sentence of the rule text and to remove obsolete text regarding the ORF rate that is no longer in effect would promote just and equitable principles of trade and remove impediments to and perfect the mechanism of a free and open market and a national market system because the proposed change would provide greater clarity to market participants regarding the Exchange's Fee Schedule. It is in the public interest for the Exchange's Fee Schedule to be accurate so as to eliminate the potential for confusion.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. This proposal does not create an unnecessary or inappropriate intra-market burden on competition because the ORF applies to all customer activity on the Exchange, thereby raising regulatory revenue to offset regulatory expenses. It also supplements the regulatory revenue derived from non-customer activity. The Exchange notes, however, the proposed change is not designed to address any competitive issues. Indeed, this proposal does not create an unnecessary or inappropriate inter-market burden on competition because it is a regulatory fee that supports regulation in furtherance of the purposes of the Act. The Exchange is obligated to ensure that the amount of regulatory revenue collected from ORF, in combination with its other regulatory fees and fines, does not exceed regulatory costs.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [15] and paragraph (f) of Rule 19b–4 [16] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–SAPPHIRE–2026–28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–SAPPHIRE–2026–28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–SAPPHIRE–2026–28 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14269 Filed 7–15–26; 8:45 am]

BILLING CODE 8011–01–P

[14] If the Exchange changes its method of funding regulation or if circumstances otherwise change in the future, the Exchange may decide to modify the ORF or assess a separate regulatory fee on Member proprietary transactions if the Exchange deems it advisable.

[15] 15 U.S.C. 78s(b)(3)(A).

[16] 17 CFR 240.19b–4(f).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENTS: 91 FR 42996, July 13, 2026.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: Thursday, July 16, 2026, at 2 p.m.

CHANGES IN THE MEETING: The Closed Meeting scheduled for Thursday, July 16, 2026, at 2 p.m., has been changed to Thursday, July 16, 2026, at 1:30 p.m.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: July 14, 2026.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2026–14379 Filed 7–14–26; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105895; File No. SR–PEARL–2026–32]

Self-Regulatory Organizations; MIAX PEARL, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the MIAX Pearl Options Exchange Fee Schedule To Extend the Temporary Discount Program for Historical Requests of Certain Open-Close Report Data Until December 31, 2026

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, MIAX PEARL, LLC (''MIAX Pearl'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Pearl Options Exchange Fee Schedule (''Fee Schedule'') to extend the temporary discount program for historical requests of certain Open-Close Report (described below) data.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/pearl-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section 6)d) of the Fee Schedule to extend the temporary discount program for historical requests of certain Open-Close Report data until December 31, 2026. In general, the Exchange currently provides a temporary 20% discount on fees assessed to Open-Close Report subscribers that purchase $20,000 or more in a single order of historical Open-Close Report data (with one exception, described below), which discount is set to expire on June 30, 2026.[3]

By way of background, the Exchange offers an end-of-day summary and two intra-day versions of the Open-Close Report (described in more detail below).[4] The End-of-Day Open-Close Report (referred to herein as the ''End-of-Day Report'') is a volume summary of trading activity on the Exchange at the option level by origin (Priority Customer,[5] Non-Priority Customer, Firm, Broker-Dealer, and Market Maker [6]), side of the market (buy or sell), contract volume, and transaction type (opening or closing). All volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts).

The Intra-Day Open-Close Report provides similar information to that of the End-of-Day Report but is produced and updated at two different intervals during the trading day: 1 minute (referred to herein as the ''1-Minute Report'') and 10 minutes (referred to herein as the ''10-Minute Report''). For the 1-Minute Report and 10-Minute Report, data is captured in ''snapshots'' taken every 1 minute or 10 minutes, respectively, throughout the trading day and is available to subscribers within five minutes of the conclusion of each 1 minute or 10 minute period. Each update represents the aggregate data captured from the current ''snapshot'' and all previous ''snapshots.'' The 1-Minute and 10-Minute Reports provides a volume summary of trading activity on the Exchange at the option level by origin (Priority Customer, Non-Priority Customer, Firm, Broker-Dealer, and Market Maker), side of the market (buy or sell), and transaction type (opening or closing). All volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts).

Each version of the Open-Close Report contains proprietary Exchange trade data and does not include trade data from any other exchange. The Intra-Day and End-of-Day Open-Close Report data products are completely voluntary products, in that the Exchange is not required by any rule or regulation to make this data available and that potential customers may purchase it on an ad-hoc basis only if they voluntarily choose to do so. The Open-Close Report is also a historical data product and not a real-time data feed.

The Exchange makes the Open-Close Report available for purchase to Members [7] and non-Members.[8] Customers may currently purchase the Open-Close Report on a subscription basis (monthly) or by ad-hoc request for a specified month or number of months. The Exchange assesses the following fees for active subscriptions: $600 per month for subscribing to the End-of-Day Report; $2,000 per month for subscribing to the 10-Minute Report; and $6,000 per month for subscribing to the 1-Minute Report.[9] The Exchange also assesses the following fees for ad-hoc historical requests: $500 per request per month for ad-hoc requests for historical End-of-Day Report data; [10] $1,000 per request per month for ad-hoc requests for historical 10-Minute Report data; [11] and $2,500 per request per month for ad-hoc requests for historical 1-Minute Report data.[12] The Exchange also provides discounts or free data for customers who request multiple subscriptions, make ad-hoc requests for historical data for multiple types of the

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 104606 (January 14, 2026), 91 FR 2406 (January 20, 2026) (SR–PEARL–2025–52).

[4] *See, generally,* Exchange Rule 531(d)(1).

[5] *See* Exchange Rule 100.

[6] *Id.* The Exchange notes that certain terms are not specifically defined in the Rulebook, including Non-Priority Customer, Firm, Broker-Dealer.

[7] *See* Exchange Rule 100.

[8] *See* Fee Schedule, Section 6)d).

[9] *Id.*

[10] An ad-hoc request for historical End-of-Day Report data can be for any number of months beginning with June 2021 for which the data is available. *Id.*

[11] An ad-hoc request for historical 10-Minute Report data can be for any number of months beginning with March 2017 for which the data is available. *Id.*

[12] An ad-hoc request for historical 1-Minute Report data can be for any number of months beginning with March 2017 for which the data is available. *Id.*

Open-Close Report, or who are Qualifying Academic Purchasers.[13]

Open-Close Report data is subject to direct competition from similar end-of-day and intra-day options trading summaries offered by several other options exchanges.[14] All of these exchanges offer essentially the same end-of-day and intra-day options trading summary information for trading activity on those exchanges.

Currently, the Exchange provides a temporary pricing incentive program in which subscribers that make ad-hoc requests for historical Open-Close Report data receive a percentage fee discount when a specific purchase threshold is met. Footnote ''e.'' below the table of fees in Section 6)d) of the Fee Schedule provides that from January 1, 2026 through June 30, 2026, any single ad-hoc purchase of historical End-of-Day Report data and/or historical 10-Minute Report data by an existing End-of-Day Report or 10-Minute Report subscriber totaling $20,000 or more, will receive a 20% discount when the subscriber purchases the same category of historical data for which they have a monthly subscription.[15] Section 6)d) of the Fee Schedule further provides that this discount cannot be combined with any other discount offered by the Exchange, including the academic discount provided to Qualifying Academic Purchasers of historical Open-Close Report data. To encourage the purchase of monthly subscriptions to Open-Close Report data, the temporary discount program is provided only to existing monthly subscribers who purchase the same category of historical data for which they have a monthly End-of-Day Report or 10-Minute Report subscription. The temporary discount program is currently set to expire on June 30, 2026.

The Exchange now proposes to extend the temporary discount program until December 31, 2026.[16] The purpose of this extension is to continue attracting subscribers of historical Open-Close Report data and making such data more widely accessible. The Exchange notes that the proposed discount will continue to not apply to ad-hoc historical requests for the 1-Minute Report.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Section 6(b)(5) of the Act,[18] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposed changes to its Fee Schedule concerning fees for the Open-Close Report is consistent with Section 6(b) of the Act [19] in general, and furthers the objectives of Section 6(b)(4) of the Act [20] in particular, in that it is an equitable allocation of dues, fees and other charges among its members and other recipients of Exchange data.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. Particularly, the Open-Close Report further broadens the availability of U.S. options market data to investors consistent with the principles of Regulation NMS. The data product also promotes increased transparency through the dissemination of the Open-Close Report. Particularly, information regarding opening and closing activity across different option series during the trading day may indicate investor sentiment, which may allow market participants to make better informed trading decisions throughout the day. Subscribers to the data may also be able to enhance their ability to analyze option trade and volume data and create and test trading models and analytical strategies. The Exchange believes that the Open-Close Report provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading and completely optional. Moreover, several other exchanges offer similar data products which offer the same type of data content through end-of-day or intra-day reports.[21]

The Exchange operates in a highly competitive environment. Indeed, there are currently 18 registered options exchanges that trade options. Based on publicly available information, no single options exchange had more than approximately 11–12% of the equity options market share for the month of May 2026 and the Exchange represented only approximately 1.69% of the equity options market share for that month.[22] The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Particularly, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [23] Making similar data products available to market participants fosters competition in the marketplace, and constrains the ability of exchanges to charge supra-competitive fees. In the event that a market participant views one exchange's data product as more or less attractive than the competition they can, and do, switch between similar products. The extension of the fee discount for historical Open-Close Report data is a result of this competitive environment, as the Exchange seeks to continue attracting subscribers of historical Open-Close

[13] In order to qualify for the academic pricing, an academic purchaser must: (1) be an accredited academic institution or member of the faculty or staff of such an institution, and (2) use the data in independent academic research, academic journals and other publications, teaching and classroom use, or for other bona fide educational purposes (*i.e.* academic use). *See* Securities Exchange Act Release No. 97305 (April 13, 2024), 88 FR 24242 (April 19, 2023) (SR–PEARL–2023–17).

[14] *See, e.g.,* Cboe DataShop, Open-Close Volume Summary products offered by Cboe Exchange, Inc. (''Cboe''), Cboe C2 Exchange, Inc. (''C2''), Cboe EDGX Exchange, Inc. (''EDGX''), and Cboe BZX Exchange, Inc. (''BZX''), *available at https://datashop.cboe.com/cboe-options-open-close-volume-summary* (last visited June 8, 2026).

[15] The discount applies on an order-by-order basis. To qualify for the discount, an order must contain an ad-hoc request for historical End-of-Day Report data and/or historical 10-Minute Report data and must total $20,000 or more. The Exchange does not aggregate purchases made throughout a billing cycle for purposes of this incentive program. The discount applies to the total purchase price once the $20,000 minimum purchase is satisfied (for example, a qualifying order of $25,000 would be discounted to $20,000, *i.e.* receiving a 20% discount of $5,000).

[16] The Exchange notes that at the end of this period, the temporary discount program will expire unless the Exchange files another 19b–4 Rule Filing with the Securities and Exchange Commission (the ''Commission'') to amend the terms or extend the discount program.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(4).

[21] *See supra* note 14.

[22] *See* the ''Market Share'' section of the Exchange's website, *available at https://www.miaxglobal.com/*.

[23] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

Report data and making such data more widely accessible.

The Exchange believes that extending the temporary discount program for any Member or non-Member who purchases historical End-of-Day Report or historical 10-Minute Report data is reasonable because such purchasers will continue to receive a 20% discount for purchasing $20,000 or more worth of such historical Open-Close Report data. The Exchange believes the extended discount is reasonable as it gives purchasers additional time to use and test the historical Open-Close Report data at a discounted rate and therefore should continue to encourage and promote users to purchase the historical Open-Close Report data. Further, the extension of the temporary discount is intended to continue promoting increased use of the Exchange's historical Open-Close Report data by defraying some of the costs a purchaser would ordinarily have to expend. Further, continuing to provide the discount only to existing subscribers of a monthly End-of-Day Report or 10-Minute Report subscription is designed to encourage the purchase of monthly subscriptions to Open-Close Report data.

The Exchange believes that the extension of the temporary discount program is equitable and not unfairly discriminatory because it applies equally to all Members and non-Members who are existing subscribers of the End-of-Day Report or 10-Minute Report and choose to also purchase historical Open-Close Report data for the same category of products. Providing the discount only to existing subscribers is not unfairly discriminatory because it is a reasonable means to encourage the purchase of monthly subscriptions to Open-Close Report data.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to exclude ad-hoc requests for historical 1-Minute Report data from the discount program because a participant who subscribes to the 1-Minute Report (or requests historical 1-Minute Reports) receives ten times the data points that they would receive in comparison to the 10-Minute Report, which is more beneficial since they are receiving additional data based on shorter intervals. The increased frequency of data intervals in the 1-Minute Report provides more current information and more data reporting intervals. As such, the Exchange believes it reasonable, equitable and not unfairly discriminatory to exclude ad-hoc requests for historical 1-Minute Report data from the discount program because of the enhanced value of the 1-Minute Report, which is 10 times the amount of data. In addition, the Exchange offers free historical data for any current subscriber to the 1-Minute Report who makes an ad-hoc request for historical 1-Minute Report data. In particular, a current 1-Minute Report subscriber who purchases historical 1-Minute Report data may submit an ad-hoc request for historical End-of-Day Report data and/or historical 10-Minute Report data for the same date or date range for no additional charge.[24]

Lastly, the purchase of this data product is discretionary and not compulsory. Indeed, no market participant is required to purchase the historical Open-Close Report data, and the Exchange is not required to make the historical Open-Close Report data available to all investors. Potential purchasers may request the data at any time if they believe it to be valuable or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment in which the Exchange must continually adjust its fees to remain competitive. Because competitors are free to modify their own fees in response, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As discussed above, Open-Close Report data is subject to direct competition from several other options exchanges that offer substantively similar substitutes to the Exchange's Open-Close Report, albeit for trading data on those exchanges.[25] Moreover, purchase of historical Open-Close Report data is entirely optional. It is designed to help investors understand underlying market trends to improve the quality of investment decisions, but is not necessary to execute a trade.

The rule change is grounded in the Exchange's efforts to compete more effectively. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Further, the Exchange believes that the proposed change will not cause any unnecessary or inappropriate burden on intermarket competition, as the extension of the temporary discount program applies uniformly to any purchaser of historical Open-Close Report data.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[26] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors, or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–PEARL–2026–32 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–PEARL–2026–32. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will

[24] *See* Fee Schedule, Section 6)d), note b.

[25] *See supra* note 14.

[26] 15 U.S.C. 78s(b)(3)(A)(ii).

be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–PEARL–2026–32 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14271 Filed 7–15–26; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–105898; File No. SR–MIAX–2026–28]

Self-Regulatory Organizations; Miami International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule To Extend the Temporary Discount Program for Historical Requests of Certain Open-Close Report Data Until December 31, 2026

July 13, 2026.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Exchange Act'' or ''Act'') [1] and Rule 19b–4 thereunder,[2] notice is hereby given that on June 30, 2026, Miami International Securities Exchange, LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the MIAX Options Exchange Fee Schedule (''Fee Schedule'') to extend the temporary discount program for historical requests of certain Open-Close Report (described below) data.

The text of the proposed rule change is available on the Exchange's website at *https://www.miaxglobal.com/markets/us-options/miax-options/rule-filings,* and at the Exchange's principal office.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Section (6)(e) of the Fee Schedule to extend the temporary discount program for historical requests of certain Open-Close Report data until December 31, 2026. In general, the Exchange currently provides a temporary 20% discount on fees assessed to Open-Close Report subscribers that purchase $20,000 or more in a single order of historical Open-Close Report data (with one exception, described below), which discount is set to expire on June 30, 2026.[3]

By way of background, the Exchange offers an end-of-day summary and two intra-day versions of the Open-Close Report (described in more detail below).[4] The End-of-Day Open-Close Report (referred to herein as the ''End-of-Day Report'') is a volume summary of trading activity on the Exchange at the option level by origin (Priority Customer,[5] Non-Priority Customer, Firm, Broker-Dealer, and Market Maker [6]), side of the market (buy or sell), contract volume, and transaction type (opening or closing). All volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts).

The Intra-Day Open-Close Report provides similar information to that of the End-of-Day Report but is produced and updated at two different intervals during the trading day: 1 minute (referred to herein as the ''1-Minute Report'') and 10 minutes (referred to herein as the ''10-Minute Report''). For the 1-Minute Report and 10-Minute Report, data is captured in ''snapshots'' taken every 1 minute or 10 minutes, respectively, throughout the trading day and is available to subscribers within five minutes of the conclusion of each 1 minute or 10 minute period. Each update represents the aggregate data captured from the current ''snapshot'' and all previous ''snapshots.'' The 1-Minute and 10-Minute Reports provides a volume summary of trading activity on the Exchange at the option level by origin (Priority Customer, Non-Priority Customer, Firm, Broker-Dealer, and Market Maker), side of the market (buy or sell), and transaction type (opening or closing). All volume is further broken down into trade size buckets (less than 100 contracts, 100–199 contracts, greater than 199 contracts).

Each version of the Open-Close Report contains proprietary Exchange trade data and does not include trade data from any other exchange. The Intra-Day and End-of-Day Open-Close Report data products are completely voluntary products, in that the Exchange is not required by any rule or regulation to make this data available and that potential customers may purchase it on an ad-hoc basis only if they voluntarily choose to do so. The Open-Close Report is also a historical data product and not a real-time data feed.

The Exchange makes the Open-Close Report available for purchase to Members [7] and non-Members.[8] Customers may currently purchase the Open-Close Report on a subscription basis (monthly) or by ad-hoc request for a specified month or number of months. The Exchange assesses the following fees for active subscriptions: $600 per month for subscribing to the End-of-Day Report; $3,000 per month for subscribing to the 10-Minute Report; and $9,000 per month for subscribing to the 1-Minute Report.[9] The Exchange also assesses the following fees for ad-hoc historical requests: $500 per request per month for ad-hoc requests for historical End-of-Day Report data; [10] $1,000 per request per month for ad-hoc requests for historical 10-Minute Report

[27] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 104607 (January 14, 2026), 91 FR 2387 (January 20, 2026) (SR–MIAX–2025–51).

[4] *See, generally,* Exchange Rule 531(e)(1).

[5] *See* Exchange Rule 100.

[6] *Id.* The Exchange notes that certain terms are not specifically defined in the Rulebook, including Non-Priority Customer, Firm, Broker-Dealer.

[7] *See* Exchange Rule 100.

[8] *See* Fee Schedule, Section (6)(e).

[9] *Id.*

[10] An ad-hoc request for historical End-of-Day Report data can be for any number of months beginning with June 2021 for which the data is available. *Id.*

data; [11] and $4,000 per request per month for ad-hoc requests for historical 1-Minute Report data.[12] The Exchange also provides discounts or free data for customers who request multiple subscriptions, make ad-hoc requests for historical data for multiple types of the Open-Close Report, or who are Qualifying Academic Purchasers.[13]

Open-Close Report data is subject to direct competition from similar end-of-day and intra-day options trading summaries offered by several other options exchanges.[14] All of these exchanges offer essentially the same end-of-day and intra-day options trading summary information for trading activity on those exchanges.

Currently, the Exchange provides a temporary pricing incentive program in which subscribers that make ad-hoc requests for historical Open-Close Report data receive a percentage fee discount when a specific purchase threshold is met. Footnote ''e.'' below the table of fees in Section (6)(e) of the Fee Schedule provides that from January 1, 2026 through June 30, 2026, any single ad-hoc purchase of historical End-of-Day Report data and/or historical 10-Minute Report data by an existing End-of-Day Report or 10-Minute Report subscriber totaling $20,000 or more, will receive a 20% discount when the subscriber purchases the same category of historical data for which they have a monthly subscription.[15] Section (6)(e) of the Fee Schedule further provides that this discount cannot be combined with any other discount offered by the Exchange, including the academic discount provided to Qualifying Academic Purchasers of historical Open-Close Report data. To encourage the purchase of monthly subscriptions to Open-Close Report data, the temporary discount program is provided only to existing monthly subscribers who purchase the same category of historical data for which they have a monthly End-of-Day Report or 10-Minute Report subscription. The temporary discount program is currently set to expire on June 30, 2026.

The Exchange now proposes to extend the temporary discount program until December 31, 2026.[16] The purpose of this extension is to continue attracting subscribers of historical Open-Close Report data and making such data more widely accessible. The Exchange notes that the proposed discount will continue to not apply to ad-hoc historical requests for the 1-Minute Report.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[17] in general, and furthers the objectives of Section 6(b)(5) of the Act,[18] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and to protect investors and the public interest, and that it is not designed to permit unfair discrimination among customers, brokers, or dealers. The Exchange also believes that its proposed changes to its Fee Schedule concerning fees for the Open-Close Report is consistent with Section 6(b) of the Act [19] in general, and furthers the objectives of Section 6(b)(4) of the Act [20] in particular, in that it is an equitable allocation of dues, fees and other charges among its members and other recipients of Exchange data.

In adopting Regulation NMS, the Commission granted self-regulatory organizations (''SROs'') and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data. Particularly, the Open-Close Report further broadens the availability of U.S. options market data to investors consistent with the principles of Regulation NMS. The data product also promotes increased transparency through the dissemination of the Open-Close Report. Particularly, information regarding opening and closing activity across different option series during the trading day may indicate investor sentiment, which may allow market participants to make better informed trading decisions throughout the day. Subscribers to the data may also be able to enhance their ability to analyze option trade and volume data and create and test trading models and analytical strategies. The Exchange believes that the Open-Close Report provides a valuable tool that subscribers can use to gain comprehensive insight into the trading activity in a particular series, but also emphasizes such data is not necessary for trading and completely optional. Moreover, several other exchanges offer similar data products which offer the same type of data content through end-of-day or intra-day reports.[21]

The Exchange operates in a highly competitive environment. Indeed, there are currently 18 registered options exchanges that trade options. Based on publicly available information, no single options exchange had more than approximately 11–12% of the equity options market share for the month of May 2026 and the Exchange represented only approximately 8.32% of the equity options market share for that month.[22] The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. Particularly, in Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [23] Making similar data products available to market participants fosters

[11] An ad-hoc request for historical 10-Minute Report data can be for any number of months beginning with January 2013 for which the data is available. *Id.*

[12] An ad-hoc request for historical 1-Minute Report data can be for any number of months beginning with January 2013 for which the data is available. *Id.*

[13] In order to qualify for the academic pricing, an academic purchaser must: (1) be an accredited academic institution or member of the faculty or staff of such an institution, and (2) use the data in independent academic research, academic journals and other publications, teaching and classroom use, or for other bona fide educational purposes (*i.e.* academic use). *See* Securities Exchange Act Release No. 97302 (April 13, 2024), 88 FR 24221 (April 19, 2023) (SR–MIAX–2023–15).

[14] *See, e.g.,* Cboe DataShop, Open-Close Volume Summary products offered by Cboe Exchange, Inc. (''Cboe''), Cboe C2 Exchange, Inc. (''C2''), Cboe EDGX Exchange, Inc. (''EDGX''), and Cboe BZX Exchange, Inc. (''BZX''), *available at https://datashop.cboe.com/cboe-options-open-close-volume-summary* (last visited June 8, 2026).

[15] The discount applies on an order-by-order basis. To qualify for the discount, an order must contain an ad-hoc request for historical End-of-Day Report data and/or historical 10-Minute Report data and must total $20,000 or more. The Exchange does not aggregate purchases made throughout a billing cycle for purposes of this incentive program. The discount applies to the total purchase price once the $20,000 minimum purchase is satisfied (for example, a qualifying order of $25,000 would be discounted to $20,000, *i.e.* receiving a 20% discount of $5,000).

[16] The Exchange notes that at the end of this period, the temporary discount program will expire unless the Exchange files another 19b–4 Rule Filing with the Securities and Exchange Commission (the ''Commission'') to amend the terms or extend the discount program.

[17] 15 U.S.C. 78f(b).

[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78f(b).

[20] 15 U.S.C. 78f(b)(4).

[21] *See supra* note 14.

[22] *See* the ''Market Share'' section of the Exchange's website, *available at https://www.miaxglobal.com/.*

[23] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (''Regulation NMS Adopting Release'').

competition in the marketplace, and constrains the ability of exchanges to charge supra-competitive fees. In the event that a market participant views one exchange's data product as more or less attractive than the competition they can, and do, switch between similar products. The extension of the fee discount for historical Open-Close Report data is a result of this competitive environment, as the Exchange seeks to continue attracting subscribers of historical Open-Close Report data and making such data more widely accessible.

The Exchange believes that extending the temporary discount program for any Member or non-Member who purchases historical End-of-Day Report or historical 10-Minute Report data is reasonable because such purchasers will continue to receive a 20% discount for purchasing $20,000 or more worth of such historical Open-Close Report data. The Exchange believes the extended discount is reasonable as it gives purchasers additional time to use and test the historical Open-Close Report data at a discounted rate and therefore should continue to encourage and promote users to purchase the historical Open-Close Report data. Further, the extension of the temporary discount is intended to continue promoting increased use of the Exchange's historical Open-Close Report data by defraying some of the costs a purchaser would ordinarily have to expend. Further, continuing to provide the discount only to existing subscribers of a monthly End-of-Day Report or 10-Minute Report subscription is designed to encourage the purchase of monthly subscriptions to Open-Close Report data.

The Exchange believes that the extension of the temporary discount program is equitable and not unfairly discriminatory because it applies equally to all Members and non-Members who are existing subscribers of the End-of-Day Report or 10-Minute Report and choose to also purchase historical Open-Close Report data for the same category of products. Providing the discount only to existing subscribers is not unfairly discriminatory because it is a reasonable means to encourage the purchase of monthly subscriptions to Open-Close Report data.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to exclude ad-hoc requests for historical 1-Minute Report data from the discount program because a participant who subscribes to the 1-Minute Report (or requests historical 1-Minute Reports) receives ten times the data points that they would receive in comparison to the 10-Minute Report, which is more beneficial since they are receiving additional data based on shorter intervals. The increased frequency of data intervals in the 1-Minute Report provides more current information and more data reporting intervals. As such, the Exchange believes it reasonable, equitable and not unfairly discriminatory to exclude ad-hoc requests for historical 1-Minute Report data from the discount program because of the enhanced value of the 1-Minute Report, which is 10 times the amount of data. In addition, the Exchange offers free historical data for any current subscriber to the 1-Minute Report who makes an ad-hoc request for historical 1-Minute Report data. In particular, a current 1-Minute Report subscriber who purchases historical 1-Minute Report data may submit an ad-hoc request for historical End-of-Day Report data and/or historical 10-Minute Report data for the same date or date range for no additional charge.[24]

Lastly, the purchase of this data product is discretionary and not compulsory. Indeed, no market participant is required to purchase the historical Open-Close Report data, and the Exchange is not required to make the historical Open-Close Report data available to all investors. Potential purchasers may request the data at any time if they believe it to be valuable or may decline to purchase such data.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange operates in a highly competitive environment in which the Exchange must continually adjust its fees to remain competitive. Because competitors are free to modify their own fees in response, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As discussed above, Open-Close Report data is subject to direct competition from several other options exchanges that offer substantively similar substitutes to the Exchange's Open-Close Report, albeit for trading data on those exchanges.[25] Moreover, purchase of historical Open-Close Report data is entirely optional. It is designed to help investors understand underlying market trends to improve the quality of investment decisions, but is not necessary to execute a trade.

The rule change is grounded in the Exchange's efforts to compete more effectively. In this competitive environment, potential purchasers are free to choose which, if any, similar product to purchase to satisfy their need for market information. As a result, the Exchange believes this proposed rule change permits fair competition among national securities exchanges. Further, the Exchange believes that the proposed change will not cause any unnecessary or inappropriate burden on intermarket competition, as the extension of the temporary discount program applies uniformly to any purchaser of historical Open-Close Report data.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[26] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) necessary or appropriate in the public interest; (ii) for the protection of investors, or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–MIAX–2026–28 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange

[24] *See* Fee Schedule, Section 6)e), note b.

[25] *See supra* note 14.

[26] 15 U.S.C. 78s(b)(3)(A)(ii).

Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to file number SR–MIAX–2026–28. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*https://www.sec.gov/rules/sro.shtml*). Copies of the filing will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–MIAX–2026–28 and should be submitted on or before August 6, 2026.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[27]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2026–14274 Filed 7–15–26; 8:45 am]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21700 and #21701; GUAM Disaster Number GU–20001]

Presidential Declaration of a Major Disaster for Public Assistance Only for the Territory of Guam

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of the Presidential declaration of a major disaster for Public Assistance Only for the territory of Guam (FEMA–4921–DR), dated June 30, 2026.

Incident: Super Typhoon Sinlaku.

DATES: Issued on June 30, 2026.

Incident Period: April 11, 2026 through April 18, 2026.

Physical Loan Application Deadline Date: August 31, 2026.

Economic Injury (EIDL) Loan Application Deadline Date: March 30, 2027.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Sharon Henderson, Office of Disaster Recovery and Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given as a result of the President's major disaster declaration on June 30, 2026, Private Non-Profit organizations providing essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or in person at other locally announced locations. For further assistance please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

The following areas have been determined to be adversely affected by the disaster:

Primary Area: Guam.

The Interest Rates are:

	Percent
For Physical Damage:	
Private Non-Profit Organizations with Credit Available Elsewhere	3.625
Private Non-Profit Organizations without Credit Available Elsewhere	3.625
For Economic Injury:	
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 217008 and for economic injury is 217010.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority:13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2026–14431 Filed 7–15–26; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

Advisory Committee Charter Renewal

AGENCY: U.S. Small Business Administration (SBA).

ACTION: Notice of advisory committee charter renewal.

SUMMARY: Pursuant to sections 14(b) (1) and 9(c) of the Federal Advisory Act (Pub. L. 92–463) and consultation with the General Services Administration, the Small Business Administration has determined that the Invention, Innovation, Entrepreneurship Advisory Committee and the Investment Capital Advisory Committee are in the public interest and essential to the conduct of agency business. Accordingly, the charters for these committees are renewed for a two-year period, effective from the date they are filed with Congress.

DATES: Renewed through July 21, 2028.

FOR FURTHER INFORMATION CONTACT: Andrienne Johnson, Committee Management Officer (CMO), Office of the Administrator, (202) 205–6685 or *FACA@sba.gov.*

SUPPLEMENTARY INFORMATION:

The Invention, Innovation, and Entrepreneurship Advisory Committee

The Invention, Innovation, and Entrepreneurship Advisory Committee provides advice and recommendations to SBA on matters relating to the innovation ecosystem, innovation commercialization and lab-to-market translation. Committee members shall examine the issues, challenges and obstacles facing U.S. innovation economy stakeholders in these subject areas and recommend to SBA policy and programmatic changes to help strengthen and refine SBA's programs and services.

Investment Capital Advisory Committee

The Investment Capital Advisory Committee provides advice and recommendations to SBA on matters relating to institutional investment market trends, innovation, and policy impacting small businesses' ability to access patient investment capital. Committee members will examine the issues, challenges and obstacles facing capital markets, investment managers, and small business entrepreneurs and the stakeholders supporting them in these subject areas and recommend to SBA policy and programmatic changes to help strengthen and refine SBA's programs and services to better facilitate the flow of investment capital to undercapitalized small businesses.

(Authority: 5 U.S.C.10.)

Dated: July 14, 2026.

Andrienne Johnson,

Committee Management Officer.

[FR Doc. 2026–14356 Filed 7–15–26; 8:45 am]

BILLING CODE 8026–09–P

[27] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21681 and #21682; Illinois Disaster Number IL–20027]

Administrative Declaration of a Disaster for the State of Illinois

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of an Administrative declaration of a disaster for the state of ILLINOIS dated July 10, 2026.

Incident: Severe Storms and Tornadoes.

DATES: Issued on July 10, 2026.

Incident Period: June 11, 2026.

Physical Loan Application Deadline Date: September 8, 2026.

Economic Injury (EIDL) Loan Application Deadline Date: April 12, 2027.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Jennifer Talarico, Office of Disaster Recovery and Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given as a result of the Administrator's disaster declaration, applications for disaster loans may be submitted online using the MySBA Loan Portal *https://lending.sba.gov* or in person at other locally announced locations. For further assistance please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Cook, LaSalle.

Contiguous Counties:

Illinois: Bureau, DeKalb, DuPage, Grundy, Kane, Kendall, Lake, Lee, Livingston, Marshall, McHenry, Putnam, Will, Woodford.

Indiana: Lake.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.750
Homeowners without Credit Available Elsewhere	2.875
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Private Non-Profit Organizations with Credit Available Elsewhere	3.625
Private Non-Profit Organizations without Credit Available Elsewhere	3.625
For Economic Injury:	
Business and Small Agricultural Cooperatives without Credit Available Elsewhere	4.000
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 21681C and for economic injury is 216820.

The states which received an SBA Administrative declaration are Illinois, Indiana.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority: 13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2026–14331 Filed 7–15–26; 8:45 am]

BILLING CODE 8026–09–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #21698 and #21699; MISSOURI Disaster Number MO–20030]

Presidential Declaration of a Major Disaster for Public Assistance Only for the State of Missouri

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is notice of the Presidential declaration of a major disaster for Public Assistance Only for the state of Missouri (FEMA–4924–DR), dated June 30, 2026.

Incident: Severe Storms, Tornadoes, and Flooding.

DATES: Issued on June 30, 2026.

Incident Period: April 23, 2026 through April 28, 2026.

Physical Loan Application Deadline Date: August 31, 2026.

Economic Injury (EIDL) Loan Application Deadline Date: March 30, 2027.

ADDRESSES: *Visit the MySBA Loan Portal at https://lending.sba.gov* to apply for a disaster assistance loan.

FOR FURTHER INFORMATION CONTACT: Jennifer Talarico, Office of Disaster Recovery and Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given as a result of the President's major disaster declaration on June 30, 2026, Private Non-Profit organizations providing essential services of a governmental nature may file disaster loan applications online using the MySBA Loan Portal *https://lending.sba.gov* or in person at other locally announced locations. For further assistance please contact the SBA disaster assistance customer service center by email at *disastercustomerservice@sba.gov* or by phone at 1–800–659–2955. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Carroll, Chariton, Greene, Holt, Howard, Monroe, Randolph, Ripley, Saline, St. Francois.

The Interest Rates are:

	Percent
For Physical Damage:	
Private Non-Profit Organizations with Credit Available Elsewhere	3.625
Private Non-Profit Organizations without Credit Available Elsewhere	3.625
For Economic Injury:	
Private Non-Profit Organizations without Credit Available Elsewhere	3.625

The number assigned to this disaster for physical damage is 21698B and for economic injury is 216990.

(Catalog of Federal Domestic Assistance Number 59008)

(Authority:13 CFR 123.3(b).)

James Stallings,

Associate Administrator, Office of Disaster Recovery & Resilience.

[FR Doc. 2026–14354 Filed 7–15–26; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 13066]

Specially Designated Global Terrorist Designations of Juarez Cartel and Los Viagras

Acting under the authority of and in accordance with section 1(a)(ii)(A) of Executive Order 13224, as amended (''E.O. 13224'' or ''Order''), I hereby determine that the person known as

Juarez Cartel (also known as Cartel de Juarez, La Linea, Vicente Carrillo Fuentes Organization, VCFO, Carrillo Fuentes Drug Trafficking Organization, Barrio Azteca) and Los Viagras (also known as Los Viagras Cartel, Cartel de Los Viagras, Los Blancos de Troya) are foreign persons who have committed or have attempted to commit, poses a significant risk of committing, or have participated in training to commit acts of terrorism that threaten the security of U.S. nationals or the national security, foreign policy, or economy of the United States.

Consistent with the determination in section 10 of E.O. 13224 that prior notice to persons determined to be subject to the Order who might have a constitutional presence in the United States would render ineffectual the blocking and other measures authorized in the Order because of the ability to transfer funds instantaneously, I determine that no prior notice needs to be provided to any person subject to this determination who might have a constitutional presence in the United States, because to do so would render ineffectual the measures authorized in the Order.

This determination shall be published in the **Federal Register**.

Dated: July 2, 2026.

Marco Rubio,

Secretary of State, U.S. Department of State.

[FR Doc. 2026–14278 Filed 7–15–26; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 13065]

Foreign Terrorist Organization Designation of Juarez Cartel and Los Viagras

Based upon a review of the Administrative Records assembled in this matter, and in consultation with the Attorney General and the Secretary of the Treasury, I have concluded that there is a sufficient factual basis to find that the relevant circumstances described in section 219 of the Immigration and Nationality Act, as amended (hereinafter ''INA'') (8 U.S.C. 1189), exist with respect to: Juarez Cartel (also known as Cartel de Juarez, La Linea, Vicente Carrillo Fuentes Organization, VCFO, Carrillo Fuentes Drug Trafficking Organization, Barrio Azteca) and Los Viagras (also known as Los Viagras Cartel, Cartel de Los Viagras, Los Blancos de Troya).

Therefore, I hereby designate the aforementioned organizations and their respective aliases as Foreign Terrorist Organizations pursuant to section 219 of the INA.

This determination shall be published in the **Federal Register**. These designations go into effect upon publication.

Dated: July 2, 2026.

Marco Rubio,

Secretary of State, U.S. Department of State.

[FR Doc. 2026–14259 Filed 7–15–26; 8:45 am]

BILLING CODE 4710–AD–P

SURFACE TRANSPORTATION BOARD

[Docket No. FD 36943]

Harrison County Railroad Authority—Change of Operators Exemption—Gulf & Ship Island Railroad LLC

Harrison County Railroad Authority (HCRA), a noncarrier, has filed a verified notice of exemption under 49 CFR 1150.31 to replace Gulf & Ship Island Railroad LLC (GSIR) as the operator over approximately 5 miles of rail line (the Line), which is part of a line of railroad commonly known as the Seaway Lead and is controlled via ownership and a lease by Harrison County Development Commission (the County), a noncarrier. The Line extends between a point approximately 800 feet east of U.S. Highway 49 on the Seaway Lead, and the end of the Seaway Lead at Bernard Bayou Industrial Park at or near Gulfport in Harrison County, Miss.

According to the verified notice, GSIR, the current operator of the Line, and the County have terminated their agreement, and HCRA will become the new operator of the Line. HCRA states that it is a subsidiary of the County, which voted on June 30, 2026, to authorize HCRA to file its verified notice. HCRA represents that GSIR stated it would not oppose the change of operating authority, which will release GSIR from its common carrier obligation.

HCRA certifies that its projected annual revenues as a result of this transaction will not result in the creation of a Class II or Class I rail carrier and will not exceed $5 million. HCRA also certifies that the proposed transaction does not impose or include an interchange commitment. Under 49 CFR 1150.32(b), a change in operators exemption requires that notice be given to shippers. HCRA certifies that it has provided a copy of its verified notice to all customers on the Line.

The transaction may be consummated on or after July 30, 2026, the effective date of the exemption (30 days after the verified notice was filed).

If the verified notice contains false or misleading information, the exemption is void ab initio. Petitions to revoke the exemption under 49 U.S.C. 10502(d) may be filed at any time. The filing of a petition to revoke will not automatically stay the effectiveness of the exemption. Petitions for stay must be filed by July 23, 2026 (at least seven days before the exemption becomes effective).

All pleadings, referring to Docket No. FD 36943, must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on HCRA's representative, Justin J. Marks, Clark Hill PLC, 1001 Pennsylvania Avenue NW, Suite 1300 South, Washington, DC 20004.

According to HCRA, this action is categorically excluded from environmental review under 49 CFR 1105.6(c) and from historic preservation reporting requirements under 49 CFR 1105.8(b).

Board decisions and notices are available at *www.stb.gov.*

Decided: July 14, 2026.

By the Board, Anika S. Cooper, Chief Counsel, Office of Chief Counsel.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2026–14319 Filed 7–15–26; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

FAA Approval of Noise Compatibility Program 14 CFR Part 150 Dane County Regional Airport, Madison, Wisconsin

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its findings on the noise compatibility program submitted by the Dane County for Dane County Regional Airport (MSN). On December 21, 2023, the FAA determined that the noise exposure maps (NEMs) submitted by Dane County were in compliance with applicable requirements. On July 10, 2026, the FAA approved the Dane County Regional Airport noise compatibility program. The noise compatibility program consisted of 18 recommended measures, including 9 noise abatement measures, 5 land use measures, and 4 program management measures. Of the measures, 12 were approved, 2 were

partially approved, 1 was approved as voluntary, 1 was disapproved, and 2 were determined to have no present FAA action.

DATES: The effective date of the FAA's approval of the Dane County Regional Airport noise compatibility program is July 10, 2026.

FOR FURTHER INFORMATION CONTACT: Emma Lienau, Chicago Airports District Office, 2300 Devon Avenue, Suite 312, Des Plaines, Illinois 60018. Tel: 847–294–7551.

SUPPLEMENTARY INFORMATION: This notice announces FAA's approval of the noise compatibility program for Dane County Regional Airport, effective July 10, 2026. Per United States Code section 47504 (49 U.S.C. 47504) and Title 14, Code of Federal Regulations (CFR) Part 150, an airport sponsor who has previously submitted a noise exposure map may submit to the FAA a noise compatibility program which sets forth the measures taken or proposed by the airport sponsor for the reduction of existing non-compatible land uses and prevention of additional non-compatible land uses within the area covered by the NEMs. As required by 49 U.S.C. 47504, such programs must be developed in consultation with interested and affected parties including local communities, government agencies, airport users, and the FAA.

The FAA does not substitute its judgment for that of the airport sponsor with respect to which measures should be recommended for action. The FAA approval or disapproval of an airport sponsor's recommendations in its noise compatibility program are made in accordance with the requirements and standards pursuant to 49 U.S.C. 47504 and 14 CFR part 150, which is limited to the following determinations:

a. The noise compatibility program was developed in accordance with the provisions and procedures of 14 CFR 150.23;

b. Program measures are reasonably consistent with achieving the goals of reducing existing non-compatible land uses around the airport and preventing the introduction of additional non-compatible land uses;

c. Program measures would not create an undue burden on interstate or foreign commerce, unjustly discriminate against types or classes of aeronautical uses, violate the terms of airport grant agreements, or intrude into areas preempted by the Federal Government; and

d. Program measures relating to the use of flight procedures can be implemented within the period covered by the program without derogating safety, adversely affecting the efficient use and management of the navigable airspace and air traffic control systems, or adversely affecting other powers and responsibilities of the Administrator prescribed by law.

Specific limitations of FAA's approval of NCPs are delineated in 14 CFR part 150.5. Approval is not a determination concerning the acceptability of land uses under Federal, state, or local law. Approval does not by itself constitute an FAA implementing action. A request for Federal action or approval to implement specific noise compatibility measures may be required, and an FAA decision on the request may require an environmental assessment of the proposed action. Approval does not constitute a commitment by the FAA to financially assist in the implementation of the program nor a determination that all measures covered by the program are eligible for grant-in-aid funding from the FAA. Where federal funding is sought, requests for project grants must be submitted to the FAA Airports District Office in Des Plaines, Illinois.

The Dane County submitted the NEMs, descriptions, and other documentation produced during the noise compatibility planning study to the FAA and the FAA determined that the NEMs for MSN were in compliance with the applicable requirements under 14 CFR part 150. The NEMs became effective on December 21, 2023. Notice of this determination was published in the **Federal Register** on Friday, February 9, 2024 (FR Doc. 2024–02660). For FAA's review and approval, Dane County submitted the updated NCP, based on the accepted NEMs, on October 24, 2025. The FAA officially began its formal review of the program on January 13, 2026, and was limited by law to approve or disapprove the program within 180 days (other than the use of new or modified flight procedures for noise control). Failure to approve or disapprove such program within the 180-day period shall be deemed to be an approval of such program. Notice of the intent to review the NCP was published in the **Federal Register** on January 15, 2026 (FR Doc. 2026–00683). The **Federal Register** Notice also announced the start of the 60-day public review period for the NCP and its documentation. The FAA received 9 comments during the public review period.

The submitted program contained 18 proposed actions to minimize impacts of aviation noise (on and/or off the airport, as applicable). The FAA completed its review and determined that the procedural and substantive requirements of 49 U.S.C. 47504 and 14 CFR part 150 were satisfied. A Record of Approval for the overall program was issued by the FAA effective July 10, 2026.

The specific program elements and their individual determinations are as follows:

NA–1: Develop Noise Abatement Flight Paths and Encourage Use of Such Flight Paths to Avoid Aircraft Overflying Educational Facilities to the South of the Airport—No Action Required at This Time.

NA–2: Encourage aircraft departing Runway 32 to pass through 2,500 feet Mean Sea Level (MSL) before turning left—Approved.

NA–3: Encourage eastbound and southbound aircraft exceeding 12,500 pounds departing Runway 3 to climb on runway heading through 2,500 feet Mean Sea Level (MSL) before turning right—Approved.

NA–4: Encourage all aircraft exceeding 12,500 pounds and departing Runway 21 to turn left 10 degrees as soon as safe and practicable—Approved.

NA–5: Encourage use of the established visual approach and departure corridors for helicopters—Approved.

NA–6: Modify the existing preferential runway use program to improve the compliance with aircraft arriving from and departing to the north—Partially Approved.

NA–7: Encourage the use of Noise Abatement Departure Profile (NADP) procedures by operators of jet aircraft—Approved as Voluntary.

NA–8: Consider Runway Reconfiguration to Address Noncompatible Land Use to the South of the Airport—No Action Required at This Time.

NA–9: Encourage the Wisconsin Air National Guard 115th Fighter Wing to limit F–35A aircraft operations to the daytime—Disapproved for the Purposes of Part 150.

LU–1: Maintain Existing Compatible Land Uses in the Airport Vicinity—Approved.

LU–2: Continue Voluntary Land Acquisition of Noncompatible Land Uses Inside The 70 DNL Noise Contour—Approved.

LU–3: Acquire Cherokee Marsh and Token Creek Park Areas Should They Be Considered for Noise-Sensitive Use—Partially Approved.

LU–4: Monitor for voluntary land acquisition of the Oak Park Terrace mobile home community—Approved.

LU–5: Implement a Sound Insulation Program to Provide Treatment to Noise Sensitive Structures Within the 65 DNL Noise Contour—Approved.

PM–1: Re-Establish And Maintain a Noise Advisory Committee—Approved.

PM–2: Continue and Improve Noise Complaint Response Program—Approved.

PM–3: Regular Updates of the Noise Exposure Map—Approved.

PM–4: Periodic Evaluation and Update of the Noise Compatibility Program when Necessary—Approved.

These determinations are set forth in detail in a Record of Approval signed by the Great Lakes Region, Airports Division Manager on July 10, 2026. The Record of Approval, as well as other evaluation materials and the documents comprising the submittal, are available for review at the FAA office listed above and at the administrative offices of the Dane County Regional Airport. The Record of Approval also will be available on-line at *https://www.faa.gov/airports/environmental/airport_noise/part_150/states.*

Issued in Des Plaines, IL.

Dated: July 10, 2026.

James Gregory Keefer,

Director, Airports Division, Great Lakes Region.

[FR Doc. 2026–14255 Filed 7–15–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Noise Exposure Map Notice; Boca Raton Airport, Boca Raton, Florida

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces its determination that the Noise Exposure Maps submitted by the Boca Raton Airport Authority for the Boca Raton Airport under the provisions of 49 U.S.C. 47501 *et seq.* (Aviation Safety and Noise Abatement Act) and 14 CFR part 150 are in compliance with applicable requirements.

DATES: The effective date of the FAA's determination on the Noise Exposure Maps is July 9, 2026.

FOR FURTHER INFORMATION CONTACT: Heather Chasez, Federal Aviation Administration, Orlando Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, Florida 32819, (407) 487–7236.

SUPPLEMENTARY INFORMATION: This notice announces that the FAA finds that the Noise Exposure Maps submitted for the Boca Raton Airport are in compliance with applicable requirements of Title 14 Code of Federal Regulations (CFR) Part 150, effective July 9, 2026. Under 49 U.S.C. 47503 of the Aviation Safety and Noise Abatement Act (''the Act''), an airport operator may submit to the FAA Noise Exposure Maps which meet applicable regulations and which depict non-compatible land uses as of the date of submission of such maps, a description of projected aircraft operations, and the ways in which such operations will affect such maps. The Act requires such maps to be developed in consultation with interested and affected parties in the local community, government agencies, and persons using the airport. An airport operator who has submitted Noise Exposure Maps that are found by FAA to be in compliance with the requirements of 14 CFR part 150, promulgated pursuant to the Act, may submit a Noise Compatibility Program for FAA approval, which sets forth the measures the airport operator has taken or proposes to take to reduce existing non-compatible uses and prevent the introduction of additional non-compatible uses.

The FAA has completed its review of the Noise Exposure Maps and accompanying documentation submitted by the Boca Raton Airport Authority. The documentation that constitutes the ''Noise Exposure Maps'' as defined in 14 CFR 150.7 includes: 2025 Existing Condition Noise Exposure Map, 2030 Future Condition Noise Exposure Map, Runway 5 Flight Tracks Map, Runway 23 Flight Tracks Map, Touch and Go Flight Tracks Map, Helicopter Flight Tracks Map, the Existing and Future Conditions Noise Exposure Map, and Supporting Documentation Report. The FAA has determined that these Noise Exposure Maps and accompanying documentation are in compliance with applicable requirements. This determination is effective on July 9, 2026.

FAA's determination on the airport operator's Noise Exposure Maps is limited to a finding that the maps were developed in accordance with the procedures contained in Appendix A of 14 CFR part 150. Such determination does not constitute approval of the airport operator's data, information or plans, or a commitment to approve a Noise Compatibility Program or to fund the implementation of that Program. If questions arise concerning the precise relationship of specific properties to noise exposure contours depicted on a Noise Exposure Map submitted under Section 47503 of the Act, it should be noted that the FAA is not involved in any way in determining the relative locations of specific properties with regard to the depicted noise exposure contours, or in interpreting the Noise Exposure Maps to resolve questions concerning, for example, which properties should be covered by the provisions of Section 47506 of the Act. These functions are inseparable from the ultimate land use control and planning responsibilities of local government. These local responsibilities are not changed in any way under 14 CFR part 150 or through FAA's review of the Noise Exposure Maps. Therefore, the responsibility for the detailed overlaying of noise exposure contours onto the map depicting properties on the surface rests exclusively with the airport operator that submitted those maps, or with those public agencies and planning agencies with which consultation is required under Section 47503 of the Act. The FAA has relied on the certification by the airport operator, under 14 CFR 150.21, that the statutorily required consultation has been accomplished.

Copies of the full Noise Exposure Maps and report are available for examination by appointment at the following location: Federal Aviation Administration, Orlando Airports District Office, 8427 SouthPark Circle, 5th Floor, Orlando, Florida 32819. The Noise Exposure Maps and report are also available for viewing and download at the airport's website (*https://bocaairport.com/noise-exposure-map-update/*).

To arrange an appointment to review the Noise Exposure Maps and report, contact Heather Chasez, Federal Aviation Administration, Southern Region/Orlando Airports District Office, 8427 SouthPark Circle, Suite 524, Orlando, FL 32819, (407) 487–7236. Questions may be directed to the individual named above under the heading, **FOR FURTHER INFORMATION CONTACT**.

Issued in Orlando Airports District Office, Orlando, FL on July 9, 2026.

Juan C. Brown,

Manager, Orlando Airports District Office.

[FR Doc. 2026–14276 Filed 7–15–26; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[FAA–2026–7459]

Notice of Intent; Anchorage Terminal Area Airspace and Procedures Study Notice of Intent for Preparation for an Environmental Assessment.

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

ACTION: Notice of Intent (NOI) for the Commencement of the Anchorage Terminal Area Airspace and Procedures Study (ATAAPS) Environmental Assessment (EA) UIN EAXX–021–12–WSC–1768398367.

SUMMARY: The FAA, in cooperation with the United States Air Force, is announcing the commencement of the ATAAPS EA for the proposed Anchorage terminal airspace redesign. ATAAPS involves changes to the airspace, aircraft flight paths, and aircraft altitudes in the Anchorage basin and surrounding areas. The EA will evaluate the potential environmental impacts of the proposed airspace redesign (Proposed Action) and alternatives, including the No Action alternative. The FAA has not made a final decision on any airspace/procedure amendments related to the Proposed Action. The FAA is currently establishing a timeline for the EA. Project updates will be posted to the FAA ATAAPS web page at: *https://www.faa.gov/about/office_org/headquarters_offices/ara/alaskan_region/ataaps.*

This project would increase safety and improve efficiency of the National Airspace System (NAS) and homeland defense capabilities, by optimizing aircraft arrival and departure procedures that serve multiple airports—specifically in the Anchorage basin and surrounding areas—including: Ted Stevens Anchorage International Airport (ANC), Elmendorf Air Force Base Airport (EDF), Bryant Army Airfield Airport (FRN), Lake Hood Airport (LHD), and Merrill Field Airport (MRI).

As a critical strategic gateway for homeland defense, Joint Base Elmendorf-Richardson (JBER) is currently restricted to operating below the facility's intended capacity and fleet mix until surrounding airspace is officially modified. The Instrument Landing System (ILS) for Runway 17 is integral to improving JBER operations and cannot become operational under the current airspace design. (JBER runway designations are currently 16/34 and 06/24, but will be updated due to Magnetic Variation changes to Runways 17/35 and 07/25 before completion of the EA.)

The FAA is initiating this EA and will engage the public, government agencies, and tribes as appropriate.

FOR FURTHER INFORMATION CONTACT: Mr. Joseph Bert, Federal Aviation Administration, Team Manager, Environmental/Community Involvement/NAS Analytics, Operations Support Group, Western Service Center|, email: *9-AJO-ATAAPS-Environmental@faa.gov.*

SUPPLEMENTARY INFORMATION:

Background

ATAAPS addresses national security concerns as well as air traffic system inefficiencies within the Anchorage basin and surrounding areas. The ATAAPS EA will be prepared pursuant to the National Environmental Policy Act of 1969. The EA will consider at least two alternatives: the Proposed Action and the No Action alternative. The Proposed Action being developed focuses on airspace optimization for aircraft routes and controlled airspace within the Anchorage basin and surrounding areas. Area navigation (RNAV)-based standard instrument departure (SID) and standard terminal arrival (STAR) procedures have been in effect in the Anchorage basin and surrounding areas for nearly 20 years. These arrival and departure procedures will be designed with advanced RNAV capabilities and will maintain safety and improve efficiency of the NAS, benefitting pilots, air traffic controllers, and the general public.

The Proposed Action is not anticipated to increase the number of aircraft operations at the study airports or involve the physical construction of any facilities.

The Proposed Action will include the following elements:

- UPDATED AIRSPACE BOUNDARIES. Aircraft operating in the Anchorage basin currently fly within the Anchorage Part 93 airspace in which specific, special air traffic rules are in effect (see 14 CFR part 93). These rules address issues like high-density traffic, unique airspace configurations, and limitations related to military operations and national parks. The evaluation of airspace in the Anchorage basin includes Class C and Class D airspace around affected airports.
- UPDATED DEPARTURE ROUTES AND/OR FIXES FROM THE STUDY AIRPORTS. Routes and fixes will connect study airports to optimized high-altitude routes using satellite-based RNAV technology.
- UPDATED ARRIVAL ROUTES AND/OR FIXES INTO THE STUDY AIRPORTS. Routes and fixes will connect transitions from high-altitude routes to existing approach procedures for the study airports using advanced RNAV procedures.

The FAA will establish a general study area, wherein proposed procedure changes below 10,000 feet above ground level (AGL) will be evaluated for potential environmental impacts. Additionally, the FAA will evaluate areas where FAA policy requires special consideration for potential noise impacts—which may include national parks, national wildlife refuges, historic sites and traditional cultural properties—for proposed procedure changes below 18,000 feet AGL. The Proposed Action may include procedure changes at altitudes greater than 18,000 feet AGL (high altitudes) within an approximate 200-nautical mile radius of Anchorage; however, these high-altitude changes are considered generally outside the affected environmental study area per FAA Order 1050.1G, *FAA National Environmental Policy Act Implementing Procedures.* The FAA will provide a notice of availability (NOA) for the draft EA at a future date.

Issued in Des Moines, Washington, on July 14, 2026.

B. G. Chew,

Group Manager, Operations Support Group, Western Service Center.

[FR Doc. 2026–14367 Filed 7–15–26; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2026–1553]

Agency Information Collection Activities; Renewal of an Approved Information Collection: Inspection, Repair and Maintenance

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FMCSA announces its plan to submit the Information Collection Request (ICR) described below to the Office of Management and Budget (OMB) for its review and approval and invites public comment. The information collection concerns records of inspection, repair, and maintenance of commercial motor vehicles (CMVs). FMCSA requests approval to renew an ICR entitled, ''Inspection, Repair and Maintenance.'' FMCSA collects this information to ensure that motor carriers have adequate documentation of their inspection, repair, and maintenance programs necessary to reduce the likelihood of CMV crashes.

DATES: Comments must be received on or before September 14, 2026.

ADDRESSES: You may submit comments identified by Docket Number FMCSA–2026–1553 by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov/docket/FMCSA-2026-1553/document.* Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W58–213, West Building, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* Dockets Operations, U.S. Department of Transportation, 1200 New Jersey Avenue SE, W58–213, Washington, DC, 20590–0001 between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Mr. José R. Cestero, Mechanical Engineer, FMCSA Vehicle and Roadside Operations Division, DOT, FMCSA, 1200 New Jersey Avenue SE, Washington, DC 20590–0001; (202) 309–9284; *jose.cestero@dot.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation and Request for Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2026–1553), indicate the specific section of this document to which your comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *https://www.regulations.gov/docket/FMCSA-2026-1553/document,* click on this notice, click ''Comment,'' and type your comment into the text box on the following screen.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing.

FMCSA will consider all comments and material received during the comment period.

Privacy Act

In accordance with 5 United States Code (U.S.C.) 553(c), DOT solicits comments from the public to better inform its regulatory process. DOT posts these comments, including any personal information the commenter provides, to *www.regulations.gov* as described in the system of records notice DOT/ALL 14 (Federal Docket Management System (FDMS)), which can be reviewed at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices.* The comments are posted without edits and are searchable by the name of the submitter.

Background

The Secretary of Transportation (Secretary) is authorized under the provisions of 49 U.S.C. 31502 to prescribe requirements for, among other things, safety of operations of equipment of motor carriers that operate CMVs in interstate commerce. Under 49 U.S.C. 31136, the Secretary also has authority to prescribe regulations to ensure that CMVs are maintained, equipped, loaded, and operated safely. Under 49 U.S.C. 31142 the Secretary must establish standards for annual or more frequent inspections of CMVs. The Secretary's authority to establish improved standards or methods to ensure brakes and brake systems of CMVs are inspected by appropriate employees and maintained properly is provided under 49 U.S.C. 31137(g). These authorities have been delegated to the Administrator of the Federal Motor Carrier Safety Administration in 49 CFR 1.87.

Motor carriers must maintain, or require maintenance of, records documenting the inspection, repair and maintenance activities performed on their owned and leased vehicles. There are no prescribed forms. Electronic recordkeeping is allowed (see 49 CFR 390.31(d)). Documents requiring a signature must be capable of replication (*e.g.,* photocopy, facsimile, etc.) in such form that will provide an opportunity for signature verification upon demand. Also, if electronic recordkeeping is used, all of the relevant data on the original documents must be included in the electronic transmission for the records to be valid.

The motor carrier industry has never questioned the need to keep CMV maintenance records. In fact, most motor carriers would keep some records without any regulatory requirements to do so. Records of inspection, repair, and maintenance; roadside inspection reports; driver vehicle inspection reports; the documentation of periodic inspections; the evidence of the qualifications of individuals performing periodic inspections; and the evidence of brake inspectors' qualifications contain the minimum amount of information necessary to document that a motor carrier has established a system of inspection, repair, and maintenance for its equipment which meets the standards in 49 CFR part 396.

FMCSA and its representatives use these records to verify motor carriers' compliance with the inspection, repair, and maintenance standards in part 396. This ICR supports DOT's strategic goal of safety. The ICR also ensures that motor carriers have adequate records to document the inspection, repair, and maintenance of their CMVs, and to ensure that adequate measures are taken to keep their CMVs in safe and proper operating condition at all times. Compliance with the inspection, repair, and maintenance regulations helps to reduce the likelihood of accidents attributable, in whole or in part, to the mechanical condition of the CMV. This ICR submittal includes updated data regarding the number of motor carriers subject to the Federal Motor Carrier Safety Regulations, vehicle counts, inspections, and other underlying data used to estimate the total burden hours.

If the recordkeeping were required to be completed less frequently, it would greatly hinder the ability of FMCSA and State officials and representatives to ascertain that CMVs are satisfactorily maintained. The timely documentation of CMV inspection, repair, and maintenance enables FMCSA and State officials to evaluate the present state of a motor carrier's CMV maintenance program and to check the current level of regulatory compliance at any point in a carrier's maintenance schedule or program.

FMCSA has identified periodic inspection standards of 22 States, the District of Columbia, the Alabama Liquefied Petroleum Gas Board, 10 Canadian Provinces, and 1 Canadian Territory that are comparable to, or as effective as, the Federal periodic inspection requirements. FMCSA does not require Federal periodic inspections and the related recordkeeping for motor carriers that comply with these equivalent periodic inspection programs. FMCSA is not aware of any other duplicative standards or recordkeeping requirements that apply to motor carriers.

FMCSA does not employ this collection of information for statistical use.

Title: Inspection, Repair and Maintenance.

OMB Control Number: 2126–0003.

Type of Request: Renewal of a currently approved information collection.

Respondents: Motor carriers and CMV drivers.

Estimated Number of Respondents: 715,289 motor carriers and 5,793,962 drivers.

Estimated Time per Response: Varies according to the requirements for specific records.

Expiration Date: March 31, 2027.

Frequency of Response: Varies according to requirements for specific records.

Estimated Total Annual Burden: 13,184,781 hours [9,023,865 hours for inspection, repair, and maintenance + 3,800,113 hours for driver inspection reports + 174,636 hours for disposition of roadside inspection reports + 144,045 hours for periodic inspections + 22,253 hours for records of inspector qualifications + 19,869 hours for records of brake inspector qualifications].

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) whether the proposed collection is necessary for the performance of FMCSA's functions; (2) the accuracy of the estimated burden; (3) ways for FMCSA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize or include your comments in the request for OMB's clearance of this information collection.

Issued under the authority of 49 CFR 1.87.

Nicole S. Michel,

Acting Associate Administrator, Office of Research and Registration.

[FR Doc. 2026–14350 Filed 7–15–26; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2009–0078]

Notice of Petition for Amendment of Waiver of Compliance

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This document provides the public notice that the American Short Line and Regional Railroad Association (ASLRRA) petitioned FRA to amend an existing waiver of certain regulations related to hours of service.

DATES: FRA must receive comments on the petition by September 14, 2026. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to this docket may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: William Smith, Railroad Safety Specialist, FRA Operating Practices Division, telephone: 682–305–6709, email: *William.Smith@dot.gov.*

SUPPLEMENTARY INFORMATION: Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letter received June 3, 2026, ASLRRA petitioned FRA for an amendment of a waiver of compliance from certain provisions of the Federal hours of service (HOS) laws contained at 49 U.S.C. 21103(a)(4). The relevant Docket Number is FRA–2009–0078.

Specifically, ASLRRA seeks to amend its existing waiver by adding 8 railroads to the list of railroad participants in the original waiver. ASLRRA stated the following railroads expressed a desire to participate in the waiver and maintain at each of their headquarters supporting documentation of employee support, as required:

- Northeast Atlanta Railroad
- Columbia Basin Railroad
- Central Washington Railroad
- Waterloo Railroad
- Cimmaron Valley Railroad
- Kansas City West Bottom Railroad
- Oregon Eastern Railroad
- Nebraska Kansas Colorado Railroad

ASLRRA states it conducts training multiple times annually for waiver participants to clarify the requirements of the waiver.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov.*

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received by September 14, 2026 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA's dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

Carolyn Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2026–14324 Filed 7–15–26; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2010–0030]

Massachusetts Bay Transportation Authority's Request To Amend its Positive Train Control System

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of availability and request for comments.

SUMMARY: This document provides the public with notice that, on July 9, 2026, the Massachusetts Bay Transportation Authority (MBTA) submitted a request for amendment (RFA) to its FRA-certified positive train control (PTC)

system. FRA is publishing this notice and inviting public comment on the railroad's RFA.

DATES: FRA will consider comments received by August 5, 2026. FRA may consider comments received after that date to the extent practicable and without delaying implementation of valuable or necessary modifications to a PTC system.

ADDRESSES:

Comments: Comments may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and the applicable docket number. The relevant PTC docket number for this host railroad is Docket No. FRA–2010–0030. For convenience, all active PTC dockets are hyperlinked on FRA's website at *https://railroads.dot.gov/research-development/program-areas/train-control/ptc/railroads-ptc-dockets.* All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information.

FOR FURTHER INFORMATION CONTACT: Gabe Neal, Staff Director, Signal, Train Control, and Crossings Division, telephone: 816–516–7168, email: *Gabe.Neal@dot.gov.*

SUPPLEMENTARY INFORMATION: In general, title 49 United States Code (U.S.C.) section 20157(h) requires FRA to certify that a host railroad's PTC system complies with title 49 Code of Federal Regulations (CFR) part 236, subpart I, before the technology may be operated in revenue service. Before making certain changes to an FRA-certified PTC system or the associated FRA-approved PTC Safety Plan (PTCSP), a host railroad must submit, and obtain FRA's approval of, an RFA to its PTC system or PTCSP under 49 CFR 236.1021.

Under 49 CFR 236.1021(e), FRA's regulations provide that FRA will publish a notice in the **Federal Register** and invite public comment in accordance with 49 CFR part 211, if an RFA includes a request for approval of a material modification of a signal or train control system. Accordingly, this notice informs the public that, on July 9, 2026, MBTA submitted an RFA to its PTC system, the Advanced Civil Speed Enforcement System II, seeking FRA's approval of a temporary outage of MBTA's PTC system to support the reconfiguration of Control Point CP–44 on the Worcester Main Line. That RFA is available in Docket No. FRA–2010–0030.

Interested parties are invited to comment on MBTA's RFA by submitting written comments or data. During FRA's review of this railroad's RFA, FRA will consider any comments or data submitted within the timeline specified in this notice and to the extent practicable, without delaying implementation of valuable or necessary modifications to a PTC system. *See* 49 CFR 236.1021; *see also* 49 CFR 236.1011(e). Under 49 CFR 236.1021, FRA maintains the authority to approve, approve with conditions, or deny a railroad's RFA at FRA's sole discretion.

Privacy Act Notice

In accordance with 49 CFR 211.3, FRA solicits comments from the public to better inform its decisions. DOT posts these comments, without edit, including any personal information the commenter provides, to *https://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.* To facilitate comment tracking, we encourage commenters to provide their name, or the name of their organization; however, submission of names is completely optional. If you wish to provide comments containing proprietary or confidential information, please contact FRA for alternate submission instructions.

Issued in Washington, DC.

Carolyn R. Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2026–14335 Filed 7–15–26; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2026–1651]

Notice of Petition for Waiver of Compliance

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: This document provides the public notice that CSX Transportation Inc. (CSXT) petitioned FRA for relief from certain regulations concerning tests and inspections of extended haul trains.

DATES: FRA must receive comments on the petition by September 14, 2026. FRA will consider comments received after that date to the extent practicable.

ADDRESSES:

Comments: Comments related to this docket may be submitted by going to *https://www.regulations.gov* and following the online instructions for submitting comments.

Instructions: All submissions must include the agency name and docket number. All comments received will be posted without change to *https://www.regulations.gov;* this includes any personal information. Please see the Privacy Act heading in the **SUPPLEMENTARY INFORMATION** section of this document for Privacy Act information related to any submitted comments or materials.

Docket: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and follow the online instructions for accessing the docket.

FOR FURTHER INFORMATION CONTACT: Michael Barron, Railroad Safety Specialist, FRA Motive Power & Equipment Division, telephone: 202–493–1367, email: *michael.barron@dot.gov.*

SUPPLEMENTARY INFORMATION: Under part 211 of title 49 Code of Federal Regulations (CFR), this document provides the public notice that by letter dated June 5, 2026, CSXT petitioned FRA for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at 49 CFR part 232 (Brake System Safety Standards for Freight and Other Non-Passenger Trains and Equipment; End-of-Train Devices). FRA assigned the petition Docket Number FRA–2026–1651.

Specifically, CSXT seeks relief from the requirements of § 232.213, *Extended haul trains,* to continue operating certain extended haul trains up to a maximum of 1,785 miles. To extend the operating miles, CSXT proposes requirements for the trains to receive a Class 1 brake test and mechanical inspection by a qualified mechanical inspector prior to each train's initial departure. Further, the petition states that the waiver applies only to trains on approved routes equipped with wayside detectors.

In support of its request, CSXT expressed that the waiver will ''maintain or enhance overall brake system safety,'' reduce employees' exposure during walking inspections, improve ''train fluidity while preserving mechanical integrity,'' and align ''inspection practices with demonstrated equipment performance.''

A copy of the petition, as well as any written communications concerning the

petition, is available for review online at *www.regulations.gov.*

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment and a public hearing, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

Communications received by September 14, 2026 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable.

Privacy Act

Anyone can search the electronic form of any written communications and comments received into any of FRA's dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov*.

Issued in Washington, DC.

Carolyn Hayward-Williams,

Director, Office of Railroad Systems and Technology.

[FR Doc. 2026–14328 Filed 7–15–26; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0127]

Deepwater Port License Application: Blue Marlin Offshore Port Project—Final Public Hearing

AGENCY: Maritime Administration, U.S. Department of Transportation.

ACTION: Notice of final public hearing.

SUMMARY: The Maritime Administration (MARAD) and the U.S. Coast Guard (USCG) announce the final public hearing for the Blue Marlin Offshore Port (BMOP) Deepwater Port license application for the export of oil from the United States to nations abroad. The BMOP Deepwater Port license application describes a project located approximately 99 statute miles off the coast of Cameron Parish, Louisiana, with an approximate water depth of 162 feet. MARAD encourages public participation in the final public hearing and is providing information on how to participate at the final public hearing and welcomes comments on the BMOP Deepwater Port license application.

DATES: MARAD and USCG will hold two final public hearings in connection with the BMOP Application. The first public hearing will be held on Aug. 4, 2026, from 6:00 p.m. to 8:00 p.m. Central Daylight Time (CDT) in the Cameron Parish Police Jury West Annex, 148 Smith Circle, Cameron, LA. The second public hearing will be held on Aug. 5, 2026, from 6:00 p.m. to 8:00 p.m. CDT in the Bob Bowers Civic Center, 3401 Cultural Center Drive, Port Arthur, TX 77640. Each public hearing will be preceded by an Informational Open House, held between 5:00 p.m. and 6:00 p.m. CDT. Materials submitted in response to this request for comments on the BMOP Deepwater Port license application may be submitted verbally or in writing during the public hearing mentioned above. If you choose to submit comments in writing regarding the BMOP Deepwater Port license application, you may do so via the Federal eRulemaking Portal or the Federal Docket Management Facility as detailed in the **ADDRESSES** section below by 11:59 p.m. EDT on Aug. 5, 2026.

ADDRESSES: You may submit comments identified by DOT Docket Number MARAD–2020–0127 by any one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Search MARAD–2020–0127 and follow the instructions for submitting comments.
- *Mail or Hand Delivery:* The DOT Docket is located at the U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building, Room W12–140, Washington, DC 20590. Documents may be delivered between 9 a.m. and 5 p.m., Monday through Friday, except on Federal holidays.

Note: If you mail or hand-deliver your comments, we recommend that you include your name, mailing address, email address, or telephone number so that we can contact you if we have questions regarding your submission.

Instructions: All submissions received must include the agency name and specific docket number. All comments received will be posted without change to the docket at *www.regulations.gov,* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mr. Brent Yezefski, Program Manager, USCG, telephone: 202–372–1351, email: *DeepwaterPorts@USCG.mil;* or Dr. Efrain Lopez, Senior Transportation Industry Analyst, Office of Deepwater Ports, MARAD, telephone: 202–366–9761, email: *Deepwater.Ports@dot.gov.*

SUPPLEMENTARY INFORMATION:

Final Public Hearing

MARAD encourages the public to attend the informational open house and final public hearing for the BMOP Deepwater Port license application. Speakers at the public hearing will be recognized in the following order: elected officials, public agencies, individuals, or groups in the sign-up order, and then anyone else who wishes to speak.

In order to allow everyone a chance to speak at the public hearing, MARAD may limit speaker time, extend the hearing hours, or both. Speakers must identify themselves, and any organization they represent, by name. All remarks will be recorded and transcribed for inclusion in the public docket.

Commenters may submit written material at the hearing either in place of, or in addition to, speaking. Written material should include the commenter's name and address and will be included in the public docket and made available to the public on the Federal Docket Management System (FDMS) website at *www.regulations.gov.* MARAD will also accept written comments submitted to FDMS by 11:59 p.m. EDT, Aug. 5, 2026 (*see* **ADDRESSES**).

If you plan to participate in the public hearing and need special assistance such as sign language interpretation, non-English language translator services or other reasonable accommodation, please notify MARAD (*see* **FOR FURTHER INFORMATION CONTACT**) at least seven business days in advance of the public hearing. Include your contact information as well as information about your specific needs.

Comments During the Final Public Hearing

MARAD encourages comments on the proposed BMOP Deepwater Port license application, verbally or in writing during the final public hearing. Comments may be used to inform MARAD's Record of Decision for the BMOP Deepwater Port license application. MARAD encourages you to review the applicant's information online on the FDMS website at

www.regulations.gov under DOT Docket Number MARAD–2020–0127. The application, all comments, and associated documentation will be found on the docket..

Privacy Act: Anyone can search the electronic form of all comments received into the FDMS website by the docket number and name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.).

Summary of the Application

BMOP is proposing to construct, own, operate, and eventually decommission a Deepwater Port terminal in the Gulf of America to export domestically produced crude oil. Use of the Deepwater Port would include the loading of various grades of crude oil at flow rates of up to 80,000 barrels per hour (bph). The BMOP Deepwater Port would allow for up to one Very Large Crude Carrier (VLCC) or other crude oil carrier to moor at the catenary anchor leg mooring (CALM) and connect with the Deepwater Port via floating connecting crude oil hoses. The maximum loading volume for VLCCs or other crude oil carriers would be approximately 2 million barrels per day, 365 days per year.

A Notice of Application that summarized the BMOP Deepwater Port License Application was published in the **Federal Register** on Nov. 4, 2020 (85 FR 70233). A Notice of Intent to Prepare an Environmental Impact Statement (EIS) and a Notice of Public Scoping Meeting was published in the **Federal Register** on November 5, 2020 (85 FR 70707). A Notice of Availability for the DEIS and Notice of Public Meeting was published in the **Federal Register** on Feb. 21, 2025 (90 FR 10444).

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.

Secretary, Maritime Administration.

[FR Doc. 2026–14337 Filed 7–15–26; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2020–0127]

Deepwater Port License Application: Blue Marlin Offshore Port Project-Final Environmental Impact Statement

AGENCY: Maritime Administration, U.S. Department of Transportation.

ACTION: Notice of availability; final environmental impact statement.

SUMMARY: The Maritime Administration (MARAD) and the U.S. Coast Guard (USCG) announce the availability of the Final Environmental Impact Statement (FEIS) for the Blue Marlin Offshore Port (BMOP) Deepwater Port license application for the export of oil from the United States to nations abroad. The BMOP Deepwater Port license application describes a project located approximately 99 statute miles off the coast of Cameron Parish, Louisiana, with an approximate water depth of 162 feet. The FEIS analyzes the potential environmental impacts of the Project and the alternatives to the proposed action, including the no action alternative. The FEIS will inform MARAD's decision to approve, approve with conditions, or disapprove the BMOP Deepwater Port license application.

ADDRESSES: The FEIS and detailed information about the Project can be found on the Federal Docket Management System (FDMS) website at *https://www.regulations.gov* and searching for Docket Number MARAD–2020–0127.

FOR FURTHER INFORMATION CONTACT: Mr. Brent Yezefski, Program Manager, USCG, telephone: 202–372–1351, email: *DeepwaterPorts@USCG.mil;* or Dr. Efrain Lopez, Senior Transportation Industry Analyst, Office of Deepwater Ports, MARAD, telephone: 202–366–9761, email: *Deepwater.Ports@dot.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Action

BMOP is proposing to construct, own, operate and eventually decommission a Deepwater Port terminal in the Gulf of America to export domestically produced crude oil. Use of the Deepwater Port would include the loading of various grades of crude oil at flow rates of up to 80,000 barrels per hour (bph). The BMOP Deepwater Port would allow for up to one Very Large Crude Carrier (VLCC) or other crude oil carrier to moor at the catenary anchor leg mooring (CALM) and connect with the Deepwater Port via floating connecting crude oil hoses. The maximum volume of loading VLCCs or other crude oil carriers would be approximately 2 million barrels per day, 365 days per year.

A Notice of Application that summarized the BMOP Deepwater Port License Application was published in the **Federal Register** for public comment on November 4, 2020 (85 FR 70233). A Notice of Intent to Prepare an Environmental Impact Statement (EIS) and a Notice of Public Scoping Meeting was published in the **Federal Register** for public comment on November 5, 2020 (85 FR 70707). A Notice of Availability for the DEIS and Notice of Public Meeting was published in the **Federal Register** for public comment on February 21, 2025 (90 FR 10444). This Notice of Availability incorporates the aforementioned **Federal Register** notices by reference.

The Notice of Intent to prepare the EIS previously anticipated a public comment period on the FEIS. However, in keeping with Executive Order 14154, *Unleashing American Energy,* and after reviewing the National Environmental Policy Act's statutory requirements, MARAD has determined that it will not solicit public comments on the FEIS, which is issued as final. Substantive comments received from the public were considered and incorporated, as appropriate, into the FEIS. Public comments generally resulted in the addition of clarifications and analysis, but comments did not identify substantial new circumstances or information relevant to environmental concerns that have a bearing on the proposed action or its impacts.

All substantive comments received, along with MARAD's responses and considerations, are available on the public docket at MARAD–2020–0127. Please note that the public will have an opportunity to provide comments on the BMOP Deepwater Port Application at the final public hearing and public comment period, announced via separate notice.

Availability of the FEIS

The FEIS and detailed information about the Project can be found on the FDMS website at *https://www.regulations.gov* and searching for Docket Number MARAD–2020–0127.

Cooperating Agencies

The following Federal agencies and State governmental entities participated as cooperating agencies under the National Environmental Policy Act (NEPA) in the preparation of the FEIS: Bureau of Safety and Environmental Enforcement; U.S. Environmental Protection Agency; National Marine Fisheries Service; Pipeline and Hazardous Materials Safety Administration; U.S. Army Corps of Engineers; Bureau of Ocean Energy Management; U.S. Fish and Wildlife Service; Texas Park and Wildlife; Louisiana Department of Natural Resources; Texas Commission on Environmental Quality; Texas Department of Transportation; Texas General Land Office; Texas Historical Commission (State Historic Preservation Office); Texas Railroad Commission;

Coastal Protection and Restoration Authority of Louisiana; Louisiana Department of Environmental Quality; Louisiana Office of State Lands; Louisiana Office of Cultural Development (State Historic Preservation Office); Louisiana Offshore Terminal Authority; Native American Tribes.

(Authority: 33 U.S.C. 1501, *et seq.;* 49 CFR 1.93(h))

By Order of the Maritime Administrator.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2026–14336 Filed 7–15–26; 8:45 am]

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Part II

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17

Endangered and Threatened Wildlife and Plants; Revised Designation of Critical Habitat for the Contiguous U.S. Distinct Population Segment of the Canada Lynx; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R6–ES–2024–0142; FXES1111090FEDR–267–FF09E21000]

RIN 1018–BH59

Endangered and Threatened Wildlife and Plants; Revised Designation of Critical Habitat for the Contiguous U.S. Distinct Population Segment of the Canada Lynx

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), revise the critical habitat designation for the contiguous U.S. distinct population segment (DPS) of the Canada lynx (*Lynx canadensis*) under the Endangered Species Act of 1973, as amended (Act). In total, approximately 14,030 square miles (36,340 square kilometers) in Colorado, Idaho, Montana, and Washington, fall within the boundaries of the revised critical habitat designation. This revision fulfills our obligations under a settlement agreement to address issues raised by the District Court of Montana regarding our 2014 final critical habitat designation.

DATES: This rule is effective August 17, 2026.

ADDRESSES: This final rule is available on the internet at *https://www.regulations.gov* and on the Service's website at *https://ecos.fws.gov/ecp/species/A073?*. Comments and materials we received are available for public inspection at *https://www.regulations.gov* at Docket No. FWS–R6–ES–2024–0142.

Availability of supporting materials: Supporting materials we used in preparing this rule, such as the species status assessment (SSA) report addendum, are available on the Service's website at *https://ecos.fws.gov/ecp/species/A073?,* at *https://www.regulations.gov* at Docket No. FWS–R6–ES–2024–0142, or both. For the critical habitat designation, the coordinates or plot points or both from which the maps are generated are included in the decision file for this critical habitat designation and are available at *https://www.regulations.gov* at Docket No. FWS–R6–ES–2024–0142 and on the Service's website at *https://www.fws.gov/species/canada-lynx-lynx-canadensis.*

FOR FURTHER INFORMATION CONTACT: Amity Bass, Field Supervisor, U.S. Fish and Wildlife Service, Montana Ecological Services Field Office, 585 Shepard Way, Suite 1, Helena, MT 59601; telephone 406–449–5225. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act (Act), any species that is determined to be threatened or endangered requires critical habitat to be designated to the maximum extent prudent and determinable. Designations and revisions of critical habitat can be completed only by issuing a rule through the Administrative Procedure Act rulemaking process (5 U.S.C. 551 *et seq.*).

The contiguous U.S. DPS of the Canada lynx was listed as a threatened species in 2000. The range of the DPS spans parts of the States of Colorado, Idaho, Maine, Minnesota, Montana, New Hampshire, New Mexico, Washington, and Wyoming. We designated critical habitat for the Canada lynx DPS in 2006 and revised the designation in 2009 and 2014. On November 29, 2024, in response to a settlement agreement, we published a proposed rule to revise critical habitat for the Canada lynx DPS.

What this document does. This final rule revises the existing designation of critical habitat for the threatened contiguous U.S. Canada lynx DPS. We are revising Canada lynx critical habitat in the western United States only because this part of the range was the subject of a 2016 court order that found fault with our 2014 final critical habitat rule for not designating critical habitat in Colorado and in five National Forests in Idaho and Montana, and because we have new scientific information on lynx habitat in the western United States. We are not making any revisions to existing critical habitat in Maine and Minnesota.

The basis for our action. Section 3(5)(A) of the Act defines critical habitat as (i) the specific areas within the geographical area occupied by the species, at the time it is listed, on which are found those physical or biological features (I) essential to the conservation of the species and (II) which may require special management considerations or protections; and (ii) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the Secretary of the Interior (Secretary) that such areas are essential for the conservation of the species. Section 4(b)(2) of the Act states that the Secretary must make the designation on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impacts of specifying any particular area as critical habitat.

Previous Federal Actions

Please refer to the proposed critical habitat rule (89 FR 94656) for the Canada lynx DPS published on November 29, 2024, for a detailed description of previous Federal actions concerning this species.

Peer Review

On December 1, 2023, a team of Service biologists, in consultation with recognized lynx and climate experts, completed an addendum to the 2017 SSA report for the Canada lynx DPS (Service 2023, entire). The SSA report (Service 2017, entire) and addendum (Service 2023, entire) represent a compilation of the best scientific and commercial data available concerning the status of the species, including the impacts of past, present, and future factors (both negative and beneficial) affecting the species.

In accordance with our joint policy on peer review published in the **Federal Register** on July 1, 1994, (59 FR 34270) and our August 22, 2016, memorandum updating and clarifying the role of peer review in listing and recovery actions under the Act, we solicited independent scientific review of the information contained in the Canada lynx SSA report addendum. We sent the SSA report addendum to five independent peer reviewers and received five responses. Results of this structured peer review process can be found at *https://www.regulations.gov* at Docket No. FWS–R6–ES–2024–0142. We incorporated the results of these reviews, as appropriate, into the SSA report, which was the foundation for the proposed rule and this final rule. A summary of the peer review comments can be found in the proposed rule (89 FR 94656 at 94659, November 29, 2024).

Summary of Changes From the Proposed Rule

In the proposed rule published on November 29, 2024, (89 FR 94656) we announced we were considering

approximately 594 square miles (mi^2) (1,541 square kilometers (km^2)) for exclusion under section 4(b)(2) of the Act. We considered excluding all Tribal lands in Montana and New Mexico as well as lands in Montana, managed in accordance with the Montana Department of Natural Resources and Conservation (DNRC) Forested State Trust Lands Habitat Conservation Plan (Montana DNRC and U.S. Fish and Wildlife Service 2010b, entire), and lands in Washington, managed in accordance with the Washington Department of Natural Resources (WDNR) Lynx Habitat Management Plan for WDNR-managed Lands (WDNR 2006, entire). The proposed exclusion of Tribal lands in New Mexico no longer applies because we have determined in this final rule that areas proposed in New Mexico, including Tribal lands, are not critical habitat. We are excluding the other areas described above from the final critical habitat designation.

We also received several comments providing information that supported excluding additional areas from the final critical habitat designation because the benefits of excluding additional areas outweighed the benefits of including the areas. These additional areas include: State of Montana Department of Fish, Wildlife, and Parks (MTFWP) Wildlife management areas (43 mi^2 (113 km^2)); and Green Diamond Resources lands in Montana (7 mi^2 (18 km^2)).

In total, we are excluding approximately 625 mi^2 (1,619 km^2) of lands from the final critical habitat designation for the Canada lynx DPS. Our rationale for each of these exclusions is provided in the Consideration of Impacts Under Section 4(b)(2) of the Act section below.

We have revised the physical and biological features (PBFs) since the proposed rule for clarity due to public comments received. We have determined that the following PBFs are essential to the conservation of the Canada lynx DPS: (1) presence of snowshoe hares that support lynx residency and reproduction over time within a mosaic of boreal/subalpine forest structural stages that includes snowshoe hare habitat with dense horizontal cover at ground- or snow-level; (2) winter conditions that provide and maintain deep persistent unconsolidated (fluffy) snow; (3) presence of denning structures, including downed trees, root wads, and accumulations of coarse woody debris; (4) habitat types, such as dry forest or meadows, that are between boreal forest patches and are likely to be used by lynx traveling between those patches within and among home ranges; and (5) landscapes with suitable habitat large enough (483 mi^2 (greater than or equal to 1,250 km^2)) to support breeding populations. These PBFs describe the most important needs for Canada lynx at the species level.

In response to public and Federal agency comments, we reviewed and made changes to the proposed critical habitat units in both the Southern Rockies (Unit 6) and in the Northern Rockies and Cascades (Units 3 and 4). These changes, in addition to the exclusions, resulted in an overall decrease from the proposed rule of 1,041 mi^2 (2,695 km^2) in Unit 3, 279 mi^2 (722 km^2) in Unit 4, and 2,642mi^2 (6,842 km^2) in Unit 6. We also made changes in the Greater Yellowstone Area (GYA; Unit 5), removing all areas from critical habitat designation. Changes in Unit 4 were relatively minor; we adjusted the boundaries to remove a few areas of lower elevation dry forest that were outside of modeled likely lynx habitat. In Unit 3 we made some similar minor boundary adjustments, removing some small areas and also adding in a few areas of likely lynx habitat that is occupied. The bigger changes in Unit 3 were to remove some smaller polygons that did not meet the minimum size requirements, including the polygon along the Montana-Idaho border near Lolo Pass as well as the polygons in the Selkirk Mountains. Changes in the Southern Rockies were made to align better with the final data from the Squires et al. 2024 modeling effort that identified areas of likely and core habitat for lynx in the Southern Rockies. The revised critical habitat polygons contain the PBFs for lynx, and they encompass the substantial areas of likely and core habitat that have supported lynx occupancy and reproduction and other habitats that provide connectivity between those patches of the best habitat.

In addition, in the proposed rule we stated that we could not map critical habitat in sufficient detail to exclude each and every developed area or other areas that are unlikely to contain the PBFs essential to the conservation of lynx. Some comments received during the public comment period requested further detail of the types of areas excluded by text from the critical habitat designation. Since the proposed rule, we revised the part of the rule that explains what areas within the boundaries of critical habitat do not contain the PBFs essential to the conservation of the lynx DPS and are thus not considered critical habitat. Those areas include: lands covered by buildings, houses, pavement, and other structures; paved highways and roads; active mines and *existing* mining infrastructure; existing developed ski runs and tree islands, ski lifts, and associated ski area infrastructure and buildings; and irrigation infrastructure.

We made minor, nonsubstantive editorial revisions and corrections throughout this rule to ensure better consistency and to clarify information.

Summary of Comments and Recommendations

In the proposed rule published on November 29, 2024 (89 FR 94656), we requested that all interested parties submit written comments on the proposal by January 28, 2025. We also contacted appropriate Federal and State agencies, Tribal entities, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. A newspaper notice inviting general public comment was published in U.S.A. Today on December 11, 2024. We did not receive any requests for a public hearing. All substantive information received during the comment period has either been incorporated directly into this final critical habitat designation or is addressed below.

Peer Reviewer Comments

As discussed in Peer Review above, we received comments from five peer reviewers on the draft SSA report addendum. We reviewed all comments we received from the peer reviewers for substantive issues and new information regarding the contents of the SSA report addendum (Service 2023, entire). The peer reviewers generally concurred with our methods and conclusions. The peer reviewers provided additional information, terminology clarifications, suggestions to explain uncertainties, clarifications to the explanation of our resiliency model, and other editorial suggestions. Peer reviewer comments and suggestions were incorporated as appropriate in the final version of the SSA report addendum (Service 2023, entire).

Federal Agency Comments

(1) Comment: The U.S. Department of Agriculture (USDA) expressed desire for more precise language regarding areas of non-suitable habitat that fall within the proposed critical habitat that includes the exclusion of lands covered by buildings, pavement, and other structures.

Our response: Given the extensive areas needed to support lynx populations, and thus the scale at which critical habitat was mapped, it was impractical to show all areas of

development, infrastructure, and other areas of non-suitable habitat that are not included in the designation. Rather, these areas are excluded by text in regulation at 50 CFR 17.95. We revised our description of these types of areas within the boundaries of the final critical habitat designation that lack the PBFs necessary for lynx, to specify that existing developed areas with buildings, pavement, and other structures, such as irrigation-related infrastructure, are not included. We do note that some areas, such as the vegetation surrounding reservoirs, may provide lynx habitat and should be assessed on site-specific bases. See *Criteria Used To Identify Critical Habitat* below for more information.

(2) Comment: USDA, through a National Forest in Colorado, requested the Service revise the moving window analysis of the Squires et al. (2024, entire) model. USDA stated that the Service appears to have used an arbitrary cutoff that is beyond the 95 percent cutoff that the paper proposes as likely habitat. USDA stated there is a large amount of ponderosa pine (*Pinus ponderosa*), mountain shrublands, mountain grasslands and dry-mixed conifer forests dominated by ponderosa pine, Douglas fir (*Pseudotsuga menziesii*), and white fir (*Abies concolor*) vegetation that is being considered as critical habitat for lynx. These vegetation types do not comprise lynx habitat nor do they provide habitat for primary or alternate prey species. USDA stated that their management in these fire adapted vegetation types is to promote forest conditions that are more resilient to natural disturbances such as insects, disease, and wildfire. USDA suggested that the designation of these vegetation types as critical habitat potentially conflicts with forest management of these vegetation types and has potential to mislead public interpretation of science-based principles for management.

Our response: We reviewed the mapping process used by the Western Lynx Biology Team (WLBT 2022, entire)—an interagency team of biologists from the Service, Forest Service, National Park Service, and Bureau of Land Management (BLM). The WLBT created tier polygons in the Southern Rockies based on an earlier draft of the model developed by Dr. John Squires and his colleagues, and our proposed critical habitat in the Southern Rockies used the tier 1 polygons from WLBT. The final model selected for publication (Squires et al. 2024) changed from what the WLBT used. Upon review of the Squires et al 2024 paper, we became aware that the WLBT polygons were based on the draft earlier model; thus, we reviewed the revised published model and revised our critical habitat polygons using the final published version of the model, following the WLBT's methods. The final critical habitat polygons for the Southern Rockies unit contain the physical or biological features for the Canada lynx and encompass all substantial areas of likely and core habitat, as well as habitats that provide connectivity in between, and they encompass the areas that have continued to support persistent lynx residency and occupancy.

In Colorado, as in other areas, high-quality lynx habitat (*e.g.,* mesic, boreal forest types) is often set within a matrix of dry forest types, rocky peaks, and other habitats that do not provide high-quality foraging or denning habitat for lynx but are important for connecting those high-quality lynx habitats to support large enough areas to provide for an individual lynx's home range. The revised critical habitat polygons substantially reduce the amount of dry forest types mentioned by USDA, and more closely map areas of high-probability lynx habitat. However, some areas of drier forest types, meadows, and mountain peaks fall within the critical habitat polygons. These areas may be used by lynx that are traveling within or between home ranges, and thus they provide connectivity, but they are not likely to contain habitat for foraging or denning. Vegetation management, fuels reduction, and other activities in these drier forest and non-boreal forest patches within the critical habitat polygons may be beneficial for reducing fire risk to the high-quality lynx habitats.

Lynx are primarily associated with mesic, boreal forest types such as spruce (*Picea* spp.) and fir *(Abies* spp.). Within lynx range in the western United States, these habitat types are often patchily distributed within a matrix of drier forest types and other habitats. Squires et al. (2024, entire) note that the relatively small areas of ''likely'' (*i.e.,* high-quality lynx habitat) and ''core'' habitats were patchily distributed and spatially limited within a matrix of ''unlikely'' habitat and that the shape of lynx habitat was convoluted due to the complex mountain topography that dominates the Southern Rocky Mountains. The critical habitat polygons capture the substantial areas of ''likely'' and ''core'' habitat, which are the habitats most likely to be used by resident lynx. The polygons also conservatively include the areas in between patches of ''likely'' habitat that provide the connective matrix. This resulted in the critical habitat polygons including some of the ''unlikely'' habitat in the matrix that connects patches of ''likely'' lynx habitat. In doing so, the critical habitat polygons capture broad areas with enough ''likely'' habitat to support multiple lynx home ranges, while also considering the within-home range and between-home range connectivity necessary for daily movements and interactions (*e.g.,* males traveling to multiple female home ranges). The critical habitat polygons do not capture areas that lynx may travel on occasion for making exploratory or long-range dispersal movements.

Forest management, fuels reduction, and most other activities within drier forest types, meadows, and other non-boreal forest types within the critical habitat polygons are unlikely to affect critical resources for lynx, such as foraging and denning habitat or winter snow conditions. The designation of critical habitat does not preclude forest management practices from occurring but provides assurance that forest management will not result in the destruction or adverse modification of the critical habitat at the scale of the entire critical habitat designation.

Comments From States

(3) Comment: Montana Fish, Wildlife, and Parks (MTFWP) supported the exclusion of lands in Montana that are managed by the Montana Department of Natural Resources and Conservation (DNRC) from critical habitat designation. The DNRC has a habitat conservation plan (HCP) and State administrative rules (MT Admin Rules 36.11.428(4)) that specifically outline the conservation, monitoring, and management of lynx and their habitat on DNRC-managed lands. This HCP ensures that important habitats for lynx will be conserved and managed for the benefit of the species. MTFWP felt that designation of these areas as critical habitat will not provide any additional protections or benefits to the species; however, designating these areas may cause unneeded restrictions.

Our response: We have excluded lands covered by the Montana DNRC HCP from the critical habitat designation because the benefits of excluding them outweigh the benefits of including them as critical habitat. See Consideration of Impacts Under Section 4(b)(2) of the Act, below, for our full exclusion analysis of these areas.

(4) Comment: MTFWP commented that their agency has six wildlife management areas (WMAs; Nevada Lake, North Swan Valley, Fish Creek, Blackfoot-Clearwater, Marshal Creek, and Bad Rock Canyon) that overlap

portions of the proposed Canada lynx critical habitat. WMAs in Montana are managed by MTFWP and have specific plans for each property. These plans include management strategies to benefit the diversity of wildlife species and their habitats, including Canada lynx. MTFWP recommended that the Service exclude WMAs in Montana from the designation of Canada lynx critical habitat.

Our response: We have excluded WMAs managed by MTFWP from the critical habitat designation because the benefits of excluding them outweigh the benefits of including them as critical habitat. See Consideration of Impacts Under Section 4(b)(2) of the Act, below, for our full exclusion analysis of these areas.

(5) Comment: MTFWP supported the removal of lynx critical habitat in the Greater Yellowstone Area (GYA) and applauded the Service for identifying the areas, according to science, that do not support resident Canada lynx populations or occupancy.

Our response: We removed the GYA from critical habitat designation, based on the limited ecological capacity of the area to support Canada lynx, and the historical and contemporary records indicating only episodic lynx occurrence, not a persistent population occupying the GYA.

(6) Comment: MTFWP supported the findings from the model presented in Olson et al. (2021, entire) as the best current model for designating critical habitat. They also commented that even though the model may estimate high-quality areas, that does not mean the areas are occupied by lynx or would support a resident population.

Our response: The Olson et al. (2021) species distribution model (SDM) was a foundational scientific resource for delineating potential lynx habitat and was developed using empirical data from verified detections and radio-collared lynx, making it one of the most robust and contemporary tools available to the Service.

We agree that areas identified as having high probability of lynx use in the SDMs represent potential habitat and do not, on their own, demonstrate current occupancy or assure that an area can support a resident population. Multiple factors beyond modeled habitat quality- such as vegetation condition, prey abundance, disturbance history, and intra- or inter-specific competition—can influence whether lynx are present in a particular area or able to persist there over time. Accordingly, while the SDM identifies where habitat capable of supporting lynx may occur, the Service does not equate modeled habitat with demonstrated occupancy or confirmed capacity to sustain resident populations. Instead, occupancy and residency evaluations incorporate additional information on local conditions, survey data, and other ecological considerations. We also appreciate the efforts of the states and other partners to continue conducting scientifically rigorous surveys and studies of occupancy to inform current and future evaluations and management for the species.

(7) Comment: Citing recent lynx occupancy surveys conducted in Montana, Idaho, and Wyoming, MTFWP stated that neither Idaho nor Wyoming detected a lynx during the study period (December 1, 2023, to April 30, 2024). MTFWP suggested that this information contradicts the Service's statement in the proposed rule that all areas proposed as critical habitat are occupied, and it does not support the need for Canada lynx critical habitat designation in northern Idaho or any of the GYA. MTFWP urged the Service to consider these newest lynx occupancy survey findings regarding any revision or elimination of those areas in the final critical habitat designation.

Our response: We reviewed the recent occupancy surveys as well as other information regarding occupancy and verified records of lynx. We are not designating any critical habitat in the GYA, in either the Montana or the Wyoming portions of the area. The contemporary occupancy survey referenced in this comment, as well as other surveys conducted for lynx in the GYA, indicate the GYA is not occupied by a persistent population, and no verified evidence of successful reproduction has been recorded in decades. Similarly, we are not designating critical habitat in the Selkirks in Idaho, where the tri-state surveys failed to detect lynx (see also response to comment 10 below).

All of the critical habitat we are designating in Montana (in Unit 3) was occupied at the time of listing and is currently occupied by persistent resident populations. The small amount of critical habitat we are designating in Idaho is part of the Purcell Mountain Range; lynx occupancy was detected in the Purcell Range in the 2023–2024 surveys, and the Purcell Range has supported a persistent reproductive population for many years. Thus, all areas we are designating have had persistent reproductive populations and verified occupancy, as evidenced by multiple survey efforts.

(8) Comment: The Colorado Department of Transportation (CDOT) requested that the Service consider removing the entire existing operational right-of-way along roads as defined in Federal Highway Administration regulations (23 U.S.C. 101) under section 4(b)(2) of the Act from critical habitat. Existing operational right-of-way refers to the right-of-way that has been disturbed for an existing transportation facility or is maintained for a transportation purpose. The existing operational right-of-way is actively maintained by transportation agencies, and therefore, would not include the PBFs essential to the conservation of lynx.

Our response: As discussed in *Criteria Used To Identify Critical Habitat,* below, paved roads and transportation facilities that fall within the boundaries of critical habitat do not contain the PBFs essential to the conservation of lynx and are not considered critical habitat. Though paved roads and adjacent graveled shoulders do not contain PBFs, other vegetated sections of operational rights-of-way may contain habitat features occasionally used by lynx and snowshoe hares and are included in this designation.

(9) Comment: CDOT expressed concerns about how critical habitat designation would influence future projects, such as road construction and maintenance and avalanche mitigation operations. They asked for clarification on what types or categories of ''road construction and maintenance'' would be included under the special management considerations that may be required for critical habitat.

Our response: When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection (see Special Management Considerations or Protection, below, for more information). As described earlier, some areas within the boundaries of mapped critical habitat do not contain the PBFs essential to the conservation of the lynx DPS and are thus not considered critical habitat. Those areas include paved highways and roads that would not be subject to the special management considerations because they do not contain PBFs essential to the conservation of lynx. However, for projects that impact designated critical habitat in areas with the PBFs (*e.g.,* road widening or vegetation removal that affect snowshoe hare densities), the areas of habitat containing the PBFs may require special management considerations or protection, although

these are not requirements. Due to the variable nature of road construction, maintenance activities, and avalanche mitigation that may occur across the range of critical habitat, it is not feasible in this rule to specify which particular activities may or may not adversely affect critical habitat or warrant additional conservation measures. In general, paved roads and highways are more likely to result in habitat loss and fragmentation as they facilitate higher traffic volumes and/or speeds than smaller unpaved forest roads (Service 2017, pp. 100–102). The spatial and temporal scale of any activity should be examined, as well as any design features or specific conservation measures, to determine whether direct or indirect alteration of habitat would occur to the extent that the value of critical habitat for the survival and recovery of lynx would be appreciably diminished. For questions regarding whether specific activities may constitute adverse effects to critical habitat, we encourage project proponents and action agencies to work with the appropriate Ecological Services Field Office (*https://www.fws.gov/locations*) to determine effects to critical habitat and ways to minimize them through project design.

(10) Comment: The Idaho Governor's Office of Species Conservation stated that they believe areas in Idaho are not essential to the conservation of lynx, and provided the following points as evidence: (1) limited observations of lynx despite combined lynx-focused camera survey efforts, camera survey efforts for other forest carnivores, and camera survey efforts for large carnivores and ungulates; (2) insufficient predicted habitat to support a breeding population, which requires a minimum of 483 mi^2 (1,250 km^2) as defined in the proposed rule (based on area alone, the proposed habitat patches could only support a small number of individuals even if all critical habitat were fully occupied); (3) even if fully occupied, this area would not contribute significantly to the population because these proposed areas are disjunct and peripheral to the larger matrix of modeled high-quality habitat and are unlikely to meaningfully contribute to population resilience (Unit 3 Northern Rockies); and (4) proposed areas in Idaho are peripheral and are not even between areas of known occupancy or sufficiently large areas of predicted high-quality, but are unoccupied, habitat. Based on the best available information, the Idaho Governor's Office of Species Conservation (OSC) suggested that the Service should not designate any critical habitat in Idaho.

Our response: The final critical habitat designation includes a small area in northern Idaho that is in the northeast corner of the state, in an area within the Purcell Mountains. This area is directly connected to the rest of the mountain range that is located in Montana, and there is no ecological separation along the state line. The Purcell Mountains support regular occupancy and reproduction by multiple individual lynx (Squires et al. 2010, p. 1498; Olson et al. 2021, p. 1669). Survey efforts in the Purcells regularly detect lynx, including in the portion of the mountain range that falls within Idaho.

We have removed other areas of Idaho, including the Selkirk Mountains and the area around Lolo Pass from the critical habitat designation. Both of those areas were included in our proposed rule, due to being identified as tier 1 polygons by the WLBT. However, upon closer examination of the best available information, including information received since the proposed rule, these areas do not meet the definition of critical habitat. See Summary of Changes From the Proposed Rule for more information. We note that the Selkirks and the Lolo Pass area may function as important areas to support intermittent or even persistent occupancy and reproduction by lynx, peripheral to the core areas within Unit 3. Although they do not meet the definition of critical habitat in this designation, we encourage conservation considerations that preserve or improve conditions that allow these areas to contribute to lynx conservation.

(11) Comment: The State of Idaho requested exclusion of Idaho State endowment trust land from the critical habitat designation for the Canada lynx DPS and challenged the assertion that the proposed critical habitat is an accurate predictor of lynx distribution and home ranges in the State.

Our response: The proposed critical habitat included tier 1 polygons in the Selkirk Mountains that overlapped some Idaho State endowment trust lands. The final designation does not include this area and thus does not include the Idaho trust lands. As such, it is not necessary to consider an exclusion.

(12) Comment: The Idaho Governor's Office of Species Conservation stated the Service should analyze how the addition of critical habitat will have an economic impact to logging contractors, counties, and small communities. They also stated that having the additional layer of critical habitat opens these areas to increased litigation. Adding additional critical habitat acreage in Idaho increases the liability for legal challenges on a larger scale. The Service should analyze how the increase in critical habitat will impact the counties, State and Federal government's costs related to litigation.

Our response: We developed an incremental effects memorandum (IEM) considering the probable incremental economic impacts that may result from this critical habitat designation. The information contained in our IEM was then used to develop a screening analysis of the probable effects of the proposed designation of critical habitat for the Canada lynx DPS (Industrial Economics, Inc. (IEc) 2024, entire). We later revised the screening analysis for the final critical habitat rule (IEc 2026, entire). We considered economic impacts to logging contractors, counties, and small communities. We did not consider any potential increase in litigation costs associated with the addition of critical habitat, as this would be speculative. The analysis found that this critical habitat rule is unlikely to meet the threshold for an economically significant rule having an annual effect on the economy on the of $100 million or more. Designating occupied areas as critical habitat typically causes little, if any, incremental impacts above and beyond the impacts of listing the species, as is the case with Canada lynx DPS.

The public may view critical habitat designation as potentially resulting in incremental impacts in the form of lower property values; however, recent analysis of critical habitat property value impacts indicates that, at a national level on average, critical habitat designation has little to no effect on values for developed and undeveloped properties (IEc 2024 and 2026, p. 21, internal citations omitted). Similarly, the Service recognizes that some segments of the public see any critical habitat designation as severely limiting property rights; however, critical habitat designation has no regulatory effect on private actions on private land that do not involve Federal approval or action. We recognize that there are private actions on private lands that involve Federal actions; however, there should already be section 7 consultations taking place in these situations. The incremental effects of revising critical habitat for the Canada lynx DPS are likely to be limited to changes in administrative effort to evaluate the potential for adverse modification of Canada lynx DPS critical habitat. See *Exclusions Based on Economic Impacts,* below.

(13) Comment: The State of Idaho is concerned that the designation of Canada lynx critical habitat will devalue

its recently-acquired land and increase the likelihood that the State will reduce future purchases of land that might otherwise be developed or ecologically impaired. The commenter is also concerned about additional economic losses from new regulatory requirements, including reduced bidding from purchasers on timber sales because of the seasonal timber harvest restrictions and transportation and infrastructure limits.

Our response: See our response to Comment 11, explaining that there are no state lands included in the final critical habitat designation in Idaho, which moots some of the concerns. We provide additional responses here regarding the economic concerns expressed in the comment. See also our response to Comment 44.

In general, real or perceived regulatory restrictions on land use can reduce the market value of the land. In the case of critical habitat for lynx, the Service finds that the rule is unlikely to generate additional restrictions on land use above and beyond any restrictions due to the presence of the species and its listing status. Nonetheless, the perception that additional restrictions may occur can affect land values. Section 4 of the economic screening analysis acknowledges that critical habitat may affect property values in certain circumstances; however, the screening analysis describes that a comprehensive review and synthesis of the economics literature on this topic found that the potential for property value impacts is species-specific and not generalizable to all critical habitat designations (IEc 2024 and 2026, p. 21). While some studies identify negative property value effects of critical habitat designation, others find that critical habitat can positively affect property values, and others find no effect. Mamun et al. (2023, entire), as cited in the economics screening memorandum (IEc 2024 and 2026, p. 21), represents the most comprehensive analysis of critical habitat property value impacts conducted to date. They found that critical habitat designation has an average of ''little to no effect'' on values for developed and undeveloped properties nationally. Nevertheless, the potential for a critical habitat designation to affect a property's value is species-specific and is acknowledged as a potential effect of this rule.

(14) Comment: The Washington Department of Fish and Wildlife (WDFW) notes that the Service is considering excluding lands in Washington from the critical habitat designation that are managed in accordance with the WDNR) Lynx Habitat Management Plan (LHMP) for WDNR-managed lands (WDNR 2006, entire). WDFW also noted that the WDNR indicated that implementation and effectiveness monitoring results would be summarized in biennial reports to the Service and WDFW (WDNR 2006, p. 63) and that their 2006 plan would be updated as more is learned about lynx habitat relationships and management strategies through periodic reviews every five years (WDNR 2006, p. 6). To their knowledge, no such reports have been produced or shared and, with the exception of a limited-scope amendment in 2011, the plan has not been updated. Without an update to the WDNR's 2006 plan, and with no reports on implementation, neither WDFW nor the Service can make any statements on effectiveness. WDFW suggests the Service should request the biennial reports and consider these lands for inclusion in the critical habitat designation.

Our response: We appreciate the concerns outlined by WDFW regarding the WDNR LHMP. In March 2025, both the Service and WDFW received a comprehensive report from WDNR on the implementation and effectiveness of their LHMP. The Service has reviewed the 2025 report and is currently working with WDFW and WDNR to evaluate the 2006 LHMP to determine the elements of the plan that warrant updating. WDNR has committed to completing any updates to the LHMP by 2028 (Crump, in lit. 2025). We appreciate the commitment of the WDNR to manage lands according to the LHMP and best available science, and we have excluded lands currently managed under the 2006 WDNR LHMP from the critical habitat designation because the benefits of excluding them outweigh the benefits of including them as critical habitat. See Consideration of Impacts Under Section 4(b)(2) of the Act, below, for our full exclusion analysis of these areas.

(15) Comment: WDNR supports the proposed rule including continuing to exclude lands managed under the 2006 WDNR LHMP from critical habitat designation. WDNR remains committed to following the LHMP until lynx are de-listed, or until 2076, whichever is shorter.

Our response: We appreciate the commitment of the WDNR to manage lands according to the LHMP, and we have excluded lands managed under WDNR's LHMP from the critical habitat designation because the benefits of excluding them outweigh the benefits of including them as critical habitat. See Consideration of Impacts Under Section 4(b)(2) of the Act, below, for our full exclusion analysis of these areas.

(16) Comment: WDFW stated that establishment of a reintroduced lynx population in the Kettle Range of Washington could prompt consideration of a critical habitat designation congruent with the delineation of critical habitat for the reintroduced lynx population in Colorado (Unit 6 Southern Rockies). WDFW explained that the Kettle Range meets the ecological needs of lynx and snowshoe hares; thus, there will need to be an analysis of the success of the reintroduction project to determine if this area is essential to the conservation of the species. WDFW requested that the Service consider whether the Kettle Range warrants inclusion as critical habitat.

Our response: We note that habitat modeling and mapping (Olson et al. 2021, entire; WLBT 2022, entire) identified roughly 283 mi^2 (732 km^2) of lynx habitat in the Kettle Range of northeastern Washington, where the Confederated Tribes of the Colville Nation and their partners are attempting to establish a lynx population by translocating lynx from southern British Columbia, Canada. Based on previously estimated lynx home range sizes and densities in Washington, that area could potentially support 10 to 20 lynx; however, the success of this effort and the ability of the area to support a reproductive population over time remain uncertain.

The Kettle Range does not contain the minimum 483 mi^2 (greater than or equal to 1,250 km^2) of suitable habitat thought to support a resilient breeding population of at least 25 lynx, which is the minimum habitat patch size the Service considered in the draft recovery outline (Service 2005, p. 5), the recovery plan (Service 2024, p. 35), and the critical habitat criteria, nor is the area in close proximity to other larger areas that do support breeding populations. The Kettle Range was not identified as a focal area in the recovery plan (Service 2024, entire). We do not consider the Kettle Range to have been occupied by lynx at the time of listing in 2000 based on historical lynx occurrence data. As such, to include the Kettle Range in the designation as unoccupied critical habitat according to the Act, we would have to make a determination that that area is essential for the conservation of the species. Although this area may contain some of the PBFs required by lynx, the area is not essential for the conservation of the Canada lynx because of its small habitat patch size, distance from other occupied areas, and the uncertainty of the success of the translocation effort. As a result, we are not including the Kettle Range in this

designation. However, the translocation effort, and continued consideration of habitat management for lynx, may provide additional areas to support redundancy and resiliency for the DPS as peripheral area to the core areas designated as critical habitat.

(17) Comment: The Wyoming Game and Fish Department applauds the Service's decision to substantially remove designated critical habitat in the GYA. However, because there is still a lack of evidence for a persistent historical population in the GYA, there is little suitable habitat present, and two recent survey efforts detected no evidence of lynx, it is inappropriate for the GYA to contain any designated critical habitat. Additionally, the State suggests it is unlikely the GYA will become prime lynx habitat given the effects of climate change, and the recovery plan is not aimed at increasing lynx populations. Thus, the Service should allocate its resources towards units already containing self-sufficient lynx populations.

Our response: See our response to comment 7 above. After reviewing the best available information, we agree that the GYA does not meet the statutory definition of critical habitat because it lacks the PBFs essential to the conservation of the species. Although species distribution models identify portions of the GYA as potentially suitable habitat, multiple lines of evidence demonstrate that the area has not supported a persistent reproductive lynx population. The last documented instances of reproduction in the GYA include one female that failed to raise kittens in the Wyoming Range in the late 1990s (Squires et al. 2003, p. 13) and one female with a kitten on the east side of Yellowstone Lake in the early 2000s (Murphy et al. 2006, p. 203). Historical and contemporary records show that lynx use of the GYA has been intermittent, with no evidence of a persistent breeding population. Extensive surveys in much of the GYA have failed to document other instances of reproduction, and surveys in the past decade have failed to detect any lynx at all.

The inability to support a persistent breeding population of lynx may be a reflection of naturally marginal and patchy habitats and relatively low hare abundance in much of the GYA, resulting in only an intermittent ability of this unit to support resident lynx (Service 2018, p. 47). The absence of a persistent breeding population for at least the past 30 years indicates that the GYA does not contain the physical or biological features (PBFs) essential to lynx conservation—most notably, PBF 1 (the presence of snowshoe hares that support lynx residency and reproduction over time) and PBF 5 (landscapes large enough to support breeding populations).

In the proposed rule, we included the tier 1 areas in the GYA identified by the WLBT in the Wyoming Range and the Union Pass and Togwotee Pass area. These areas comprise 12 percent of the GYA (as identified in the SSA; Service 2018, p. 153–158), and are the areas with the most documented lynx use and predicted habitat in the GYA. Although Berg et al. (2012, entire) documented relatively high snowshoe hare densities in the Wyoming Range, compared with those in Yellowstone National Park (Hodges et al. 2009), this part of the GYA has still not supported a persistent breeding population. The only documented reproductive attempt in this area was from a female in the late 1990s whose kittens did not survive to adulthood; she later died of starvation (Squires and Oakleaf 2005, Squires et al. 2003). The radio-collared male present at that same time made multiple long-range movements out of the area, possibly due to food limitation (Squires and Oakleaf 2005). Other lynx that briefly occupied the Wyoming Range after dispersing from their reintroduction sites in Colorado remained only short periods (all less than a year) before moving on (Ivan 2017, p. 12–36). Surveys in the past decade have not detected any lynx (MT FWP 2024, entire; Abernathy and Cook 2024, entire; J. Wilmot, June 17, 2026, personal communication). Despite the habitat models indicating potential habitat, the lack of a persistent reproducing lynx population demonstrates these tier 1 areas do not contain the habitat features essential for lynx conservation.

We also found no evidence that land management practices are responsible for the absence of persistent breeding lynx populations in the GYA. The Wyoming Range and other tier 1 areas have been managed by the U.S. Forest Service under the same management direction that has been applied in other areas that support persistent breeding populations (*e.g.,* Units 3, 4, and 6 managed under the LCAS; ILBT 2013). Despite active conservation measures and sufficient time for some impacted areas to regenerate into higher-quality post-fire hare and lynx habitat, lynx have not naturally recolonized this unit, and reintroduced Colorado lynx that dispersed into the area have not maintained longterm home ranges or produced kittens (Service 2018, p. 47). Because the best available science shows the GYA does not support a persistent breeding lynx population and that this area does not contain the physical and biological features essential to lynx, the Service has concluded that no portion of the GYA meets the statutory definition of critical habitat and therefore is not designating critical habitat in this area.

Although we are not designating critical habitat in the GYA, the area may provide movement and foraging opportunities during rare population irruptions or for dispersing individuals. Habitats in the GYA may retain favorable temperatures and snow conditions for lynx in the future, though it is unknown if that will translate to the potential to support resident breeding populations (Service 2023, p. 66–70). Periodic monitoring for lynx, including efforts to detect multiple individuals and evidence of reproduction, will provide valuable insight into the area's condition and its ability to support the species as future conditions change. However, recovery of the DPS does not rely on establishing a breeding population in the GYA, and all recovery criteria can be met by existing populations elsewhere (Service 2024, entire).

(18) Comment: The Utah Public Lands Policy Coordinating Office commented that although the Service was court-ordered to designate critical habitat in Colorado, the State of Utah does not support the Service's decision to designate critical habitat in Colorado. The Utah Public Lands Policy Coordinating Office believes that the inclusion of those areas punishes proactive conservation efforts and has, and will continue to, discourage future actions taken by States to restore species' ranges. Colorado's lynx introductions began just before the species' listing, and the populations occur primarily on Federal land. Colorado has invested heavily in lynx introductions and demonstrated a consistent record of conservation actions for the species. Based on these actions and the commitments contained in the Conservation Plan for Canada Lynx in Colorado (Colorado Division of Wildlife 2002, entire), the Utah Public Lands Policy Coordinating Office stated the exclusion of Colorado from the critical habitat designations would not lead to extinction.

Our response: We commend the State of Colorado for the success of their Canada lynx reintroduction program and contribution to the conservation of this species. In determining whether we would conduct an exclusion analysis, we first evaluated whether the proponent of those exclusions presented credible information to support the

benefits of excluding these areas. We found Utah Public Lands Policy Coordinating Office's request to exclude Colorado from the critical habitat designation did not meet this standard. The Conservation Plan for Canada Lynx in Colorado referenced in the comment is largely a plan to minimize take of reintroduced lynx and to ensure success of the reintroduction program rather than a plan to enact habitat conservation measures that would benefit lynx habitat in Colorado. We find that the commenters have not provided credible information that a meaningful impact may support benefits of excluding these areas from critical habitat. Therefore, an exclusion analysis was not warranted. We note that the State of Colorado did not comment on the proposed rule and did not request an exclusion. In terms of the position that designating critical habitat would deter future reintroductions of species, we acknowledge that position but point out that a species reintroduction does not cause a critical habitat designation.

Although we omitted Colorado from initial critical habitat designations, a court found that to be inconsistent with the Act and best available science. In fact, recent modeling (Squires et al. 2024) has confirmed the presence of the essential physical or biological features for the Canada lynx. Although beyond the scope of this rulemaking, we recognize that conservation benefit agreements and other conservation tools—such as establishing an experimental population under section 10(j) of the Act—can offer meaningful support to states and other partners engaged in species restoration efforts. We encourage individuals interested in reintroduction and restoration efforts to work with their local Field Office to explore how these tools can best provide regulatory assurances to support proactive conservation.

Comments From Tribes

(19) Comment: The Jicarilla Apache Nation requests that the Service exclude the Jicarilla Apache Nation lands from the final designation of lynx critical habitat.

Our response: We announced in the proposed rule that we were considering exclusions of Jicarilla Apache Nation lands from the critical habitat designation because the benefits of excluding them outweigh the benefits of including them as critical habitat. However, upon reexamination of the Southern Rockies Unit (Unit 6), we have determined in this final rule that areas proposed as critical habitat in New Mexico, including Jicarilla Apache Nation lands, do not meet our criteria for designation as critical habitat. Thus, there is no need for an exclusion in the final rule.

(20) Comment: The Kootenai Tribe of Idaho believes areas in Bonner and Boundary Counties in Idaho should be included in the critical habitat designation. The habitat in this area appears to meet the criteria for designation as critical habitat for lynx. The Tribe expressed support for the revised delineation of critical habitat in the western United States, particularly the inclusion of areas in the Northern Rocky Mountains and Southern Rocky Mountains; however, they urge the Service to continue prioritizing connectivity corridors that are vital for maintaining genetic diversity and the resilience of lynx populations, particularly those at the southern periphery of the species' range.

Our response: Areas in both Bonner and Boundary Counties contain likely lynx habitat and were included in the proposed rule (89 FR 94656, November 29, 2024). However, only the area of Boundary County that is within the Purcell Mountains is designated as final critical habitat. Other areas, including the Selkirk Mountains and part of the Cabinet Mountains in northern Idaho contain some habitat for lynx and may play a role in providing peripheral habitat and habitat for connectivity, but they do not meet the definition of critical habitat. We acknowledge the importance of connectivity to the conservation of the Canada lynx DPS. The PBFs essential to the conservation of Canada lynx we have used to delineate critical habitat include permeable landscapes conducive to within-unit daily movements and dispersal (see *Criteria Used To Identify Critical Habitat,* below).

Public Comments

(21) Comment: Several commenters called for the protection of connectivity areas between lynx populations, particularly between core habitat units. Commenters argued that without robust protections in these areas, the potential for genetic interchange and resilience against climate impacts may be severely compromised, making populations more vulnerable to extinction. Some viewed the term ''connectivity'' as ambiguous, with suggestions to use clearer language regarding lynx movement and its implications for habitat designation. Commenters pointed out what they felt were inconsistencies between critical habitat and scientific studies, especially regarding the GYA. They argued that the proposed critical habitat did not reflect areas that are crucial for lynx movement and genetic exchange. There were suggestions for further research into lynx migration paths, especially those connecting Canada to the United States, and for these pathways to be designated as critical habitat to support the species' recovery.

Our response: We considered two main types of connectivity in relation to the critical habitat units, which roughly encompass the different lynx populations for the DPS. When evaluating habitat for those populations, we considered intra-unit connectivity, which refers to connectivity related to daily movements within a lynx home range (*i.e.,* an individual walking through an open meadow in between two stands of dense boreal forest). We also considered inter-unit connectivity, which regards individuals that move from one critical habitat unit to another; for example, a lynx that resides in Unit 6 (Southern Rockies) dispersing to Unit 3 (Northern Rockies). Our response to comment 2 above addresses intra-unit connectivity. The remainder of this response will focus on inter-unit connectivity.

Areas of mapped lynx habitat outside of the critical habitat polygons may provide important habitat for individual lynx. Many areas outside of critical habitat contain likely lynx habitat, or even moderate-probability habitat, and some of those areas may support periodic occupancy and/or provide foraging and resting habitat for dispersing individuals.

Lynx have also been documented dispersing long distances from areas that support populations, including individuals that roamed widely after being reintroduced in Colorado and in the Kettle Range (Ivan 2012 and 2017, entire; Piccinini 2026, personal communication), as well as individuals that have traveled long distances in the GYA (Squires and Oakleaf 2005, entire), or moved north from Unit 3 (Northern Rockies) into Canada (Squires 2025, unpublished data). During such movements, lynx have used a variety of habitat types, occurring intermittently and temporarily in suboptimal, marginal, and unsuitable habitats that do not contain the PBFs essential to lynx in enough abundance and proximity to support reproductive populations of lynx over time. Lynx are able to find smaller patches of suitable habitat that will support an individual but not a persistent population. Thus, some habitats outside of critical habitat polygons may play an important role in facilitating inter-unit connectivity, but they are not included in designated critical habitat, as lynx have shown to be adept dispersers that are capable of using a wider range of habitats for

dispersal than what they use for residency (Squires 2025, personal communication March 2025; Ivan 2012 and 2017, entire; Arnold et al. 2025, entire).

Lynx populations in the contiguous Unites State are believed to be influenced by lynx population dynamics in Canada, and many of the populations in Canada are directly interconnected with United States populations. Therefore, retaining connectivity with the larger lynx population in Canada is thought to be important to ensuring long-term persistence of lynx populations in the United States. Critical habitat Units 3 (Northern Rockies) and 4 (North Cascades) are directly connected to Canada, whereas Units 5 (Greater Yellowstone Area) and 6 (Southern Rockies) are more isolated with swaths of low probability lynx habitat in between, as well as some areas of moderate or even smaller amounts of high-quality habitat in certain areas. The WLBT (2022, entire) identified tier 2 and tier 3 areas as those that may support connectivity, either by providing habitat for resident animals and/or providing stepping stones of habitat for dispersers. We do not want to discredit the value of these areas; however, lynx are wide-ranging animals with a well-documented ability to make long journeys across both suitable and unsuitable habitats (Service 2017, p. 40–43; Interagency Lynx Biology Team (ILBT) 2013, p. 8, Ivan 2012 and 2017, entire). There is no evidence that human-caused factors have significantly reduced the ability of lynx to disperse or resulted in the loss of genetic or demographic interchange (ILBT 2013, p. 34). The level of diminished connectivity at which DPS populations could be affected is unknown; however, we have no evidence that current connectivity between lynx populations in the DPS and those in the core of the lynx's range are inadequate to maintain the genetic and demographic health of the DPS population or that this situation is likely to change in the foreseeable future.

Areas of lynx habitat outside of critical habitat may provide valuable habitat for individual lynx and for inter-population connectivity. This is especially true for tier 1 areas not included as critical habitat and tier 2 and 3 polygons identified by the WLBT, as well as areas of habitat adjacent to or connecting areas of critical habitat. Because the species list area for lynx is much broader than critical habitat, many areas of mapped lynx habitat may still be considered in section 7 consultations for the species, in which effects to connectivity and peripheral habitat will be considered.

(22) Comment: Some commenters suggested that the Service include both ''moderate-'' and ''high-'' quality habitats (as identified in Olson et al. 2021), or all areas identified as tier 1 and 2 (as identified in WLBT 2022, entire) in the critical habitat designation to enhance connectivity and support lynx populations. Many commenters advocated for expanding the critical habitat designation rather than reducing it. Specific areas suggested for inclusion included, but are not limited to, the Mummy and Never Summer Mountain Ranges in Colorado, the Little Pend Oreille and Salmo Priest landscapes in Washington, the Bitterroot Mountains and Beaverhead-Deerlodge National Forest in Montana, and other areas that may facilitate movement in between areas of high-quality habitat.

Our response: We considered all of the areas mentioned in comments, but we did not add any to the final critical habitat designation. This final critical habitat designation focuses on the areas most capable of supporting persistent breeding populations, as described in *Criteria Use to Identify Critical Habitat.* We relied primarily on the process developed by WLBT to identify areas large enough and with enough high-quality habitat to support multiple lynx home ranges. As such, not all areas modeled as ''moderate'' or ''high'' probability are included in the critical habitat designation. We also did not include the tier 2 and 3 areas identified by WLBT, since those areas are less naturally capable of supporting persistent breeding populations. Many of the tier 2 and 3 polygons have very few verified records of lynx occurrences, no evidence that they ever supported lynx over time, and are not essential to lynx conservation and recovery. Tier 1 polygons not included in critical habitat, as well as tier 2 and 3 areas and other areas of mapped habitat may provide habitat for connectivity, occasional occupancy, and even occasional reproduction. These areas may contain some of the PBFs, but do not provide enough habitat in close enough juxtaposition to support at least 25 individuals; thus they do not contain landscapes with suitable habitat large enough (483 mi^2 (greater than or equal to 1,250 km^2)) to support breeding populations (*i.e.,* PBF 5).

Finally, in our consideration of additional areas outside of what we proposed for critical habitat, we made sure to consider the areas specifically addressed in the 2016 court order from the Montana District Court, including Colorado and parts of the Beaverhead-Deerlodge, Bitterroot, Nez Perce, Lolo, and Helena National Forests of Montana and Idaho. Our decision to include, or not include, Colorado and portions of those National Forests followed the same rationale provided above for all other areas suggested by commenters.

(23) Comment: Some comments advocated for the inclusion of Federal, State, Tribal, and local agencies as cooperating partners in the critical habitat planning process. Commenters saw this collaboration as essential for balancing habitat protection with local economic interests. Commenters stressed the importance of working with local collaborative groups already engaged in forest resilience projects to identify and protect critical lynx habitats.

Our response: The Service has worked with multiple partners over the past 25 years, since lynx were first listed as threatened, to support and interpret the best available science and information to guide recovery of the species. In particular, the proposed rule for critical habitat was built on the foundation of the WLBT (2022, entire) Framework for Conservation of Canada Lynx, which was an interagency effort between the majority land managers where lynx habitat is found in the western United States. An important part of the critical habitat process was the opportunity for partners and the public to review the proposed rule and provide comments and relevant information during the public comment period. We received comments from several States and Tribes in response to our November 29, 2024, proposed rule (89 FR 94656). See comments 1 through 20 above. The Service then considered all of the comments received when finalizing the critical habitat designation. We modified proposed critical habitat as a result of information provided in those comments. Additionally, the Service works with partners, particularly the U.S. Forest Service (USFS), which manages the vast majority of lynx habitat in the western United States, as well as other landowners (*e.g.* State trust land managers, willing private partners) to develop habitat management strategies (*e.g.* HCPs) to conserve lynx habitat and work towards recovery of the species.

(24) Comment: We received requests from Mineral and Sanders Counties in Montana, to exclude several areas, including all USFS lands in the timber base (*i.e.,* lands identified in National Forest land and resource management plans, or forest plans, as suitable for timber harvest). They asserted various reasons for these requests, including: reducing government processes,

reducing litigation, a need to provide management flexibility and ease of administration, economic impacts, and other reasons. Several other commenters also recommend excluding areas from critical habitat designation that are currently used for timber production or other economic activities. They argued that these areas are vital for local economies and cultural heritage.

Our Response: Much of the designated critical habitat falls within the suitable timber base on National Forests, and the Forest Service must consult with the Service regarding any actions that may affect the critical habitat. Under the Endangered Species Act, the question is not whether an action causes *any* adverse effect to critical habitat, but whether it causes effects that are so substantial that they *appreciably diminish* the habitat's ability to support the conservation (survival and recovery) of the species. Activities may cause limited or temporary adverse effects to some physical or biological features of critical habitat without reaching this threshold. Given the need for a mosaic that includes dense early-successional forests that support snowshoe hares, some disturbance is needed within lynx critical habitat, which can come from both natural and anthropogenic causes, including timber harvest. Therefore, the designation of critical habitat for Canada lynx does not, by itself, prevent logging.

However, we recognize that a critical habitat designation creates an increased administrative workload and associated economic impacts. Within designated critical habitat, Federal agencies must consult with the Service on any actions that may affect critical habitat. Consultation already occurs for the species, but critical habitat adds an additional analysis in consultation workloads.

Consistent with 50 CFR 424.12, our economic screening analysis considered the probable incremental economic impacts of designating critical habitat. The Service may rely on this information as part of the weighing of the benefits of excluding particular areas from critical habitat against the benefits of including them. As described in the economic screening analysis, the Service finds that it is unlikely that critical habitat will change how projects and activities are managed (IEc 2024 and 2026, entire). Accordingly, additional timber harvest restrictions are not a probable outcome of the critical habitat rule, and economic impacts of the designation are limited to relatively minor administrative costs (IEc 2024 and 2026, entire).

We did not conduct an exclusion analysis for these areas based on government process requirements or ease of administration because the commenters did not provide information that there are meaningful impacts pertaining to these areas, or information that may support the benefits of excluding these areas. We do not agree with the assertion that the critical habitat designation conflicts with a need to provide management flexibility, because critical habitat designation in and of itself does not dictate or prescribe any management restrictions or requirements. Most Federal land management agencies have restrictions in their existing land and resource management plans to conserve the species (*e.g.,* USFS's 2007 Northern Rockies Lynx Management Direction Final Environmental Impact Statement), but those are actions the land management agencies determined they would undertake to do their part to conserve the species, as required under 7(a)(1) of the Act.

Similarly, critical habitat designation has no effect on private actions on private land that do not involve Federal approval or action, and even if there is a Federal nexus, critical habitat does not come with specific restrictions—only the requirement for Federal agencies to consult and avoid destruction or adverse modification of critical habitat (see also our response to comment 26 below). Thus, we did not consider the information provided by the commenter to be credible information that there are meaningful impacts to timber production. We also did not conduct an exclusion analysis for these areas based on economic impacts because the commenters did not provide information on the economic impacts of a designation to consider in an analysis of the exclusion requests listed here.

(25) Comment: Many commenters emphasized the necessity for further research on lynx habitat, including the impacts of climate change, habitat connectivity, and the adaptability of lynx to various stressors. Specific areas of concern include the habitat requirements of snowshoe hares and alternative prey species. Commenters contended that more research is necessary to determine lynx occupancy before eliminating areas of critical habitat, and expressed concern that we were not considering areas of refuge and stepping stone areas between core areas, and that more comprehensive monitoring and surveys must be conducted in connectivity areas. Some commenters questioned the adequacy of the data used to support the proposed critical habitat reductions, suggesting that additional research and consideration of various habitat models are needed to make informed decisions.

Our response: To ensure that our final determination is based on the best available information, we conducted a thorough literature review, as represented in the SSA report (Service 2017, entire) and the SSA report addendum (Service 2023, entire). We also considered any literature published after the SSA report addendum and all information provided to us in public comments. While more research may further enhance our understanding of the species' needs and refine mapping, such information is not currently available. Critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery implementation strategies, HCPs, or other species conservation planning efforts if new information available at the time of these planning efforts calls for a different outcome.

(26) Comment: Several commenters expressed concern that the designation of critical habitat could lead to increased restrictions on land use, potentially affecting agricultural and rural residential properties.

Our response: The designation of critical habitat only affects activities that involve a Federal permit, license, or funding. Federal agencies that carry out, fund, or permit activities (*i.e.,* Federal nexus) on private lands must consider effects to critical habitat. If there is a Federal nexus for a project that may affect lynx or lynx habitats associated with agricultural and rural residential properties, the associated Federal agency must review the actions to determine whether consultation with the Service is necessary to ensure that these activities do not destroy or adversely modify critical habitat. We recognize that there may be private actions on private lands that involve Federal permits or funds, and that may trigger the need for the Federal agency to consult with the Service on those actions; however, there should already be section 7 consultations taking place in these situations to consider impacts to lynx and to support a jeopardy determination in all areas where the species may be present. Since lynx currently occupy all areas we are designating as critical habitat, the added consideration of critical habitat is primarily an administrative effort.

Section 7 consultation is necessary when a Federal agency funds, authorizes, or carries out an action that may affect critical habitat. If adverse effects to the critical habitat are

expected, the Service prepares a biological opinion to determine whether the proposed action results in destruction or adverse modification of the critical habitat, meaning effects that are so substantial that they appreciably diminish the habitat's ability to support the conservation of the species. If destruction or adverse modification is not expected, no additional requirements are required, although the Service may provide voluntary conservation recommendations. Only if the project is expected to result in destruction or adverse modification of the critical habitat would the Service require additional conservation measures in the form of a reasonable and prudent alternative. Based on past section 7 consultations for lynx in designated critical habitat, consultations on private lands are very rare, and none have resulted in a destruction or adverse modification determination.

Due to the very small amount of private land in the critical habitat designation (less than 1 percent), it is unlikely any activities on private lands would destroy or adversely modify critical habitat. We do not anticipate significant restrictions on otherwise lawful activities as a result of these consultations, and we expect little, if any, impacts to private landowners because activities on private lands will only undergo section 7 consultation if they have a Federal nexus.

(27) Comment: A comment from the Montezuma County Board of Commissioners in Colorado requested that the Service exclude all private lands. The commenter explained that private lands make up only 4 percent of the proposed critical habitat area and most are already surrounded by protected lands or ''unlikely'' habitat. Private lands are economically and culturally important to local communities, especially those that do not have large scale commercial recreation. The comment further states that, in most cases, future development is already strictly regulated by local governments for private lands near large-scale commercial recreation.

Our response: Canada lynx critical habitat would only affect projects or activities on private lands where there is a Federal nexus, because section 7 of the Act requires Federal agencies to consult with the Service when there is potential for activities to destroy or adversely modify critical habitat. Absent critical habitat designation, projects and activities with a Federal nexus occurring on private lands within lynx habitat are already subject to section 7 consultation due to the listing status of the Canada lynx DPS, to ensure those projects and activities do not adversely affect the species. In developing the critical habitat rule, the Service considered the potential for critical habitat to result in different project modifications than those typically recommended to avoid adverse effects on the species and found that it would most likely make the same recommendations for project modification with or without the critical habitat designation. Therefore, it is unlikely that the critical habitat designation would result in additional or different project modifications on private lands above and beyond what would already be recommended due to the listing status of the species The economic screening analysis found that the critical habitat designation is unlikely to generate economic costs beyond minor administrative efforts for projects and activities with a Federal nexus that require section 7 consultation (IEc 2024 and 2026, entire). Therefore, we are choosing not to exclude private lands from the critical habitat designation for the Canada lynx DPS.

(28) Comment: Commenters objected to eliminating 88 percent of critical habitat for the Canada lynx in the GYA, which is already under stress from human activities including tourism and roadkill incidents. Commenters also provided citations to historical data regarding lynx occupancy and population estimates in an effort to show the GYA's importance to lynx conservation and contended that the GYA was essential to conservation due to its role in connectivity.

Our response: See our responses to comments 7, 17, and 21, above. In addition, we reviewed all of the information provided during the public comment period, information in our records regarding historical and contemporary lynx use of the GYA and current habitat models. After reviewing the best available scientific information—including historical records, recent surveys, and analyses of lynx movement and habitat use—the Service has determined that no areas within the GYA meet the statutory definition of critical habitat. Lynx use of the GYA has been intermittent, with historical occurrences largely reflecting dispersal events rather than evidence of a persistent population, and no verified lynx detections have been documented in recent survey efforts (MT FWP 2024; J. Wilmot, personal communication, 2026; Service 2023, p. 27). The few verified attempts at reproduction by lynx in the GYA have failed to produce any kittens that survived to adulthood (Squires and Oakleaf 2005; Ivan 2017).Although lynx have occasionally moved through or temporarily resided in parts of the region for a few months to a few years at a time, this limited use does not demonstrate that the area contains the physical or biological features essential to lynx conservation, particularly when considering there has not been verified successful reproduction nor evidence of multiple individuals occupying home ranges to constitute a resident population.

The recovery plan for lynx (Service 2024, entire) also informed our determination; although the plan recognizes that portions of the GYA may function as a potential climate refugium in the future, it does not identify the GYA as necessary for achieving recovery and does not recommend establishing a population there as part of the recovery strategy. While conserving habitat that may provide long-term resilience is valuable, the potential for future suitability does not satisfy the statutory criteria for critical habitat today. Because the GYA neither contains essential features nor plays an essential role in the species' current conservation, the Service is not designating any critical habitat within this area.

(29) Comment: We received several comments related to the Kettle Range in Washington. Commenters argued that this area has a long history of lynx presence and reproduction, and it is essential for connectivity between lynx populations in Washington and Canada. Commenters described the Kettle Range as a core habitat area that should be included in the critical habitat designation. Commenters expressed concern with the Service's assertion that the Kettle Range was unoccupied at the time of listing. They cited evidence from past reports and scientific studies that confirm the presence of lynx in this area, arguing that the Service's conclusions are inconsistent with the best available data.

Our response: The Kettle Range in northeastern Washington historically supported a lynx population (Stinson 2001, pp. 13–14), and habitat models indicate the area provides probable habitat for lynx (Olson et al. 2021, entire). The WLBT identified the Kettle Range as a tier 1 area, meaning it is a relatively large area of contiguous habitat with a high abundance of high probability modeled habitat capable of supporting multiple home ranges (WLBT 2022, p. 23). While the Kettle Range was a traditional lynx stronghold for fur trappers in Washington, the population declined to very few by the 1980s. When critical habitat was designated in 2009 and in 2014, the Service concluded that the Kettle Range

was unoccupied at the time of listing in 2000. We reviewed the information provided by commenters challenging the question of occupancy at the time of listing. The primary evidence supporting occupancy at the time of listing came from materials submitted to the Service by WDFW in response to the 2009 critical habitat designation, which refuted the Service's reported number of lynx detections. However, by 2014, WDFW had changed their position relative to lynx occupancy in the Kettle Range.

The Service's determination that the Kettle Range was unoccupied at the time of listing was upheld in *Wildearth Guardians* v. *U.S. Department of the Interior,* 205 F. Supp. 3d 1176 (D. Mont 2016). Lynx surveys conducted over the past few decades detected no to very few lynx (WDFW 2016, p. 4) until 2021 when the Confederated Tribes of the Colville Reservation began a lynx reintroduction effort in the Kettle Range. Many of the individuals released in the area have traveled north back into Canada, although some have remained in the Kettle Range. The success of the reintroduction program is still being evaluated. The best available information continues to suggest that the Kettle Range was not occupied by a persistent population of lynx at the time of listing in 2000. In addition, the reintroduction efforts are too recent to know if lynx will persist in this area into the future.

Regardless of the current occupancy and reintroduction efforts, the Kettle Range contains some of the PBFs important to lynx, but its spatial configuration and quantity of habitat do not appear to be sufficient to provide for the conservation of lynx as we describe in our response to comment 16, above. We also considered whether the Kettle Range acts as part of a larger network of habitat with areas to the north in Canada and/or to the east and west in Washington. The Kettle Range is substantially more isolated than other habitat areas within the lynx range, and the area is smaller than the criteria we established to meet the definition of critical habitat. There has been no evidence that the Kettle Range supports lynx making east-west movements into or out of the Kettle Range to connect with other populations in the Cascades and Northern Rockies. Further, we did not determine this area is essential to the conservation and recovery of the DPS, as described in our recovery plan (Service 2024, p. 25), though we highlighted it as an area that may contribute to the DPS. Therefore, the Kettle Range was not included as critical habitat for the above reasons.

(30) Comment: Some commenters thought that critical habitat should be designated in Oregon.

Our response: In the SSA report, we state that it seems likely that lynx occurred historically in Oregon only intermittently as dispersers, or as small, naturally ephemeral populations; not as persistent resident breeding populations (Service 2017, pp. 43–44). This assessment is based on a comprehensive, peer-reviewed analysis of verified historical lynx records that was published at the time the DPS was listed (McKelvey et al. 2000a, entire) and on research and monitoring that have occurred since then. We conclude that Oregon has not historically or recently contributed to the persistence and conservation of lynx in the DPS and is unlikely to do so in the future (Service 2017, p. 44). There is no evidence that any areas in Oregon were occupied at the time of listing or that habitats in Oregon are capable of supporting resident breeding populations (Service 2017, p. 44). No areas of Oregon were included in the recovery plan for lynx as being necessary to support recovery goals. Thus, because the state is unoccupied, does not contain habitat capable of supporting resident breeding populations, and is not essential for meeting conservation or recovery goals for the species, we did not designate any areas of Oregon as critical habitat for lynx.

(31) Comment: Commenters requested a comprehensive National Environmental Policy Act (NEPA) analysis to assess the potential impacts of the proposed rule, including a review of economic costs and benefits.

Our response: The Department has determined that this agency action does not require an environmental analysis under NEPA. See *National Environmental Policy Act (42 U.S.C. 4321 et seq.),* below.

(32) Comment: Some commenters were critical of State management plans, particularly those from Washington and Montana, and stated current measures may not adequately protect lynx populations. Some commenters called for a thorough evaluation of existing HCPs to ensure they provide adequate protections for lynx habitats. These commenters suggested that exclusions from the critical habitat designation should only occur if these plans demonstrate stronger conservation measures than currently identified.

Our response: We reviewed the WDNR LHMP and Montana DNRC HCP, as well as monitoring reports from both of those agencies (WDNR 2025, entire; Montana MTDNRC 2025, entire) as well as data showing lynx regularly use lands covered by the State management plans. The plans include conservation measures to conserve the PBFs of habitat to support dense snowshoe hares and to provide a mosaic of structural stages, which provides protection for lynx populations. These plans have been in place since 2006 and 2010, respectively, and the affected State lands continue to be used by resident lynx and contribute to resiliency of Units 3 (Northern Rockies) and 4 (North Cascades). WDNR has recently committed to reviewing its LMHP with the Service, and Montana DNRC meets annually with the Service to review its HCP and discuss any new science that may need to guide their management. These commitments are adequate for the Service to have determined that the plans provide conservation benefits for the species and its habitat, and the benefits of excluding them outweigh the benefits of including them as critical habitat. See Consideration of Impacts Under Section 4(b)(2) of the Act, below, for our full exclusion analysis of these areas.

(33) Comment: Commenters urged the Service to consider historical range and population data when designating critical habitat, arguing that many areas deemed ''unoccupied'' may still be essential for lynx conservation. Many comments referenced historical data on lynx detections in areas not included in critical habitat. Commenters presented evidence of past detections and potential populations to argue for the retention of these areas in the critical habitat designation. Commenters emphasized the necessity for the Service to incorporate the best available science, particularly Thornton and Murray (2024a, entire), which discusses the historical distribution of lynx.

Our response: The Service has examined instances of lynx detections on multiple occasions, including in our review of data submitted with public and agency comments, in the SSA report (Service 2017, entire) and in previous critical habitat rules. In determining the geographic area occupied by the species at the time of listing, we used data providing verified evidence of lynx occurrence. We examined additional information provided in public comments on the proposed rule, including Thornton and Murray (2024a, entire) which implies a broad historical occupancy by lynx and substantial range contractions over the 20th century. This implication is contrary to the information we present in the SSA report (Service 2017, entire) and SSA report addendum (Service 2023, entire). Substantial concerns exist

from other lynx researchers about the Thornton and Murray (2024a, entire) analysis, including several issues that limit the application of the paper to lynx conservation, including model design and validation, extensive extrapolation, ambiguous source data, and plausibility of the results (Ivan et al. 2024, entire). Given the extensive concerns about the Thornton and Murray (2024a, entire) paper (Ivan et al. 2024, entire; also see Thornton and Murray 2024b, entire), we did not rely on it for evidence of past occupancy of lynx, and join Ivan et al. (2024, entire) in disagreeing with Thornton and Murray's characterizations of historical or potential future lynx habitat. Instead, we relied on verified records (as defined in McKelvey et al. (2000, entire) and the species distribution models developed by Olson et al. (2021, entire) and Squires et al. (2024, entire), for indicating where habitat exists that may support resident lynx, which were developed using empirical data from collared lynx as well as verified locations of individual lynx, and thus are more robust and represent the best available science.

We did not include all areas where lynx have historically been detected. Lynx are adept dispersers, as evidenced by genetic connectivity indications (Schwartz et al. 2002, entire) and recent global positioning system (GPS) collar data (Ivan 2012, entire; Squires 2025, unpublished data; Arnold et al. 2025, entire), such that a single verified record does not indicate regular occupancy or habitat suitability. We explain below how we used verified records to determine areas occupied at the time of listing and the contemporary habitat models (Olson et al. 2021, entire; Squires et al. 2024, entire) to indicate where suitable habitat exists to support lynx populations. None of the unoccupied areas, and very little of the other areas suggested by commenters fall within areas identified in the recovery plan (Service 2024, entire). Thus, we did not find reason to designate unoccupied areas nor all areas within the historical range as critical habitat because they are not essential for the conservation of the species.

(34) Comment: Commenters argued that areas like the GYA and Colorado may offer resilience against climate change and should be preserved for lynx conservation. Some commenters called for protections that consider the long-term viability of high-elevation forests, which are expected to retain suitable habitat conditions longer than lower-elevation areas.

Our response: In the SSA Addendum (Service 2023, Chapter 6.1) and recovery plan for lynx (Service 2024, entire), the Service considered that some high elevation areas in Colorado and parts of the GYA may retain suitable temperature and climate conditions for lynx longer than lower elevation portions of the range. These are important considerations to monitor into the future, but they do not warrant critical habitat designation in and of themselves.

We are designating critical habitat in some areas of Colorado where high elevation boreal forests currently contain the physical or biological features (PBFs) essential to lynx conservation, where lynx occupancy at the time of listing was documented, and where the PBFs are present and support a persistent resident reproductive lynx population. In contrast, although the recovery plan recognizes that parts of the GYA may function as a potential future climate refugium, it does not identify the GYA as necessary for achieving recovery, does not recommend establishing a population there, and current data show that the area lacks the PBFs necessary to support resident or persistent lynx populations.

(35) Comment: Commenters called for the Service to clarify our criteria for determining suitable lynx habitat. Commenters also asked for clarity on the specific PBFs required for lynx habitat, and how those PBFs need to be assessed when evaluating project effects to critical habitat.

Our response: Our determination of suitable lynx habitat and thus critical habitat designation was based primarily on lynx SDMs developed by Olson et al. (2021, entire) and Squires et al. (2024, entire) and refined by the WLBT (2022, entire), with modifications as described in *Criteria Used To Identify Critical Habitat.* These SDMs predict areas likely to be used by lynx, based on primarily abiotic factors (temperature, moisture) and broad-scale vegetation data. These models predict areas with environmental conditions that correspond to lynx occurrence, based primarily on abiotic factors such as temperature and moisture and broad-scale vegetation characteristics. The SDMs are necessary to identify large landscapes capable of supporting multiple overlapping lynx home ranges.

However, the models do not depict fine-scale habitat attributes known to influence lynx presence and reproduction—specifically snowshoe hare habitat, denning structures, and snow characteristics—which we identify as PBFs. Because mapped data for these finer-scale PBFs are not available at the spatial resolution of lynx home ranges in the western United States, we used the SDMs as a proxy to identify areas likely capable of supporting those PBFs. Lynx presence strongly correlates with the occurrence of these PBFs, and therefore areas predicted by the SDMs are expected to contain the habitat conditions essential to the species.

The SDMs strongly correlate high-probability lynx habitat with areas of high snowshoe hare densities, including a strong alignment with the Holbrook et al. (2017, entire) model of areas with high snowshoe hare densities in western Montana and with Hodges et al. (2009, entire) finding of overall low snowshoe hare densities across most of Yellowstone National Park. Because snowshoe hare densities are strongly influenced by dynamic stand structure conditions—such as horizontal cover, which can be affected by wildfire, forest thinning, and natural regeneration—these attributes cannot be mapped at a consistent scale suitable for defining critical habitat.

In response to comments requesting a definition of ''deep, fluffy'' snow, we have revised the PBF for clarity and provide here a functional explanation of this PBF. These snow conditions are essential because they confer a competitive advantage to Canada lynx over other carnivores such as bobcats and coyotes. While snow characteristics vary across the species' range, we are not aware of a universally accepted quantitative metric for this feature. However, we qualitatively define it as primarily unconsolidated (fluffy) snow that is sufficiently deep to impede predators with higher foot loads than lynx and that persists for a substantial portion of the year, particularly during winter months when foraging opportunities are most limited. The SDMs incorporate temperature and moisture data that serve as proxies for snowpack characteristics—such as depth, moisture (which affects compaction), and persistence—thus capturing regional variation in snow conditions and predicting areas where lynx are likely to be found.

(36) Comment: Some commenters expressed support for excluding Tribal lands and lands managed by the Montana DNRC and Washington DNR from lynx critical habitat designation. They argued that existing management plans and conservation initiatives, such as the Montana DNRC HCP, already provide adequate protection for lynx and their habitats. Other commenters expressed concerns about excluding state lands and urged the Service to carefully evaluate whether those plans provide adequate protection for the species and its habitat.

Our response: We evaluated the request and have excluded all Tribal lands and the Montana DNRC and Washington DNR lands from the final critical habitat designation, as explained below in the section titled Consideration of Impacts Under Section 4(b)(2) of the Act.

(37) Comment: A timber company requested exclusions for their northern forestlands around Richards Mountain, citing their management under the Native Fish HCP and adherence to Sustainable Forestry Initiative (SFI) standards, which promote sustainable practices and habitat protection.

Our response: We evaluated the request and have excluded those lands from the final critical habitat designation, as explained below in the section titled Consideration of Impacts Under Section 4(b)(2) of the Act.

(38) Comment: Commenters commended the Service for using advanced habitat modeling to refine critical habitat boundaries, emphasizing the importance of focusing on tier 1 habitats (as documented in WLBT 2022, entire) that are crucial for lynx occupancy and reproductive success.

Our response: The recent habitat modeling has been foundational to this critical habitat revision (Olson et al. 2021, entire; Squires et al. 2024, entire), along with the WLBT (2022, entire) identification of key habitat areas from the models and the tiered approach to model outputs by evaluating the extent and proportion of modeled high-quality habitat.

(39) Comment: A timber company urged the Service to conduct a cost-benefit analysis regarding the designation of Federal lands as critical habitat, arguing that the economic costs may outweigh the benefits of habitat protection. They stressed the importance of maintaining non-wilderness Federal forests for timber supply and regional economic health.

Our response: As stated in our response to comment 12, above, we developed an IEM considering the probable incremental economic impacts that may result from this designation of critical habitat. The information contained in our IEM was then used to develop a screening analysis of the probable economic effects of the designation of critical habitat for the Canada lynx DPS (IEc 2024 and 2026, entire). The analysis found that this critical habitat rule is unlikely to meet the threshold for an economically significant rule as defined in section 3(f)(1) of Executive Order (E.O.) 12866. Designating occupied areas as critical habitat typically causes little, if any, incremental impacts above and beyond the impacts of listing the species, as is the case with lynx. The incremental effects of revising critical habitat for lynx are likely to be limited to changes in administrative effort to evaluate the potential for adverse modification of Canada lynx critical habitat. The economic screening analysis also considers the potential benefits of designating critical habitat. According to the analysis, additional efforts to conserve lynx are not predicted. As the designation is unlikely to lead to additional or different project modifications and recommendations, no ancillary economic benefits are anticipated (see *Exclusions Based on Economic Impacts,* below).

Under the Act, critical habitat serves an important conservation function by identifying areas essential for the recovery of listed species and ensuring that federal actions do not destroy or adversely modify those areas (16 U.S.C. 1536). This designation for lynx provides several non-economic benefits. Critical habitat helps guide Federal agencies in project planning and consultation, ensuring that habitat features vital for species survival and recovery—such as within-population connectivity and potential foraging areas—are maintained. Identifying critical habitat also raises awareness of the species' conservation needs and fosters partnerships among Federal, state, tribal, and private stakeholders. This can lead to voluntary conservation measures and improved land-use planning, and it can add value to areas for conservation initiatives. For example, some conservation organizations seek to invest in conservation easements or acquisitions in areas identified as critical to the conservation of listed species. Other landowners may voluntarily develop habitat management plans or HCPs in designated critical habitat. This revised designation helps focus conservation efforts on areas most important for the species.

(40) Comment: Various commenters requested that ski area lands not be designated as lynx critical habitat, asserting that these areas do not represent high-quality lynx habitat and have been managed for recreation for decades. One commenter representing the Colorado ski industry requested a comprehensive NEPA process to analyze the impacts of the proposed designation, particularly regarding ski areas in Colorado, which they believe should not be classified as critical habitat due to their long-standing management for recreational use.

Our response: We examined the science regarding ski areas, and particularly relied upon the Olson et al. (2018, entire) study from Colorado regarding lynx use of developed ski areas versus areas where dispersed recreation occurs. The study found that lynx appeared to avoid high-intensity developed ski resorts, especially when recreation was most intense; however, lynx did not exhibit strong negative responses to dispersed recreation and used areas in which little to no recreation occurred. Because of that research, we determined it was not appropriate to include developed ski runs and lifts and associated infrastructure as critical habitat, as specified in the section *Criteria Used To Identify Critical Habitat,* below. However, some ski areas have permit areas or boundaries that extend beyond the existing developed footprint, where existing recreation is not resulting in lynx avoidance. These areas still provide habitat for lynx.

The Department has determined that this agency action does not require an environmental analysis under NEPA. See *National Environmental Policy Act (42 U.S.C. 4321 et seq.),* below.

(41) Comment: Commenters argued that Colorado (Unit 6, Southern Rockies) does not meet the Act's requirements for critical habitat designation, noting that much of it was unoccupied when the lynx DPS was listed and questioning its essentiality for lynx conservation.

Our response: When the Canada lynx DPS was listed in 2000, the State of Colorado had recently begun a lynx reintroduction effort. As such, some areas of Colorado that overlap with Unit 6 were occupied when the DPS was listed, as individual lynx were exploring the new area. Over the past 25 years, lynx have settled into certain areas that are regularly occupied and where the habitat has proven to support a persistent breeding population. In the recovery plan, we identified Unit 6, particularly the focal areas, as being essential for recovery (Service 2024, p. 22), and these areas meet the definition of critical habitat. The areas we are designating as critical habitat are a subset of the focal areas, are centered around the concentrated areas of likely habitat, and are large enough to support population goals outlined in the recovery plan. Other areas of potential lynx habitat in Colorado may be important for supporting connectivity, exploratory movements, or occasional occupancy, but do not meet the definition of critical habitat in this rule.

(42) Comment: Citing economic implications and lack of habitat, a mining company requested the exclusion from critical habitat designation of their private lands in

Colorado related to the Climax and Henderson mines.

Our response: In determining our response to this request, we first considered the commenter's claim that the areas associated with the mines do not provide habitat for lynx. In evaluating the areas using aerial imagery and lynx habitat maps, we observed some areas have been developed and no vegetation exists (*i.e.,* mine pits and associated infrastructure). These developed areas are already excluded from critical habitat by text in the rule. However, in other portions of the properties, forested vegetation exists, and some is mapped as potential habitat for lynx, and/or it may provide habitat to facilitate within-unit permeability and connectivity and there has been evidence of lynx use of forested areas adjacent to the mines in recent years (Baigas et al. 2017, p. 206). Thus, there is biological value in parts of the lands in question. Next, we evaluated whether the proponent of those exclusions presented credible information of a meaningful impact that supports the benefits of excluding these areas outweighing the benefits of including these areas. We found that the request did not provide credible information and the asserted costs and economic impacts are based on a misunderstanding that critical habitat designation restricts activities on private lands that would impede any future development or activities associated with the mines, which it does not.

As described in the economic screening analysis (IEc 2024 and 2026, entire), one of the purposes of the assessment is to provide the Service with information necessary to inform its decision making as part of the section 4(b)(2) exclusion process. The economic screening analysis finds that critical habitat designation is unlikely to generate economic costs beyond minor administrative efforts for projects and activities with a Federal nexus that require section 7 consultation. If future actions on the mine properties are being authorized, funded, or carried out by a Federal agency, such as the surrounding National Forests, the Federal agency must consider the impacts to designated critical habitat and ensure the action does not destroy or adversely modify the critical habitat. We encourage private landowners to consider conservation measures that may retain the value of the habitat for lynx when developing future projects.

(43) Comment: Some commenters opposed the exclusion of Tribal and State lands from critical habitat protections. Commenters advocated for partnerships with Tribal and State leaders to co-manage lands that are essential for lynx habitat rather than excluding them.

Our response: The Secretary may exclude any area from critical habitat if the benefits of exclusion outweigh those of inclusion, so long as exclusion will not result in extinction of the species concerned. In this rule, we have excluded some Tribal and State lands from the final critical habitat designation. These exclusions represent existing partnerships and management objectives that benefit the species. See Consideration of Impacts Under Section 4(b)(2) of the Act, below, for further explanation of why exclusion of these areas outweighs the benefits of including them in critical habitat.

(44) Comment: Several commenters expressed concerns about how critical habitat designation could curtail forest management, timber production, and fuels reduction activities. Others worried that the absence of critical habitat designation could lead to increased logging or thinning in lynx habitat.

Our response: A critical habitat designation does not by itself impose specific restrictions or forest management requirements unless a proposed action would result in the destruction or adverse modification (DAM) of the critical habitat. If the Service determines that a proposed action would cause DAM, the Service must develop a Reasonable and Prudent Alternative (RPA) to the proposed action. The RPA would include additional conservation measures necessary to avoid DAM.

Of the 157 formal consultations reviewed from 2018 through 2024, most of which were forest management and fuels reduction project, none resulted in a DAM determination. In fact, since critical habitat was first designated for lynx in 2006, no proposed action has resulted in DAM or required an RPA. When evaluating Forest Service and BLM land management plans that incorporate the Lynx Conservation Assessment and Strategy (LCAS) and/or have been revised to include Northern Rockies Lynx Management Direction (NRLMD) or Southern Rockies Lynx Amendment (SRLA) standards, guidelines, and objectives, the Service has consistently determined in both plan-level and project-level biological opinions that these conservation measures are sufficient to avoid jeopardy to the species and DAM where critical habitat is designated. Most of these existing plans include allowances for timber harvest and fuels reduction within lynx habitat in certain structural stages and allow for treatment of all structural stages within the wildland urban interface. Forest management and fuel reduction projects proposed under current land management plan direction have incorporated adequate restrictions to avoid jeopardy to the species, under current conditions. Additional considerations for critical habitat have provided redundancy without imposing further restrictions.

The effects of timber harvest depend on the size, scale, and spatial arrangement of treatments. When used judiciously and at scales biologically relevant to lynx, logging and other forest management tools are an important part of managing critical habitat. The Lynx Conservation Assessment and Strategy (ILBT 2013) recommends using fire and mechanical treatments to maintain or create a mosaic of successional stages within lynx habitat and recommends focusing treatments in areas that have the potential to improve snowshoe hare habitat by developing dense horizontal cover. Existing forest management plans, such as the NRLMD (USFS 2007) and SRLA (USFS 2008), already provide sideboards for timber harvest in lynx habitat, regardless of critical habitat designation. We anticipate that this designation will not impose additional restrictions beyond those already in place to avoid jeopardy to the species.

Lynx habitat conservation can include forest management, including timber harvest, as a tool for creating and maintaining valuable structural stages to support foraging, denning, and other needs. The LCAS includes a conservation measure for vegetation management in lynx habitat that provides a ''mosaic that includes dense early-successional coniferous and mixed-coniferous-deciduous stands, along with a component of mature multi-story coniferous stands to produce the desired snowshoe hare density'' at spatial scales approximately the size of female lynx home ranges (ILBT 2013, p. 90–91). The WLBT Framework synthesized additional science that was published since the LCAS and included recommendations for vegetation mosaics based on published scientific literature (*e.g.,* Kosterman et al. 2018, Holbrook et al. 2017 and 2019). Such a mosaic can be created by using such tools as prescribed fire, mechanical vegetation treatments, and natural disturbances, among others. The LCAS and WLBT documents are useful tools for guiding conservation measures within lynx critical habitat and informing effects analyses in Section 7 consultations. However, we also acknowledge that the WLBT Framework is not a comprehensive lynx conservation strategy and does not

incorporate all vegetation designations needed for applied forest management, wildfire risk reduction, and lynx conservation decision-making. We encourage action agencies, landowners, and others to consider these recommendations, alongside other relevant science on lynx, forest management and fire risk, and other best available vegetation information, when developing projects and management strategies within lynx critical habitat.

Critical Habitat

Background

Critical habitat is defined in section 3(5)(A) of the Act as:

(1) The specific areas within the geographical area occupied by the species, at the time it is listed in accordance with the Act, on which are found those physical or biological features.

(a) Essential to the conservation of the species, and

(b) Which may require special management considerations or protection; and

(2) Specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Our regulations at 50 CFR 424.02 define the geographical area occupied by the species as an area that may generally be delineated around species' occurrences, as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals).

Conservation, as defined under section 3 of the Act, means to use and the use of all methods and procedures that are necessary to bring an endangered or threatened species to the point at which the measures provided pursuant to the Act are no longer necessary. Such methods and procedures include, but are not limited to, all activities associated with scientific resources management such as research, census, law enforcement, habitat acquisition and maintenance, propagation, live trapping, and transplantation, and, in the extraordinary case where population pressures within a given ecosystem cannot be otherwise relieved, may include regulated taking.

Critical habitat receives protection under section 7 of the Act through the requirement that each Federal action agency ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to result in the destruction or adverse modification of designated critical habitat. The designation of critical habitat does not affect land ownership or establish a refuge, wilderness, reserve, preserve, or other conservation area. Such designation also does not allow the government or public to access private lands. Such designation does not require implementation of restoration, recovery, or enhancement measures by non-Federal landowners. Rather, designation requires that, where a landowner requests Federal agency funding or authorization for an action that may affect an area designated as critical habitat, the Federal agency consult with the Service under section 7(a)(2) of the Act. If the action may affect the listed species itself (such as for occupied critical habitat), the Federal agency would have already been required to consult with the Service even absent the designation because of the requirement to ensure that the action is not likely to jeopardize the continued existence of the species. Even if the Service were to conclude after consultation that the proposed activity is likely to result in destruction or adverse modification of the critical habitat, the Federal action agency and the landowner are not required to abandon the proposed activity, or to restore or recover the species; instead, they must implement ''reasonable and prudent alternatives'' to avoid destruction or adverse modification of critical habitat.

Under the first prong of the Act's definition of critical habitat, areas within the geographical area occupied by the species at the time it was listed are included in a critical habitat designation if they contain physical or biological features (1) which are essential to the conservation of the species and (2) which may require special management considerations or protection. For these areas, critical habitat designations identify, to the extent known using the best scientific data available, those physical or biological features that are essential to the conservation of the species (such as space, food, cover, and protected habitat).

Under the second prong of the Act's definition of critical habitat, we can designate critical habitat in areas outside the geographical area occupied by the species at the time it is listed, upon a determination that such areas are essential for the conservation of the species.

Section 4(b)(2) of the Act requires that we designate critical habitat on the basis of the best scientific data available. Further, our Policy on Information Standards Under the Endangered Species Act (published in the **Federal Register** on July 1, 1994 (59 FR 34271)), the Information Quality Act (section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (Pub. L. 106–554; H.R. 5658)), and our associated Information Quality Guidelines provide criteria, establish procedures, and provide guidance to ensure that our decisions are based on the best scientific data available. They require our biologists, to the extent consistent with the Act and with the use of the best scientific data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat.

When we are determining which areas should be designated as critical habitat, our primary source of information is generally the information compiled in the SSA report and information developed during the listing process for the species. Additional information sources may include any generalized conservation strategy, criteria, or outline that may have been developed for the species; the recovery plan for the species; articles in peer-reviewed journals; conservation plans developed by States and counties; scientific status surveys and studies; biological assessments; other unpublished materials; or experts' opinions or personal knowledge.

Habitat is dynamic, and species may move from one area to another over time. We recognize that critical habitat designated at a particular point in time may not include all of the habitat areas that we may later determine are necessary for the recovery of the species. For these reasons, a critical habitat designation does not signal that habitat outside the designated area is unimportant or may not be needed for recovery of the species. Areas that are important to the conservation of the species, both inside and outside the critical habitat designation, will continue to be subject to: (1) conservation actions implemented under section 7(a)(1) of the Act; (2) regulatory protections afforded by the requirement in section 7(a)(2) of the Act for Federal agencies to ensure their actions are not likely to jeopardize the continued existence of any endangered or threatened species; and (3) the prohibitions found in the 4(d) rule. Federally funded or permitted projects affecting listed species outside their designated critical habitat areas may

still result in jeopardy findings in some cases. These protections and conservation tools will continue to contribute to recovery of the species. Similarly, critical habitat designations made on the basis of the best scientific data available at the time of designation will not control the direction and substance of future recovery plans, HCPs, or other species conservation planning efforts if new information available at the time of those planning efforts calls for a different outcome.

Physical or Biological Features Essential to the Conservation of the Species

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12(b), in determining which areas we will designate as critical habitat from within the geographical area occupied by the species at the time of listing, we consider the physical or biological features that are essential to the conservation of the species and which may require special management considerations or protection. The regulations at 50 CFR 424.02 define ''physical or biological features essential to the conservation of the species'' as the features that occur in specific areas and that are essential to support the life-history needs of the species, including, but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity. For example, physical features essential to the conservation of the species might include gravel of a particular size required for spawning, alkaline soil for seed germination, protective cover for migration, or susceptibility to flooding or fire that maintains necessary early-successional habitat characteristics. Biological features might include prey species, forage grasses, specific kinds or ages of trees for roosting or nesting, symbiotic fungi, or absence of a particular level of nonnative species consistent with conservation needs of the listed species. The features may also be combinations of habitat characteristics and may encompass the relationship between characteristics or the necessary amount of a characteristic essential to support the life history of the species.

In considering whether features are essential to the conservation of the species, we may consider an appropriate quality, quantity, and spatial and temporal arrangement of habitat characteristics in the context of the life-history needs, condition, and status of the species. These characteristics include, but are not limited to, space for individual and population growth and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, or rearing (or development) of offspring; and habitats that are protected from disturbance.

Species Needs, Habitat, Ecological Requirements

A comprehensive review of the species description, biology, taxonomy, genetics, life history, ecology, distribution, species needs, habitat, and ecological requirements of the Canada lynx DPS is presented in the SSA report (Service 2017, entire) and SSA report addendum (Service 2023, entire). Here we present a summary of information relevant to the PBFs essential to the conservation of lynx.

The Canada lynx is a North American wild cat that is most strongly associated with northern-latitude boreal forests (*e.g.,* taiga) of Canada and Alaska (McCord and Cardoza 1982, p. 729; Agee 2000, pp. 39–41; Aubry et al. 2000, pp. 373–374; Mowat et al. 2000, p. 272). The southern peripheries of the boreal forest and lynx range extend into the northern contiguous United States. The lynx is a medium-sized cat with long legs and large, well-furred paws, which make it well-adapted for traversing and hunting in deep, unconsolidated snow. Its low foot-loading (weight per surface area of foot) is thought to provide a competitive advantage (Buskirk et al. 2000a, p. 90; Buskirk et al. 2000b, p. 400; ILBT 2013, pp. 26, 36, 81) over other terrestrial predators of snowshoe hare, the lynx's primary prey.

Lynx rely heavily on snowshoe hares to support survival, reproduction, recruitment, and therefore, population persistence (Ruggiero et al. 2000a, p. 110; Mowat et al. 2000, p. 270; Steury and Murray 2004, pp. 128, 136–138; Service 2005, p. 2; ILBT 2013, p. 30–34; 79 FR 54782, September 12, 2014). All aspects of lynx life history are inextricably tied to the snowshoe hare, which comprises most of the lynx diet throughout its range (Nellis et al. 1972, pp. 323–325; Brand et al. 1976, pp. 422–425; Koehler and Aubry 1994, pp. 75, 85; Apps 2000, pp. 358–359, 363; Aubry et al. 2000, pp. 375–378; Mowat et al. 2000, pp. 267–268), including the DPS (Koehler 1990, p. 848; von Kienast 2003, pp. 37–38; ; Moen 2009, p. 7; Vashon et al. 2012, p. 11; Olson 2015, pp. 60–69; Ivan and Shenk 2016, p. 1053). Being highly specialized hare predators, lynx require landscapes that consistently support relatively high hare densities (McCord and Cardoza 1982, p. 744; Quinn and Parker 1987, pp. 684–685; Aubry et al. 2000, pp. 375–378).

The best available science, including recent research in the lynx DPS' range, suggest that landscape-level snowshoe hare densities that are consistently greater than 0.2 hares/acre (0.5 hares/hectare) and have favorable snow conditions, that is, deep and persistent unconsolidated (''fluffy'') snow, for about 4 months per year are needed to support lynx occupancy, reproduction, and recruitment (Hoving et al. 2005, p. 749; Gonzalez et al. 2007, p. 7; Squires and Ruggiero 2007, pp. 313–314; Moenand Windels 2012, pp. 352–354; Simons-Legaard et al. 2013, pp. 567, 574–575). At the southern periphery of lynx distribution, some places, including within the range of the DPS, seem to be at minimum thresholds to meet these requirements or do so inconsistently.

Lynx and snowshoe hares are strongly associated with moist boreal forests, where winters are long, cold, and snowy (Bittner and Rongstad 1982, p. 154; McCord and Cardoza 1982, p. 743; Quinn and Parker 1987, pp. 684–685; Agee 2000, pp. 39–47; Aubry et al. 2000, pp. 373–382; Hodges 2000a, pp. 183–191; Hodges 2000b, pp. 136–140; McKelvey et al. 2000a, pp. 211–232). The predominant vegetation of boreal forest is conifer trees, primarily species of spruce and fir (*Picea* spp. and *Abies* spp., respectively; Elliot-Fisk 1988, pp. 34–35, 37–42). Snowshoe hares feed on conifers, deciduous trees, and shrubs (Hodges 2000a, pp. 181–183) and are most abundant in forests with dense understories that provide forage, cover to escape from predators, and protection during extreme weather (Wolfe et al. 1982, pp. 665–669; Litvaitis et al. 1985, pp. 869–872; Hodges 2000a, pp. 183–195; Hodges 2000b, pp. 136–140). Lynx population dynamics, survival, and reproduction are closely tied to snowshoe hare availability, making snowshoe hare habitat the primary component of lynx habitat.

Lynx distribution and population persistence are also influenced by snow conditions (Peers et al. 2012, pp. 4–9). The species is generally restricted to areas that receive deep and persistent unconsolidated snow, which is thought to allow lynx to outcompete other terrestrial hare predators that are less efficient in such conditions because of

their proportionately longer limbs and very large feet (McCord and Cardoza 1982, pp. 748–749; Quinn and Parker 1987, p. 684; Buskirk et al. 2000a, pp. 89–94; Buskirk et al. 2000b, pp. 400–401; Ruggiero et al. 2000b, pp. 445–449; Hoving 2001, p. 75; Hoving et al. 2005, pp. 744–749; Carroll 2007, entire; Gonzalez et al. 2007, entire; ILBT 2013, pp. 25–26; 79 FR 54782). The lynx's physical adaptations (*i.e.,* long legs and large, well-furred paws) are thought to provide the lynx a seasonal advantage over potential terrestrial competitors and predators, which generally have higher foot-loading, causing them to sink into the snow more than the lynx (McCord and Cardoza 1982, p. 748; Murray and Boutin 1991, entire; Buskirk et al. 2000a, pp. 86–95; Ruediger et al. 2000, pp. 1–11; Ruggiero et al. 2000b, pp. 445, 450).

Buskirk et al. (2000a, entire) described potential exploitation (for food) and interference (avoidance) competition between lynx and other terrestrial and avian predators of hares, several of which have also been documented to prey on lynx. Coyotes (*Canis latrans*) were thought most likely to exert local or regionally important exploitation competition impacts to lynx (Buskirk et al. 2000a, p. 89); however, subsequent research showed an insignificant amount of competition for hares between lynx and coyotes in winter (Kolbe et al. 2007, p. 1416; Dowd and Gese 2012, entire; Guillaumet et al. 2015, pp. 141–144), and evidence of competition with, and displacement of lynx by, bobcats (*Lynx rufus*) (Robinson 2006, pp. 120–129; Peers et al. 2012, pp. 4–9; Peers et al. 2013, entire; Sirén et al. 2021, p. 1768; Sirén et al. 2022, pp. 761–762). Coyotes, bobcats, and cougars (*Puma concolor;* also, mountain lion) are capable of imparting interference competition (*i.e.,* aggressive encounters) effects on lynx (Buskirk et al. 2000a, p. 89; Scully et al. 2018, pp. 765–766; King et al. 2020, p. 338). Interference would most likely occur during summer but could also occur during winter in areas lacking deep, unconsolidated snow (ILBT 2013, p. 36).

Individual lynx require large landscapes with hare densities that maximize their chances of (1) surviving from birth to independence, (2) establishing and maintaining a home range, (3) breeding successfully, and (4) contributing genes to future generations (Breitenmoser et al. 1993, p. 552). These landscapes also must provide conditions that allow lynx to compete sufficiently for hares and minimize the likelihood of predation and other sources of lynx mortality.

Lynx populations need large (thousands of km^2) boreal forest landscapes with hare densities capable of supporting (1) multiple lynx home ranges, (2) reproduction and recruitment most years, and (3) at least some survival, even during years when hare numbers are low. Lynx populations estimated at fewer than 25 individuals or occupying habitat areas too small to support at least 25 individual lynx (less than 483 mi^2 (1,250 km^2)) are considered ''not resilient/functionally extirpated'' because populations that small are unlikely to persist over time (Service 2023, pp. 50–51). Small populations are more vulnerable to catastrophic events, such as disease outbreaks or large wildfires that can affect multiple home ranges. At the periphery of the species' range, source-sink dynamics within a metapopulation structure mean that some populations may be naturally ephemeral (Service 2023, p. 58): smaller populations or individuals may occupy limited habitat for a time, then disappear, a pattern observed within the lynx DPS. While the overall contribution of these smaller habitat areas to metapopulation dynamics is not fully understood, they may play important roles in dispersal, range expansion, and demographic connectivity. However, core areas for the species are those with enough high-capability habitat to support resilient populations. Habitat patches of at least 483 mi^2 (1,250 km^2) are critical for providing the redundancy, resiliency, and representation needed for recovery across the DPS (Service 2024, p. 14).

Large boreal forest landscapes also must have snow conditions (consistency, depth, and duration) that allow lynx to outcompete other terrestrial hare predators. To persist, lynx populations must exhibit recruitment and immigration rates that equal or exceed mortality and emigration rates on average over the long term. Immigration may be particularly important to the persistence and stability of lynx populations at the southern periphery of the range, including those within the DPS, where hare densities are generally low and hare populations are either non-cyclic or weakly-cyclic compared to northern populations. Low hare densities reduce the likelihood that lynx recruitment will consistently equal or exceed mortality. Non-cyclic or weakly-cyclic hare populations are unlikely to allow the rapid lynx population recovery observed in northern lynx populations outside of the DPS when hare numbers increase dramatically after cyclic population crashes. Conversely, more stable hare populations, even at lower landscape-level densities, likely provide stability (*i.e.,* prevent periodic steep declines) among lynx populations on the periphery of the DPS' range and southern Canada. Although immigration rates for DPS populations are unknown, as is the rate and periodicity of immigration needed to provide demographic stability among them, connectivity with, and immigration from, lynx populations in Canada are believed to be important to the persistence of lynx populations in the DPS (McKelvey et al. 2000a, pp. 232–242; McKelvey et al. 2000b, pp. 32–34; Schwartz et al. 2002, entire; Service 2005, p. 2; ILBT 2013, pp. 34, 42, 47, 54, 60, 65; Squires et al. 2013, p. 187; 79 FR 54782). Genetic data indicate that north-south movement renders the contiguous U.S. and Canada populations panmictic (Schwartz et al. 2002, entire), indicating a strong propensity for lynx to make north-south movements; however, telemetry data from marked individuals to date exhibit few east-west dispersals between populations (Olson et al. 2021, p. 1669; Ivan 2012 and 2017, entire).

Lynx are highly vagile, capable of moving long distances (several thousand km) over varied terrain and through a wide range of habitats, and they are even capable swimmers. As such, there are likely few complete barriers to dispersal or exploratory movements (Arnold et al. 2025, p. 1577; Ivan 2012, entire; Squires 2025, unpublished data), which genetic research supports, given high gene flow (Service 2017, p. 24–25, internal citations omitted). Within home ranges, however, residents are less tolerant of poor-quality habitats and rugged terrain. Natural features such as rivers and rocky peaks, as well as anthropogenic features such as highways and railways and residential developments, may be navigable but they create more challenges for individuals by increasing exposure, mortality risk, and energetic requirements (Service 2017, p. 100–102). Changes to vegetation structure can influence lynx movements within home ranges; in Montana, fragmentation from forest thinning decreased the probability of lynx movements across the forested landscape (Squires et al. 2013, p. 192). Lynx in the Northern Rockies also seem sensitive to changes in forest structure and avoid large forest openings like recent clearcuts and thinned areas, particularly in winter (Squires et al. 2010, p. 1654). Kosterman et al. (2018, entire) suggested that mature forest in a connected configuration creates an energetically efficient context for Canada lynx to

acquire snowshoe hares and successfully reproduce. While no single feature typically prevents movement outright, the accumulation of natural and human-generated barriers can fragment boreal forest habitat within an individual's home range. This fragmentation can raise energetic costs, reduce access to high-quality foraging and denning areas, and thereby affect overall fitness, reproductive success, and survival.

Lynx dens have been documented in both mature and younger boreal forest stands and the amount of structure (*e.g.,* downed trees; large, woody debris; tip-up mounds) seems to be more important than the age of the forest stand for lynx denning habitat (Service 2017, p. 29, internal citations omitted). Denning habitat is not thought to be a limiting factor for lynx in the DPS, given the abundance of denning structures in dense boreal forest stands. Management actions that maintain coarse woody debris in areas occupied by lynx, such as leaving large-diameter logs in piled configurations or by retaining patches of dense burned forests that will windthrow over time, may provide future den sites as managed or burned stands regenerate (Squires et al. 2008, p. 1505).

The greatest challenges to the long-term viability of the DPS include projected warming and drought-related impacts (*e.g.,* loss of temperature, snow, and vegetation conditions supportive of lynx populations) and increases in the size, frequency, and severity of wildfires and vegetation-damaging insect outbreaks in lynx habitats. Modeled future warming is projected to cause a gradual but steady decline in lynx habitat distribution and quality of all focal areas and thus, a reduction in their ability to support persistent breeding populations in the future (Service 2023, p. 5). Large forest disturbances, such as wildfire, may influence how a landscape can produce sufficient hare densities, with some areas taking long periods of time for forest recovery, while other areas respond within a few decades to provide high-quality lynx foraging and denning habitat. The pace and scale of wildfires and other natural and anthropogenic disturbances within the SSA units in the future will strongly influence the DPS. Strategic forest management and fuels reduction within lynx critical habitat can ensure a mosaic of lynx habitat with abundant foraging for individuals while also reducing the risks of catastrophic wildfire that can negatively affect lynx as well as human infrastructure in the wildland urban interface. Thus, a special management consideration for lynx critical habitat should include updated strategies for incorporating the best available scientific information into management plans that manage proactively for desired mosaics and fuels reduction at spatial scales relevant to individual lynx within the critical habitat units.

Summary of Essential Physical or Biological Features

We derive the specific physical or biological features essential to the conservation of Canada lynx from studies of the species' habitat, ecology, and life history as described below. Additional information can be found in the 2014 final critical habitat rule (79 FR 54782, September 12, 2014), the 2017 SSA report (Service 2017, entire), and the SSA report addendum (Service 2023, entire); available on *https://www.regulations.gov* under Docket No. FWS–R6–ES–2024–0142.

We have determined that the following PBFs are essential to the conservation of the Canada lynx DPS:

(1) Presence of snowshoe hares that support lynx residency and reproduction over time within a mosaic of boreal/subalpine forest structural stages that includes snowshoe hare habitat with dense horizontal cover at ground- or snow-level.

(2) Winter conditions that provide and maintain deep persistent unconsolidated (fluffy) snow.

(3) Presence of denning structures, including downed trees, root wads, and accumulations of coarse woody debris.

(4) Habitat types, such as dry forest or meadows, that are between boreal forest patches and are likely to be used by lynx traveling between those patches within and among home ranges.

(5) Landscapes with suitable habitat large enough (483 mi^2 (greater than or equal to 1,250 km^2)) to support breeding populations.

The PBFs identified above are those that are known to be important to lynx conservation based on decades of lynx research (as summarized in Service 2017, entire). The PBFs work in concert with one another, and must be present in the right amounts and juxtaposition to be able to support lynx in their various functions. We focused our identification of critical habitat on those areas where the PBFs are likely to occur in enough quantity and proximity to support persistent, breeding populations of lynx. The scientific literature does not confer precisely what quantities and spatial arrangements of the physical and biological features are needed to support lynx populations throughout the range of the DPS. However, we find that evidence of breeding populations is the best way to verify that the physical and biological features essential to lynx are present in sufficient quantity and spatial configuration to meet the needs of the species.

Because mapping has not been conducted to assess each of the PBFs at the scale of the lynx range in the western United States, we chose to use a proxy to identify areas with the PBFs that can support persistent resident breeding populations. We found the best proxy for identifying those PBFs was using the SDMs created by Olson et al. (2021, entire) and Squires et al. (2024, entire), and refined by the WLBT (2022, entire). The SDMs were based on GPS locations from collared lynx in reproductive populations in Montana, Washington, Wyoming, and Colorado, respectively. This proxy was appropriate because research has shown that lynx employ multi-scale selection of habitats by first choosing landscapes where the PBFs are abundant and then choosing home ranges within those larger landscapes that have appropriate amounts of snow depth, snowshoe hare occupancy, and boreal forest (Holbrook et al. 2017, entire). Within home ranges, lynx preferentially use stands with certain structural conditions that support high hare densities. The SDMs predict lynx habitat probability based on primarily abiotic factors (*e.g.,* temperature and moisture) as well as forest productivity. It is highly probable these three covariates are proxies for snow amount, duration, density, and consistency that give lynx a sufficiently long seasonal competitive advantage in hunting their primary prey species, snowshoe hares, over other terrestrial hare predators (*e.g.,* bobcats and coyotes). These variables also likely influence hare populations and density, and, by extension, lynx, which are indirectly reliant on the environmental conditions that favor hares (Service 2023, p. 61). The attributes that explained the lynx locations were then extrapolated across the western United States to identify potential habitats in all areas, regardless of current vegetation structure (*i.e.,* regardless of whether forests are dense or if they have been thinned) and regardless of whether lynx have been detected there in recent years. In other words, by using models that were built using recorded lynx movements to tell us where potential habitat occurs, we are considering all the PBFs that are identified above at the same time to identify areas that are essential to the conservation of lynx.

For individual project-level analysis of effects to critical habitat, it is most appropriate to assess effects to the PBFs themselves rather than the SDMs, which were tools used to help identify the

areas to designate as critical habitat. Assessing the PBF related to snowshoe hares and their habitat is best conducted at the site or project-specific scale, where regionally specific information on horizontal cover and vegetation conditions can be used to evaluate the condition of the PBF at the time a project is proposed. Abundant information is available to help correlate snowshoe hare relative abundance with vegetation variables that describe stand-level characteristics, which are often more reasonable to measure and describe. Definitions of ''dense horizontal cover'' may vary by region and by season. Similarly, we do not expect project proponents to have to measure or quantify snow conditions when evaluating effects to the critical habitat; rather, project evaluations should consider any actions that may affect snow compaction or overall quantity and discuss effects to the PBF as such. The presence of denning structures is not thought to be a limiting factor for lynx in the DPS, and dens have been documented in both mature and younger forest stands. It is not necessary for project-level evaluations to quantify denning sites, but project development should ensure that potential denning structures (*e.g.,* downed trees, woody debris, tip-up mounds) are retained and/or recruited such that they continue to be present and distributed across multiple areas at the scale of a female home range. The PBF related to permeable landscapes is also best suited to qualitative versus quantitative evaluations that consider any barriers or disruptions to connectivity within or between home ranges within the critical habitat polygons. Widescale habitat probability models and/or SDMs are necessary for identifying and assessing the PBF regarding landscapes with suitable habitat to support breeding populations. We do not anticipate individual projects, such as forest management or small development projects, to impact this PBF, as it is mostly driven by bioclimatic features at broad spatial scales. Programmatic plans (such as land or resource management plans) are likely the best level for assessing effects to this PBF.

We note here that the 2014 critical habitat rule included a discussion of primary constituent elements (PCEs) essential to the conservation of lynx (79 FR 54782 at 54811, September 12, 2014). The Service no longer uses PCEs to define critical habitat; rather, we now evaluate and describe the PBFs that are essential to the conservation of the species in accordance with the definitions in the Act and our implementing regulations at 50 CFR 424.12(b). We have identified the PBFs in this revised critical habitat rule for the Canada lynx DPS in the western United States. The analysis provided in the 2014 critical habitat rule in support of critical habitat Units 1 (Maine) and 2 (Minnesota), including the description of PCEs, still applies to those units and is not subject to this revision. Even though the eastern critical habitat units are based on PCEs, those PCEs are biologically similar to the PBFs used in this rule.

Special Management Considerations or Protection

When designating critical habitat, we assess whether the specific areas within the geographical area occupied by the species at the time of listing contain features which are essential to the conservation of the species and which may require special management considerations or protection. The features essential to the conservation of lynx may require special management considerations or protections to reduce the following threats: climate change; vegetation management; wildland fire management; and habitat loss/fragmentation through development, roads, and mining (ILBT 2013, pp. 68–78; Service 2017, pp. 51–105). A detailed discussion of activities influencing the Canada lynx DPS and its habitat can be found in the SSA report (Service 2017, pp. 51–105) and SSA report addendum (Service 2023, pp. 31–46). This critical habitat rule does not prohibit these or any other activities within lynx critical habitat.

Since the DPS was listed in 2000, nearly all Federal forest plans and resource management plans throughout the DPS range have been revised in coordination with the Service and the lynx research community to include science-based measures and management practices consistent with lynx conservation, thereby greatly reducing the potential for population-scale habitat deterioration on Federal lands. These efforts have contributed significantly to addressing the threat for which the DPS was listed—the inadequacy of regulatory mechanisms in USFS and BLM land and resource management plans at that time. Additionally, Federal partners continue to incorporate the best available science into lynx habitat management practices on Federal lands; however, climate change-related impacts have the potential to reduce lynx and snowshoe hare habitat within the DPS in the future. Special management considerations or protections that may be required within critical habitat areas to address these threats include, but are not limited to, maintaining high-quality lynx habitat and potential climate refugia areas; maintaining boreal forest vegetation communities that support high densities of snowshoe hares and resident lynx breeding populations; supporting connectivity within and between home ranges; implementation of forest management practices that prevent or reduce risk of catastrophic wildfire; reducing indirect impacts to habitat from activities adjacent to critical habitat units; and minimizing habitat disturbance, fragmentation, and destruction through use of best management practices for vegetation management activities. Tools to create or maintain a desired mosaic of structural stages that are beneficial to lynx within critical habitat can include logging and timber management, prescribed and natural fire, and others (ILBT 2013, p. 91; WLBT 2022, p. 27). Other management considerations or protections may relate to ensuring highways and developments are permeable for lynx crossing within critical habitat polygons.

Conservation Strategy and Selection Criteria Used To Identify Critical Habitat

Conservation Strategy

We developed a conservation strategy for the Canada lynx DPS to determine and select areas occupied at the time of listing that contain the PBFs essential to the conservation of the species, which was heavily informed by our recovery plan (Service 2024). The goal of our conservation strategy for lynx is to recover the DPS to the point where the protections of the Act are no longer necessary. The role of critical habitat in achieving this conservation goal is to identify the specific areas within the range of the Canada lynx DPS that provide the essential PBFs without which the lynx's range-wide resiliency, redundancy, and representation would be insufficient to achieve recovery. This, in turn, requires an understanding of the fundamental parameters of lynx biology and ecology based on well-accepted conservation biology and ecological principles for conserving species and their habitats, such as those described in the SSA report (Service 2017, entire), SSA report addendum (Service 2023, entire), and recovery plan (Service 2024, entire).

The conservation strategy is the outline for the long-term viability of the Canada lynx DPS. In developing our conservation strategy, we focused on maintaining sufficient representation

and redundancy within the DPS by maintaining or improving the resiliency of lynx populations and conserving their habitats. The conservation strategy includes the following:

(1) Maintenance or improvement of the current resiliency of the five breeding lynx populations (Maine, Minnesota, North Cascades, Northern Rocky Mountains, Southern Rocky Mountains) to preserve the redundancy and representation of the DPS.

(2) Identification and conservation of high-quality lynx habitat and potential climate refugia within the previously mentioned five areas.

(3) Continued implementation and refinement of regulatory mechanisms and other conservation measures that incorporate the best available science to ensure the conservation of lynx habitats and populations.

(4) Populations distributed across the three large representative units in the DPS range (Northeast, Midwest, and West), and

(5) Habitat that:

(a) Supports high- or moderately-resilient resident lynx breeding populations.

(b) Supports connectivity between DPS populations and the core of the lynx's range in Canada.

(c) Provides the climatic conditions that support resident populations.

(d) Provides the boreal forest vegetation communities that support high densities of snowshoe hare and resident lynx breeding populations.

(e) Is potentially capable of providing climate refugia.

Criteria Used To Identify Critical Habitat

As required by section 4(b)(2) of the Act, we use the best scientific data available to designate critical habitat. In accordance with the Act and our implementing regulations at 50 CFR 424.12(b), we review available information pertaining to the habitat requirements of the species and identify specific areas within the geographical area occupied by the species at the time of listing and any specific areas outside the geographical area occupied by the species to be considered for designation as critical habitat. The occupied areas identified encompass the varying habitat types and distribution of lynx and provide sufficient habitat to allow for maintaining the populations. We are not designating any areas outside the geographical area occupied by the species at the time of listing because we have not identified any unoccupied areas that meet the definition of critical habitat. Designating areas outside the geographical area occupied by lynx at the time of listing would not improve the likelihood of recovery (the point at which the protections of the Act are no longer necessary and delisting the DPS would be appropriate). The recovery plan did not identify any areas that were not occupied at the time of listing as necessary for recovery. Thus, because these areas are not essential for the conservation and recovery of the lynx DPS, designating them would not comply with the Act.

We considered connectivity to be important factors for the DPS, as populations in the lower 48 states function as a metapopulation—a network of local populations that exchanges individuals but has somewhat independent dynamics. To maintain genetic diversity and resilience, connectivity is important both within the SSA units (*i.e.,* intra-unit connectivity) and between units (*i.e.,* inter-unit connectivity). Population connectivity has two components: genetic and demographic. Genetic connectivity is defined as the degree to which gene flow affects evolutionary processes within populations, and demographic connectivity is the relative contribution of dispersal to population dynamics (Lowe and Allendorf 2010, p. 3039). Both are influenced by inter- and intra- unit movement of individuals. Within a population unit, connectivity is important for accessing daily resources, finding mates, and shifting home ranges to respond to disturbances or changing habitats. While lynx primarily use boreal forest habitats for feeding and other daily life functions, those habitats are often naturally fragmented in the range of the DPS, separated by drier forest types, meadows, mountain peaks, and other habitats. The WLBT (2022) tier 1 polygons capture some of those other habitats where they are interspersed with boreal forest habitats, and thus we considered those other habitats to be part of the critical habitat for lynx to support intra-unit connectivity. However, given the well-documented ability of lynx to make long journeys across both suitable and unsuitable habitats (Service 2017, p. 40–43; ILBT 2013, p. 8, Ivan 2012 and 2017, entire) and the lack of evidence that human-caused factors have significantly reduced the ability of lynx to disperse (Arnold et al. 2025, entire; ILBT 2013, p. 34), no additional management constraints or restrictions would be placed on those other habitats within the critical habitat. Between population units, dispersal and transitory movements can provide genetic and demographic connectivity. Given that lynx are adept dispersers and given the vast array of habitats used during transitory and dispersal movements (*e.g.,* Ivan 2012 and 2017, entire; Squires and Oakleaf 2005, entire; Squires 2025, unpublished data), we did not identify any specific habitats or areas to designate as critical habitat.

The 2024 recovery plan for the Canada Lynx DPS identifies the maintenance of multiple, resilient populations across the DPS's range as essential for recovery. The plan emphasizes that populations occupying areas smaller than 483 mi^2 (1,250 km^2) are unlikely to be demographically or genetically viable in the long term, due to increased risks of stochastic events, genetic drift, and local extirpation. By using 483 mi^2 (1,250 km^2) as a minimum area criterion for critical habitat, the Service ensures that designated units are large enough to support the ecological processes necessary for population persistence and recovery, consistent with the recovery plan's goals for redundancy, resiliency, and representation across the DPS.

In previous critical habitat designations, we identified lynx habitat using expert judgement of vegetation and habitat types and elevation thresholds. For the western United States, we now have new, state-of-the-art lynx habitat models (Olson et al. 2021, entire; Squires et al. 2024, entire) based on the best empirical data of lynx locations across the western United States. The models accurately map environmental covariates (abiotic and biotic features) found at lynx locations, as compared to a random sample of background locations, within and outside of known home ranges. These models were built using data from thousands of verified fine-scale GPS locations of radio-marked resident lynx in Montana, Washington, Wyoming, and Colorado. Additionally, the models were tested and verified using location data withheld from building the models and incidental lynx occurrence data that included locations within home ranges and locations outside of home ranges. The models cover the western extent of the Canada lynx DPS range and indicate the relative likelihood of lynx presence in Washington, Idaho, western Montana, northwestern and south-central Wyoming, northeastern Utah, western Colorado, and northern New Mexico.

These models and their use to identify high-quality lynx habitat were documented in the WLBT report (2022, entire). The WLBT included species experts from the Service, USFS, and BLM, as well as scientists from the USDA Rocky Mountain Research

Station who led the development of the new habitat models. The interagency team used a science-based approach to identify key habitat areas from the models and developed a tiered approach to model outputs by evaluating the extent and proportion of modeled high-quality habitat. The WLBT framework underwent review from lynx researchers (WLBT 2022, p. 45–47).

The WLBT used the models to identify areas of high conservation value for lynx where high-quality habitat is abundant, and further assigned those areas into three tiers. Tier 1 polygons provide large and well-connected areas with high proportions of high-quality habitat and support long-term lynx occupancy and reproduction. Tier 2 polygons contain lower proportions of high-quality habitat, and they provide habitat for expansion or redundant habitat areas. In tier 2, the objective is to provide habitat to support periodic to regular occupancy, which may include reproductively successful individuals. Tier 3 areas are generally smaller islands of habitat that may function as ''stepping stones for dispersing lynx; these areas may be important to maintain connectivity and facilitate dispersal across the landscape and among tiers.

The WLBT mapping effort and underlying SDMs identify habitat with the climatic and vegetation characteristics necessary to support lynx residency and reproduction. This includes boreal and subalpine forested habitats with a mosaic of variable forest successional and structural stages, dense horizontal cover, persistent snow, and moderate to high snowshoe hare densities, set within a matrix of other habitat types that provide areas for connectivity. Our proposed critical habitat maps relied heavily on the tier 1 areas described by the WLBT (2022, p. 23), and we made changes to the proposed critical habitat maps based on comments received, as detailed in *Criteria Used To Identify Critical Habitat.* When designating critical habitat, we are not required to designate all areas where a species occurs. We chose to focus on tier 1 polygons because these are the areas that have at least 50 percent of the polygon in the highest quality habitat. Tier 1 habitat is the most valuable to long-term lynx occupancy and reproduction and sufficient to provide for the conservation of the Canada lynx DPS. We did not use tier 2 or 3 polygons because those areas have lower proportions of high-quality lynx habitat; thus, they are not likely to support long-term occupancy and reproduction.

Following the public comment period on our proposed rule, we reviewed all of the proposed critical habitat polygons. We removed some polygons entirely, and we refined the boundaries of several proposed critical habitat units. These changes were made to the Service's critical habitat boundaries, not to the original WLBT polygons.

In Unit 3, we removed some areas from the final critical habitat designation that lacked evidence of regular lynx reproduction, and they also lacked adequate size and close proximity to other larger areas of modeled high-quality habitat with known persistent occupancy and reproduction; these include the Lolo Pass polygon and the 3 Selkirk Mountains polygons. These polygons are all smaller than 483 mi^2 (1,250 km^2), both individually and when combined, which is the minimum area thought necessary to support a resilient lynx population as identified in the SSA report addendum (Service 2023, pp. 50–51). We retained a few smaller polygons where they exist within close proximity (<10 mi or 16 km) of other large tier 1 areas (such that in combination with those larger areas they do provide habitat areas greater than or equal to 483 mi^2 (1,250 km^2)) and have known persistent lynx residency and reproduction (*i.e.,* the Garnet Range and the Dalton Mountain areas in Unit 3).

We also refined the boundaries of the critical habitat in a few areas to better align with likely habitat from the Olson et al. (2021, entire) model outputs (*i.e.,* the 95 percent withheld threshold that the WLBT used), trimming out edge areas of low or moderate probability habitat where vegetation types are dry or unsuitable. We did not remove any patches of dry forest, meadows, or rocky areas within the interior of critical habitat polygons, in an effort to acknowledge the role those areas likely play in providing within-home range and between-home range connectivity. We also added additional area onto two polygons in two locations: southwest of Seeley Lake, Montana, and in the northern Swan Range in Montana. In these areas, the best available information—such as lynx detections, known family group use, or lynx movement data—showed that high-quality or well used habitat exists in areas with some likely lynx habitat. In several places, we chose *not* to make any changes to the proposed polygons where doing so would contradict localized knowledge, collar data, or Resource Selection Function (RSF) models (*e.g.,* Holbrook 2017, entire; Squires 2013, entire). Collectively, these edits refined our critical habitat polygon boundaries to reflect high-quality, regularly used, and ecologically supported lynx habitat.

In Unit 5, the GYA, we removed all of the areas that were included in the proposed rule, and we did not add any areas, resulting in no areas of designated critical habitat in the GYA. Although habitat models identify portions of the GYA—such as the Wyoming Range and areas around Union and Togwotee Pass—as having some potential habitat, and the WLBT identified those areas as tier 1, historical and contemporary data indicate only intermittent use and lack of a persistent breeding population in those areas or any other areas of the GYA, and recent State and Federal surveys have repeatedly failed to detect lynx populations in the region. The absence of a persistent breeding population for at least the past 30 years or more indicates that the GYA does not contain the physical or biological features (PBFs) essential to lynx conservation—most notably, PBF 1—the presence of snowshoe hares that support lynx residency and reproduction over time, and PBF 5—suitable habitat enough to support a persistent breeding population.

In Unit 6, the Service discovered that the WLBT had relied on an earlier version of the Southern Rockies lynx habitat model (cited in WLBT 2022 as Squires et al. in prep.), to develop the tier polygons in the Southern Rockies. We chose to re-map polygons in the Southern Rockies using the final habitat model (published as Squires et al. 2024, entire) and using the same delineation process originally applied by WLBT to delineate new polygons that captured the substantial areas of likely lynx habitat. This process produced six revised polygons for the Southern Rockies. Two polygons fell within WLBT's original tier 2 areas, were smaller than 483 mi^2 (1,250 km^2), and lacked confirmed persistent occupancy or reproduction. Thus, we treated those the same as the original tier 2 areas and did not include them in the critical habitat designation. The remaining four polygons fell within WLBT tier 1 areas; expert review confirmed that three adjacent northern polygons function ecologically as a single unit despite their separation in the final model, and the southernmost San Juans polygon reflects the most persistent and well-documented lynx use since reintroduction. Therefore, the critical habitat designation for the Southern Rockies includes the four revised polygons occurring within the original WLBT tier 1 areas.

These polygons were then reviewed by Service biologists, using the best

available information, to ensure that all polygons have the PBFs essential to Canada lynx. These features include: (1) presence of snowshoe hares that support lynx residency and reproduction over time within a mosaic of boreal/subalpine forest structural stages that includes snowshoe hare habitat with dense horizontal cover at ground- or snow-level; (2) winter conditions that provide and maintain deep persistent unconsolidated (fluffy) snow; (3) presence of denning structures, including downed trees, root wads, and accumulations of coarse woody debris; (4) habitat types, such as dry forest or meadows, that are between boreal forest patches and are likely to be used by lynx traveling between those patches within and among home ranges; and (5) landscapes with suitable habitat large enough (483 mi^2 (greater than or equal to 1,250 km^2)) to support breeding populations.

When determining critical habitat boundaries, we made an effort to avoid including developed areas because such lands lack physical or biological features necessary for lynx. We could not map critical habitat at a granular scale in order to exclude each and every developed area or other areas that are unlikely to contain the PBFs. The scale of the maps we prepared under the parameters for publication within the Code of Federal Regulations may not reflect the exclusion of such developed lands. Areas within the boundaries of this final critical habitat designation that do not include the PBFs necessary for lynx and are not designated as critical habitat include: lands covered by buildings, houses, pavement, and other structures; paved highways and roads; active mines and existing mining infrastructure; existing developed ski runs and tree islands, ski lifts, and associated ski area infrastructure and buildings; and irrigation infrastructure. Any such lands inadvertently left inside critical habitat boundaries shown on the maps of this rule have been excluded by text in the final rule and are not designated as critical habitat. Therefore, a Federal action involving these lands would not trigger section 7 consultation with respect to critical habitat and the requirement of no adverse modification unless the specific action would affect the physical or biological features in the adjacent critical habitat.

The critical habitat designation is defined by the map or maps, as modified by any accompanying regulatory text, presented at the end of this document under Regulation Promulgation. We include more detailed information on the boundaries of the critical habitat designation in the preamble of this document. We will make the coordinates or plot points or both on which each map is based available to the public on *https://www.regulations.gov* at Docket No. FWS–RX–ES–2024–0142, and on our internet site: *https://www.fws.gov/species/canada-lynx-lynx-canadensis.*

Final Critical Habitat Designation

Critical habitat was last designated for the Canada lynx DPS in 2014 and included five units in the contiguous United States (79 FR 54782, September 12, 2014). We are revising critical habitat for the Canada lynx in the western United States to fulfill our obligations under a settlement agreement to address issues raised by the District Court of Montana regarding our previous critical habitat designation in 2014. Existing critical habitat units 1 (Maine) and 2 (Minnesota) were not implicated in the court order; we also did not find new habitat modeling or information that would necessitate a reassessment of critical habitat for those areas. Thus, the existing critical habitat units 1 (Maine) and 2 (Minnesota) are not addressed in this revision to lynx critical habitat and remain in place as described in the 2014 critical habitat final rule. We did, however, take a comprehensive look at critical habitat for lynx in the western United States, considering new science that was not available at the time of the 2014 critical habitat revision. The critical habitat areas we describe below constitute our current best assessment of areas that meet the definition of critical habitat for lynx in the western United States. The three areas we designate as critical habitat are: (1) Unit 3: Northern Rockies; (2) Unit 4: North Cascades; and (3) Unit 6: Southern Rockies. Table 1, below, shows the critical habitat units and the approximate area of each unit. All units were occupied at the time of listing in 2000. Table 1 lists the critical habitat units and their approximate sizes broken down by major land ownership.

TABLE 1—WESTERN CRITICAL HABITAT UNITS FOR CANADA LYNX (MI^2 (KM^2))

[Area estimates reflect all land within critical habitat unit boundaries]

Critical habitat unit	Federal	State	Private	Other	Total
3. Northern Rockies	6,911 (17,900)	1 (2)	6 (16)	0 (0)	6,918 (17,918)
4. North Cascades	2,072 (5,367)	1 (1)	3 (7)	0 (0)	2,076 (5,375)
6. Southern Rockies	4,898 (12,685)	6 (16)	126 (326)	8 (20)	5,038 (13,047)
Total	13,881 (35,952)	8 (19)	135 (349)	8 (20)	14,030 (36,340)

Note: Area sizes may not sum due to rounding. Numbers are calculated using the U. S. Geological Survey's (USGS) Protected Areas Database for the United States 3.0 dataset (USGS 2022) supplemented with the BLM 2023 Surface Management Agency dataset (BLM 2023).

We present brief descriptions of all units, and reasons why they meet the definition of critical habitat for the Canada lynx DPS below.

Unit 3: Northern Rockies

Unit 3 consists of 6,918 mi^2 (17,900 km^2) located in northwestern Montana in portions of Flathead, Glacier, Granite, Lake, Lewis and Clark, Lincoln, Missoula, Pondera, Powell, and Teton Counties and northern Idaho in portions of Boundary County. The revision represents a 2,865-mi^2 (7,419-km^2) reduction from the 2014 designation for this unit (approximately 29 percent reduction), although it includes new areas of critical habitat in northern Idaho. This unit was occupied by lynx at the time of listing and is currently occupied by the species. Lynx are known to be widely distributed throughout this unit and breeding has been documented in multiple locations. This unit supports a resident population with regular occupancy and reproduction. The historical and current sizes of the resident lynx population in this unit are unknown, but it is currently thought to be capable of supporting 200 to 300 lynx home ranges (Service 2017, p. 110). This unit is directly connected to lynx habitats and populations in southwestern Alberta and southeastern British Columbia, Canada. Lynx in this unit represent the southern extent of a larger cross-border population, most of which occurs in western Canada.

Land ownership within the unit is over 99 percent Federal, with less than one 1 percent state or private. Federal lands in this unit include National Forest System lands within the Kootenai, Flathead, and Helena-Lewis and Clark National Forests in Montana and the Idaho Panhandle National Forest in Idaho; National Park Service lands in Glacier National Park; and BLM lands in the Garnet Resource Area. Most state lands in this unit were excluded, as explained in *Exclusions Based on Other Relevant Impacts* section below, including lands managed by the Montana DNRC and MTFWP. Tribal lands within this unit were also excluded, including parts of the Confederated Salish and Kootenai Tribes Flathead Reservation and the Blackfeet Reservation, both in Montana.

The PBFs essential to the conservation of the Canada lynx in this unit may require special management considerations or protections to address activities that may result in removal or reduction of boreal/subalpine forest conditions that support Canada lynx and snowshoe hares. Such activities may include, but are not limited to, forestry and fuel reduction; efforts to reduce extensive high-severity fires in lynx habitat; highway construction and maintenance; and commercial, recreational, and energy/mineral development. These activities may remove or reduce boreal forest in a manner that impacts snowshoe hare densities, the size of suitable habitat patches to support breeding lynx populations, and permeability of landscapes for lynx daily movements and dispersal in this unit. Climate change is expected to negatively impact the duration of deep fluffy snow conditions favorable to lynx in this unit over time.

Unit 4: North Cascades

Unit 4 consists of 2,076 mi^2 (5,375 km^2) located in north-central Washington in portions of northern Chelan, Okanogan, and eastern Skagit and Whatcom Counties. The revision represents a 241-mi^2 (624-km^2; 13 percent) increase from the 2014 designation for this unit. Most of the increase is on the western side of the unit, in the North Cascades National Park. This unit was occupied by lynx at the time of listing and is currently occupied by the species. Lynx are known to be distributed throughout much of this unit, and breeding has been documented. The Service estimates that this unit is potentially capable of supporting a resident population of 90 to 120 lynx, but extensive large wildfires in roughly half of lynx habitat over the past 15 to 20 years are thought to have reduced its carrying capacity commensurately (but perhaps temporarily). Nonetheless, a systematic lynx DNA collection effort between 2018 and 2024 documented 73 individual lynx in north central Washington, including 40 males and 33 females (Akins and Preckler-Quisquater 2025, unpublished report). This unit is directly connected to lynx habitats and populations in southern British Columbia, Canada. Lynx in this unit represent the southern extent of a larger cross-border population, most of which occurs in western Canada.

Land ownership within the unit is over 99 percent Federal, with small parcels of private land that represents less than one-half of 1 percent of the unit. The 2,072 mi^2 (5,367 km^2) of Federal lands in the unit include mostly lands within the Okanogan-Wenatchee National Forest and a small amount of North Cascades National Park. It also includes a small area of state land on the Methow Wildlife Area, but the majority of state land was excluded, including State Forest lands managed by the WDNR (see *Exclusions Based on Other Relevant Impacts* section below).

The PBFs essential to the conservation of the Canada lynx in this unit may require special management considerations or protections to address activities that may result in removal or reduction of boreal/subalpine forest conditions that support Canada lynx and snowshoe hares. Such activities may include, but are not limited to, timber and fuels management; efforts to reduce extensive high-intensity wildfires; highway construction and maintenance; and commercial, recreational, and energy/mineral development. These activities may remove or reduce boreal forest in a manner that impacts snowshoe hare densities, the size of suitable habitat patches to support breeding lynx populations, and permeability of landscapes for lynx daily movements and dispersal in this unit. Climate change is expected to negatively impact the duration of deep fluffy snow conditions favorable to lynx in this unit over time.

Unit 6: Southern Rockies

Although there is no critical habitat Unit 5 in this designation, other documents including the SSA and SSA Addendum and the recovery plan all refer to the Southern Rockies as Unit 6 (Service 2017, entire; Service 2023, entire; Service 2024, entire). Thus, we have retained that nomenclature in this critical habitat designation to retain consistency. Unit 6 consists of 5,038 mi^2 (13,047 km^2) located in west-central and southwestern Colorado in portions of Archuleta, Chaffee, Clear Creek, Conejos, Dolores, Eagle, Gilpin, Grand, Gunnison, Hinsdale, La Plata, Lake, Mineral, Montezuma, Ouray, Park, Pitkin, Rio Grande, San Juan, San Miguel, and Summit Counties. Critical habitat was not previously designated in the Southern Rockies. At the time of listing, this unit was occupied by lynx translocated from Canada and Alaska, and it is currently occupied by the descendants of those released lynx. It is uncertain whether this unit historically supported a resident population or if lynx presence was naturally ephemeral and intermittent (Service 2017, p. 43, 112).

The area currently supports a resident breeding population that is the result of the State of Colorado's Canada Lynx Reintroduction Program, which included the 1999 to 2006 translocations of 218 lynx from Canada and Alaska into the San Juan Mountains in southwestern Colorado, with continued lynx occurrence and reproduction documented annually since then. Lynx researchers with Colorado Parks and Wildlife estimate the current size of the population at 75 to 150 resident lynx. This unit is not directly connected to lynx habitats and populations elsewhere in the DPS range or in the core of the species' range in western Canada; however, historical records suggest that dispersing lynx associated with cyclic irruptions of lynx from Canada into the northern contiguous U.S. occasionally reached the Southern Rockies. Some of the lynx released into Colorado dispersed into surrounding states, with some traveling into the GYA, Montana, Idaho, Utah, Nebraska, and New Mexico. The recovery plan for lynx (Service 2024, entire) identifies maintaining a population with moderate resiliency for the Colorado population as a component of the recovery strategy, as that population adds to redundancy and resiliency for the DPS.

Land ownership within the unit is approximately 97 percent Federal, less than 3 percent private, and less than 1 percent State and local government. Most of the Federal lands (95 percent) occur on National Forests, including the Arapaho, Gunnison, Pike, Rio Grande, Roosevelt, San Isabel, San Juan, Uncompahgre, and White River National Forests in Colorado. Approximately 5 percent of Federal lands occur on BLM lands and smaller parcels of Service and Bureau of Reclamation lands.

The PBFs essential to the conservation of the Canada lynx in this

unit may require special management considerations or protections to address activities that may result in removal or reduction of boreal/subalpine forest conditions that support lynx and snowshoe hare. Such activities may include, but are not limited to, road construction and maintenance and commercial, recreational, and energy/mineral development. These activities may remove or reduce boreal forest in a manner that impacts snowshoe hare densities, the size of suitable habitat patches to support breeding lynx populations, and permeability of landscapes for lynx daily movements and dispersal in this unit. Climate change is expected to negatively impact the duration of snow conditions favorable to lynx in this unit over time; however, this unit is among the most resilient to climate change given the geography and high altitudes available for subalpine forests to respond to various climatic scenarios (Service 2023, pp. 60–70).

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a)(2) of the Act requires Federal agencies, including the Service, to ensure that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of any endangered species or threatened species or result in the destruction or adverse modification of designated critical habitat of such species. Destruction or adverse modification means a direct or indirect alteration that appreciably diminishes the value of critical habitat for the conservation of a listed species. Such alterations may include, but are not limited to, those that alter the physical or biological features essential to the conservation of a species or that preclude or significantly delay development of such features (50 CFR 402.02). Compliance with the requirements of section 7(a)(2) is documented through our issuance of:

(1) A concurrence letter for Federal actions that may affect, but are not likely to adversely affect, listed species or critical habitat; or

(2) A biological opinion for Federal actions that may affect, and are likely to adversely affect, listed species or critical habitat.

When we issue a biological opinion concluding that a project is likely to jeopardize the continued existence of a listed species and/or destroy or adversely modify critical habitat, we provide reasonable and prudent alternatives to the project, if any are identifiable, that would avoid the likelihood of jeopardy and/or destruction or adverse modification of critical habitat. We define ''reasonable and prudent alternatives'' (at 50 CFR 402.02) as alternative actions identified during formal consultation that:

(1) Can be implemented in a manner consistent with the intended purpose of the action,

(2) Can be implemented consistent with the scope of the Federal agency's legal authority and jurisdiction,

(3) Are economically and technologically feasible, and

(4) Would, in the Service Director's opinion, avoid the likelihood of jeopardizing the continued existence of the listed species or avoid the likelihood of destroying or adversely modifying critical habitat.

Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 set forth requirements for Federal agencies to reinitiate consultation. Reinitiation of consultation is required and shall be requested by the Federal agency or by the Service, where discretionary Federal involvement or control over the action has been retained or is authorized by law and: (1) If the amount or extent of taking specified in the incidental take statement is exceeded; (2) if new information reveals effects of the action that may affect listed species or critical habitat in a manner or to an extent not previously considered; (3) if the identified action is subsequently modified in a manner that causes an effect to the listed species or critical habitat that was not considered in the biological opinion or written concurrence; or (4) if a new species is listed or critical habitat designated that may be affected by the identified action. As provided in 50 CFR 402.16, the requirement to reinitiate consultations for new species listings or critical habitat designation does not apply to certain agency actions (*e.g.,* certain land management plans issued by the BLM or USFS).

Due to the ephemeral and dynamic nature of some of the PBFs (*e.g.* snow, mosaic structural stages, etc.) we do not expect all PBFs to be present at all times. Project proponents or action agencies can use qualitative or quantitative measures to determine the functionality of the PBFs and proposed project related changes. The Service will evaluate proposed actions with a Federal nexus occurring within critical habitat based on whether or not they maintain or contribute to the overall functionality of the critical habitat.

Destruction or Adverse Modification of Critical Habitat

The key factor related to the destruction or adverse modification determination is whether implementation of the proposed Federal action directly or indirectly alters the designated critical habitat in a way that appreciably diminishes the value of the critical habitat for the conservation of the listed species (*i.e.,* Canada lynx DPS). As discussed above, the role of critical habitat is to support physical or biological features essential to the conservation of a listed species and provide for the conservation of the species.

Section 4(b)(8) of the Act requires that our proposed or final regulations include, to the maximum extent practicable, a brief description and evaluation of those activities (whether public or private) which, in the opinion of the Secretary, if undertaken may adversely modify critical habitat, or may be affected by such designation. Activities that may be affected by designation of critical habitat for the Canada lynx include those that may affect the physical or biological features of the Canda lynx' critical habitat (see Physical or Biological Features Essential to the Conservation of the Species, above). Importantly, determinations of destruction or adverse modification consider whether the proposed action is likely to appreciably diminish the value of the critical habitat for the conservation of lynx. Adverse effects to one or more PBFs do not necessarily constitute destruction or adverse modification of the critical habitat.

Exemptions

Application of Section 4(a)(3) of the Act

Section 4(a)(3)(B)(i) of the Act provides that the Secretary shall not designate as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DoD), or designated for its use, that are subject to an integrated natural resources management plan (INRMP) prepared under section 101 of the Sikes Act Improvement Act of 1997 (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is proposed for designation. There are no DoD lands with a completed INRMP within the final critical habitat designation.

Consideration of Impacts Under Section 4(b)(2) of the Act

Section 4(b)(2) of the Act states that the Secretary shall designate and make revisions to critical habitat on the basis of the best available scientific data after taking into consideration the economic impact, the impact on national security, and any other relevant impact of specifying any particular area as critical habitat. The Secretary may exclude any area from critical habitat if the benefits of exclusion outweigh those of inclusion, so long as exclusion will not result in extinction of the species concerned. Exclusion decisions are governed by the regulations at 50 CFR 424.19 and the Policy Regarding Implementation of Section 4(b)(2) of the Endangered Species Act (hereafter, the ''2016 Policy;'' 81 FR 7226, February 11, 2016)—both of which were developed jointly with the National Marine Fisheries Service (NMFS). We also refer to a 2008 Department of the Interior Solicitor's opinion entitled, ''The Secretary's Authority to Exclude Areas from a Critical Habitat Designation under Section 4(b)(2) of the Endangered Species Act'' (M–37016). We explain each decision to exclude areas, as well as decisions not to exclude, to demonstrate that the decision is reasonable.

When evaluating the exclusion of a particular area from the designation, we identify the benefits of including the area in the designation, identify the benefits of excluding the area from the designation, and evaluate whether the benefits of exclusion outweigh the benefits of inclusion. If the analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, the Secretary may exercise discretion to exclude the area only if such exclusion would not result in the extinction of the species. In making the determination to exclude a particular area, the statute on its face, as well as the legislative history, are clear that the Secretary has broad discretion regarding which factor(s) to use and how much weight to give to any factor. In this final rule, we explain any decision to exclude areas, as well as decisions not to exclude, to make clear the rational basis for our decision. We describe below the process that we undertook for deciding whether to exclude any areas—taking into consideration each category of impacts and our analysis of the relevant impacts.

Exclusions Based on Economic Impacts

Section 4(b)(2) of the Act and its implementing regulations require that we consider the economic impact that may result from a designation of critical habitat. In order to consider economic impacts, we prepared an IEM and screening analysis which, together with our narrative and interpretation of effects, we consider to be our economic analysis of the critical habitat designation and related factors (IEc 2024 and 2026, entire). The analysis, dated August 12, 2024, was made available for public review from November 29, 2024, through January 28, 2025. The economic analysis addressed probable economic impacts of critical habitat designation for the Canada lynx. Following the close of the comment period, we reviewed and evaluated all information submitted during the comment period that may pertain to our consideration of the probable incremental economic impacts of this critical habitat designation. Additional information relevant to the probable incremental economic impacts of critical habitat designation for the Canada lynx is summarized below and available in the screening analysis for the Canada lynx (IEc 2026, entire), available at *https://www.regulations.gov.*

The full description of the findings from the economic analysis is outlined in the proposed rule (89 FR 94656; November 29, 2024). We received an updated economic analysis on April 30, 2026, which incorporated changes made between the proposed and final rule and updated to 2026 dollars (IEc 2026, entire). The incremental effects of revising critical habitat for the Canada lynx are likely to be limited to changes in administrative effort to evaluate the potential for adverse modification of Canada lynx critical habitat. The entities most likely to incur incremental costs are parties who are required to conduct section 7 consultations, including Federal action agencies and, in some cases, third parties, most frequently State agencies or municipalities. This analysis finds that administrative costs and cost savings are on the order of $42,000 and $48,000 respectively, in a given year (2026 dollars). The expected net effect of revising critical habitat for the Canada lynx is a $5,200 decrease in administrative costs per year. Incremental economic benefits and forgone benefits are not anticipated. The economic analysis concludes that the revised rule for lynx critical habitat is unlikely to reach $100 million, which would make it a significant regulatory action under section 3(f)(1) of E.O. 12866.

Following the issuance of E.O. 14225 (*Immediate Expansion of American Timber Production*) and E.O. 14308 (*Empowering Commonsense Wildfire Prevention and Response*), the Service reviewed the revised critical habitat designation for Canada lynx to assess potential impacts in forested areas prioritized for timber production and wildfire mitigation. The E.O.s emphasize increasing domestic timber output and streamlining forest management. This critical habitat designation does not impart any restrictions on forest management activities. The designation does necessitate section 7 consultations for any actions, including timber and fuels, when there is a Federal nexus, to ensure the proposed action will not result in the destruction or adverse modification of the critical habitat. Approximately 52 percent of revised critical habitat overlaps with areas designated under the Forest Health and Fuels Emergency Situation Determination, where emergency authorities may be used to expedite forest health and fuels reduction projects, including emergency consultations.

Forest management activities, including timber harvest and wildfire risk reduction projects, can be beneficial tools for creating a mosaic of differing successional forest stages within lynx critical habitat (ILBT 2013, p. 91). Fuels reduction projects not only protect human infrastructure, they may also be designed to sustain high-quality lynx habitat by reducing the likelihood of extensive wildfire spread to mature forest areas of clynx habitat. Forest management can also create dense regenerating forest stands that support high hare densities as they regrow. All of these activities, when conducted strategically and informed by the best available science, can be a part of managing critical habitat for lynx.

The USFS has been consulting with the Service on projects affecting lynx critical habitat under the 2014 critical habitat designation on National Forests in units 3, 4, and 5. Thus, this revision is not expected to result in substantial changes for those National Forests in terms of consultations. In areas where critical habitat has not previously been designated (for example, National Forests in Colorado), the USFS will have to consider effects to critical habitat in addition to effects on the species and consult with the Service on projects that may affect the critical habitat. As a result, there will be incremental economic impacts resulting from the administrative costs associated with section 7 consultations that must include additional analysis for National Forests in Colorado. As such, the incremental economic impact of the designation is expected to be limited to minor administrative costs associated with section 7 consultation. Because this designation results in a 37 percent

decrease in critical habitat compared to the 2014 rule, administrative costs will be less in areas that are no longer designated.

As discussed above, we considered the economic impacts of the critical habitat designation, and the Secretary is not exercising his discretion to exclude any areas from this designation of critical habitat for the Canada lynx based on economic impacts.

Exclusions Based on Impacts on National Security and Homeland Security

In preparing this rule, we determined that there are no lands within the designated critical habitat for the Canada lynx that are owned or managed by the DoD or Department of Homeland Security, and, therefore, we anticipate no impact on national security or homeland security. We did not receive any additional information during the public comment period for the proposed critical habitat designation regarding impacts of the designation on national security or homeland security that would support excluding any specific areas from the final critical habitat designation under the authority of section 4(b)(2) of the Act and our implementing regulations at 50 CFR 424.19, as well as the 2016 Policy.

Exclusions Based on Other Relevant Impacts

Under section 4(b)(2) of the Act, we consider any other relevant impacts, in addition to economic impacts and impacts on national security as discussed above. To identify other relevant impacts that may affect the exclusion analysis, we consider a number of factors, including whether there are approved and permitted conservation agreements or plans covering the species in the area such as safe harbor agreements (SHAs), candidate conservation agreements with assurances (CCAAs), ''conservation benefit agreements'' or ''conservation agreements'' (CBAs) (CBAs are a new type of agreement replacing SHAs and CCAAs in use after April 2024 (89 FR 26070; April 12, 2024)) or HCPs—or whether there are non-permitted conservation agreements and partnerships that would be encouraged by designation of, or exclusion from, critical habitat. In addition, we look at whether Tribal conservation plans or partnerships, Tribal resources, or government-to-government relationships of the United States with Tribal entities may be affected by the designation. We also consider any State, local, social, or other impacts that might occur because of the designation.

When identifying the benefits of inclusion for an area, we consider the additional regulatory benefits that area would receive due to the protection from destruction or adverse modification as a result of actions with a Federal nexus, the educational benefits of mapping essential habitat for recovery of the listed species, and any benefits that may result from a designation due to State or Federal laws that may apply to critical habitat. In the case of the Canada lynx, the benefits of critical habitat include public awareness of the presence of Canada lynx and the importance of habitat protection.

When identifying the benefits of exclusion, we consider, among other things, whether exclusion of a specific area is likely to result in conservation, or in the continuation, strengthening, or encouragement of partnerships. Additionally, continued implementation of an ongoing management plan that provides equal to or more conservation than a critical habitat designation would reduce the benefits of including that specific area in the critical habitat designation.

We evaluate the existence of a conservation plan when considering the benefits of inclusion. We consider a variety of factors, including, but not limited to, whether the plan is finalized; how it provides for the conservation of the essential physical or biological features; whether there is a reasonable expectation that the conservation management strategies and actions contained in a management plan will be implemented into the future; whether the conservation strategies in the plan are likely to be effective; and whether the plan contains a monitoring program or adaptive management to ensure that the conservation measures are effective and can be adapted in the future in response to new information.

After identifying the benefits of inclusion and the benefits of exclusion, we carefully weigh the two sides to evaluate whether the benefits of exclusion outweigh those of inclusion. If our analysis indicates that the benefits of exclusion outweigh the benefits of inclusion, we then determine whether exclusion would result in extinction of the species. If exclusion of an area from critical habitat will result in extinction, we will not exclude it from the designation.

Based on the information provided by entities seeking exclusion, as well as additional public comments we received, and the best scientific data available, we evaluated whether certain lands in critical habitat Units 3, and 4 are appropriate for exclusion from the final designation under section 4(b)(2) of the Act. If our analysis indicates that the benefits of excluding lands from the final designation outweigh the benefits of designating those lands as critical habitat, then the Secretary may exercise their discretion to exclude the lands from the final designation. In the paragraphs below, we provide our analysis of the areas being excluded under section 4(b)(2) of the Act.

Private or Other Non-Federal Conservation Plans or Agreements Associated With Permits Under Section 10 of the Act

As mentioned above, as part of our 4(b)(2) analysis, we consider whether there are approved and permitted conservation agreements or plans covering the species in the area such as SHAs, CCAAs, CBAs or HCPs. Under sections 10(a)(1)(A) and 10(a)(1)(B) of the Act, non-Federal entities may develop these agreements or plans when they seek authorization for take that may otherwise be prohibited under section 9 through an enhancement of survival (EOS) or incidental take permit (ITP), respectively.

Property owners seeking an EOS permit collaborate with the Service to develop a CBA to support the application. The EOS permit authorizes take associated with implementing the agreement and ongoing land management activities that provide a net conservation benefit to the covered species. The CBA replaces two previous types of voluntary agreements (SHAs and CCAAs) going forward for new agreements after May 2024. However, permitted SHAs and CCAAs or those noticed in the **Federal Register** prior to May 2024 remain in effect.

For incidental take permits issued under section 10(a)(1)(B) of the Act, applicants are required to develop a conservation plan, more commonly known as an HCP, to support their application. ITPs authorize take that is incidental to, but not the purpose of, carrying out otherwise lawful activities provided that the impact of the taking is minimized and mitigated to the maximum extent practicable.

For both section 10(a)(1)(A) and 10(a)(1)(B) permits, we provide permittees with assurances. In the case of 10(a)(1)(A) permits, we may not require additional or different conservation measures to be undertaken by a permittee without the consent of the permittee. In the case of section 10(a)(1)(B), we will not impose further land-, water-, or resource-use restrictions, or require additional commitments of land, water, or finances, beyond those agreed to in the HCP.

We place great value on the partnerships that are developed during the preparation and implementation of conservation plans and agreements. In some cases, permittees agree to do more for the conservation of the species and their habitats on private lands than designation of critical habitat would provide alone.

When we undertake a discretionary section 4(b)(2) exclusion analysis based on conservation plans or agreements, we anticipate consistently excluding such areas if incidental take caused by the activities in those areas is covered by the permit under section 10 of the Act and the plan meets all of the following three factors (see the 2016 Policy for additional details. Because combining types of agreements such as SHAs and CCAAs into the term ''CBAs'' is a recent development (see 89 FR 26070, April 12, 2024), the 2016 Policy did not expressly reference CBAs. However, because CBAs replace CCAAs and SHAs moving forward we treat CBAs similarly to how we treat CCAA/SHA/HCPs described below:

a. The permittee is properly implementing the CCAA/SHA/HCP and is expected to continue to do so for the term of the agreement. A CCAA/SHA/HCP is properly implemented if the permittee is and has been fully implementing the commitments and provisions in the CCAA/SHA/HCP, implementing agreement, and permit.

b. The species for which critical habitat is being designated is a covered species in the CCAA/SHA/HCP, or very similar in its habitat requirements to a covered species. The recognition that the Services extend to such an agreement depends on the degree to which the conservation measures undertaken in the CCAA/SHA/HCP would also protect the habitat features of the similar species.

c. The CCAA/SHA/HCP specifically addresses that species' habitat and meets the conservation needs of the species in the planning area.

The Montana DNRC Forested Trust Lands HCP (Montana DNRC and USFWS 2010a, entire; 2010b as amended, entire; 2010c, entire) was permitted in 2012 under section 10(a)(1)(B) of the Act for a period of 50 years (Service 2011a, entire; 2011b, entire). The HCP was amended in 2018 to incorporate the terms of a 2015 Settlement Agreement on the Stillwater State Forest, and it was amended again in 2022 to add newly acquired forest lands. The permit has been amended twice to address issues and concerns and to add lands that the Montana DNRC acquired (Service 2018, entire; 2022, entire). The HCP covers about 889 mi^2 (2,561 km^2) of forested State trust lands in western Montana. The HCP trust lands occur on both blocked and scattered parcels within three Montana DNRC land offices: the Northwestern, Central, and Southwestern Land Offices. Blocked lands are primarily in three State Forests: Stillwater, Coal Creek, and Swan. Scattered parcels refer to all other HCP project lands outside of blocked lands. About 179 mi^2 (463 km^2) of lands managed in accordance with the HCP overlap with the area we proposed as lynx critical habitat in Unit 3. Most of those lands occur in areas identified in the HCP as high-priority areas for lynx conservation known as Lynx Management Areas (LMAs), with the remainder in scattered blocks (Montana DNRC and USFWS 2010b as amended, pp. 2–46–2–61).

The HCP covers activities that are primarily associated with commercial forest management and also includes grazing on forested trust lands. In addition to lynx, the HCP also covers grizzly bears (*Ursus arctos horribilis*) and bull trout (*Salvelinus confluentus*), both listed as threatened species under the Act, and two non-listed fish species, the westslope cutthroat trout (*Oncorhynchus clarkii lewisi*) and the Interior (Columbia River) redband trout (*Oncorhynchus mykiss gairdneri*).

The HCP includes a Lynx Conservation Strategy consisting of a suite of lynx habitat commitments that apply to all lands in the HCP project area supporting lynx habitat and additional commitments that apply to LMAs (Montana DNRC and USFWS 2010b as amended, pp. 2–46–2–61). The Montana DNRC has been implementing the Lynx Conservation Strategy since the first year of implementation in 2012 and reports to the Service annually (*e.g.,* Montana DNRC 2025, entire). The conservation commitments of the plan were officially added into the State's Administrative Rules for Forest Management in 2021, including the Lynx Conservation Strategy. The Lynx Conservation Strategy minimizes impacts of forest management activities on lynx and lynx critical habitat associated with the HCP, while allowing Montana DNRC to meet its fiduciary and stewardship trust responsibilities. Montana DNRC requested that lands subject to the HCP be excluded from critical habitat.

The goal of the Lynx Conservation Strategy is to support Federal lynx conservation efforts by managing for habitat elements important to lynx and their prey that contribute to the landscape-scale occurrence of lynx. HCP commitments in the strategy are associated with two types of habitat areas: (1) lynx habitat on lands within the HCP, and (2) lynx habitat on specific LMA subunits of HCP lands where resident lynx are known to occur or likely to occupy the area periodically. The HCP includes specific objectives to achieve this goal:

(1) Minimize potential for disturbance to known den sites;

(2) Map potential lynx winter foraging, summer foraging, and temporarily non-suitable habitats;

(3) Retain coarse woody debris and other denning attributes;

(4) Limit conversion of suitable lynx habitat to temporarily nonsuitable habitat per decade in LMAs;

(5) Ensure adequate amounts of foraging habitat are maintained in LMAs;

(6) Provide for habitat connectivity where vegetation and ownership patterns allow; and

(7) Maintain suitable lynx habitat on Montana DNRC scattered parcels outside LMAs (Montana DNRC and USFWS 2010b as amended, pp. 2–46–2–61).

The Lynx Conservation Strategy places an additional conservation emphasis on geographic areas most likely to remain high-priority areas to promote lynx conservation into the future (Montana DNRC and USFWS 2010b as amended, p. 2–53). These HCP lands occur in primary lynx habitat types, which are likely to provide snow depths and the vegetation species compositions necessary for preferred winter foraging conditions as well as ensure that the HCP helps support Federal efforts to provide adequate amounts of suitable lynx habitat. It also describes how Montana DNRC will monitor and evaluate the implementation and effectiveness of the HCP (Montana DNRC and USFWS 2010b as amended, pp. 4–27–4–37). Prior to the HCP, Montana DNRC had been managing for lynx diligently for over a decade under existing ARMs. The HCP and the ARMs will ensure that habitat features important for the conservation of lynx will occur on Montana DNRC's HCP-managed lands long term.

In the 2014 final revised critical habitat designation (79 FR 54782; September 12, 2014), we determined that the benefits of excluding lands managed in accordance with the Montana DNRC HCP outweighed the benefits of including them in the designation, and that doing so would not result in extinction of the species. We reaffirm that determination in this rule based on the analysis below.

Benefits of Inclusion—

On Montana DNRC HCP State lands, it is relatively infrequent for an action with a Federal nexus that triggers consultation under section 7 of the Act to occur; therefore, little benefit would be realized through section 7 consultation if these lands were included in the critical habitat designation. Some educational benefits of designating critical habitat for lynx on Montana DNRC HCP-managed lands may exist; however, we believe there is already substantial awareness of lynx conservation issues because of the following: lynx are listed under the Act and addressed by Montana State law, the public review process for the Montana DNRC HCP, Montana DNRC's forest management alignment with the recovery plan (Service 2024, entire), and lynx and snowshoe hare research and surveys being conducted by various entities within the state of Montana.

Benefits of Exclusion—

The Montana DNRC HCP provides substantial protection of features essential to the conservation of lynx on HCP-managed lands and provides a greater level of lynx management on these State lands than would be achieved with designation of critical habitat. Because the HCP provides lynx-specific objectives and strategies for different geographic locations, guidelines to meet the objectives, and monitoring to evaluate implementation and effectiveness, the measures contained in the HCP exceed any measures that might result from critical habitat designation. As a result, we do not anticipate any actions on these lands that would reduce the landscape-scale availability of important lynx and hare habitats or would otherwise diminish the conservation value of these lands to the lynx DPS.

The exclusion of Montana DNRC HCP-managed lands from critical habitat would help preserve the partnerships that have developed between the Service and the State through development and implementation of the HCP, the existing ARMs, and the intent of the State Forest Land Management Plan, all of which provide for long-term lynx conservation. Requiring additional redundant processes of permit applicants/holders who have already undergone an extensive Federal process to apply for a permit also appreciably undermines the benefit of HCPs for cooperators and reduces the certainty otherwise provided by a single clear plan.

Benefits of Exclusion Outweigh the Benefits of Inclusion—

We have evaluated the exclusion of approximately 179 mi^2 (463 km^2) of lands managed by the Montana DNRC in accordance with the HCP. We have determined that it is unlikely that including these HCP-managed areas in the final designation would lead to any changes in Montana DNRC management (*i.e.,* no additional conservation measures would be recommended to further avoid impacts to lynx and hare habitats); therefore, the benefits of inclusion are low.

We find that few, if any, additional conservation benefits would be realized through section 7 of the Act because activities with a Federal nexus are infrequent on these State lands. Additionally, the habitat conservation measures addressing the features essential to conservation of lynx are already being implemented on Montana DNRC lands under the HCP, have been demonstrated to be effective, will be in place until at least 2061, and are providing for the maintenance and protection of the PBFs essential to the conservation of the lynx DPS.

Therefore, we have determined that the benefits of excluding lands managed in accordance with the Montana DNRC HCP in Unit 3 outweigh the benefits of including these lands as critical habitat. Based on the above considerations, and consistent with the direction provided in section 4(b)(2) of the Act, we find that greater benefits to lynx are likely to be achieved by excluding Montana DNRC HCP lands from the final designation rather than by including them.

Exclusion Will Not Result in Extinction of the Species—

The Montana DNRC HCP (1) provides biologically meaningful and quantifiable measures for the long-term conservation of lynx and the PBFs essential to the species, (2) includes long-term certainty of implementation, (3) employs rigorous monitoring and reporting requirements, and (4) applies an adaptive management approach. Therefore, it is our determination that the exclusion of Montana DNRC HCP lands from critical habitat will not result in the extinction of the lynx DPS. We therefore exclude 179 mi^2 (463 km^2) of lands managed in accordance with the Montana DNRC HCP from Unit 3 of this final revised lynx critical habitat designation.

Non-Permitted Conservation Plans, Agreements, or Partnerships

Shown below is a non-exhaustive list of factors that we consider in evaluating how non-permitted plans or agreements affect the benefits of inclusion or exclusion. These are not required elements of plans or agreements. Rather, they are some of the factors we may consider, and not all of these factors apply to every plan or agreement. We also consider information provided by proponents of an exclusion on the non-permitted plan or agreement.

(i) The degree to which the record of the plan, or information provided by proponents of an exclusion, supports a conclusion that a critical habitat designation would impair the realization of the benefits expected from the plan, agreement, or partnership.

(ii) The extent of public participation in the development of the conservation plan.

(iii) The degree to which there has been agency review and required determinations (*e.g.,* State regulatory requirements), as necessary and appropriate.

(iv) Whether National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*) was required.

(v) The demonstrated implementation and success of the chosen mechanism.

(vi) The degree to which the plan or agreement provides for the conservation of the physical or biological features that are essential to the conservation of the species.

(vii) Whether there is a reasonable expectation that the conservation management strategies and actions contained in a management plan or agreement will be implemented.

(viii) Whether the plan or agreement contains a monitoring program and adaptive management to ensure that the conservation measures are effective and can be modified in the future in response to new information.

The proposed critical habitat designation included areas that are covered by the following non-permitted plans providing for the conservation of the Canada lynx: (1) State of Montana Department of Fish, Wildlife, and Parks Wildlife Management Areas (MTFWP WMAs); (2) WDNR) Lynx Habitat Management Plan for DNR-managed Lands (WDNR LHMP); (3) Green Diamond Resource Company lands; and (4) Idaho State Trust lands.

MTFWP WMAs

The MTFWP manages multiple state-owned WMAs across the state of Montana. These WMAs are managed with wildlife and wildlife habitat conservation as the priority. Six WMAs are within the proposed critical habitat boundary, including Nevada Lake, North Swan Valley, Fish Creek, Blackfoot-Clearwater, Marshal Creek, and Bad Rock Canyon WMAs. Each WMA has a specific management plan that includes management strategies to benefit the diversity of wildlife species and their habitats, including Canada lynx. The state manages the WMAs with the goal of providing wildlife habitat. Some of the WMAs have seasonal

closures that restrict public access to the WMA during the winter and spring, which allows for undisturbed habitat during the breeding season for lynx and during winter and early spring when food sources are most limited. The Marshal Creek WMA, sits in the heart of some of the best lynx habitat in Montana (Olson et al. 2021, entire), and it has supported multiple reproductively successful female lynx (Kosterman et al. 2018, entire) and regular occupancy (Southwestern Crown Carnivore Monitoring Team 2023, p. 25–26) under the State's management. Management goals for the Marshal Creek WMA include permanently protecting and restoring critical wildlife habitat, and forest management projects are designed to recruit, enhance, and maintain multistoried mature mesic and boreal forest stands, which provides benefits to lynx (MTFWP 2010, entire). The Blackfoot-Clearwater WMA (BCWMA) has been managed by FWP since 1948 and has continued to support habitat for primarily big game but also for Canada lynx and other native species since that time (MTFWP 1989, 2025, entire). A recent forest management project proposed on the BCWMA was designed to reduce fuels and promote forest health and will result in overall benefits to lynx habitat. Other WMAs also provide habitat for lynx, and the MTFWP often confers with the Service regarding lynx management when planning land management projects in the WMAs. MTFWP requested that lands in the WMAs be excluded from critical habitat.

Benefits of Inclusion—

On MTFWP WMAs, it is relatively infrequent for an action with a Federal nexus that triggers consultation under section 7 of the Act to occur; therefore, little benefit would be realized through section 7 consultation if these lands were included in the critical habitat designation. Minimal educational benefits of designating critical habitat for lynx on MTFWP WMAs may exist. We believe there is already substantial awareness of lynx conservation issues because of the following: lynx are listed under the Act; the public review process MTFWP must undertake for habitat management activities that MTFWP proposes to conduct on its WMAs, including compliance with the Montana Environmental Protection Act (MEPA); the MTFWP's inclusion of lynx conservation considerations in their State Wildlife Action Plan (MTFWP, in prep); and lynx and snowshoe hare research and surveys being conducted by various entities within the state of Montana, including lynx occupancy surveys conducted by MTFWP.

Benefits of Exclusion—

The MTFWP's management that specifically prioritizes habitat for wildlife on WMAs provides a greater level of management for the lynx on these State lands than would be achieved with designation of critical habitat. Since WMAs are already under active management for wildlife habitat conservation, adding them to the critical habitat designation would be redundant and would not provide additional conservation benefits. While the consultation requirement associated with critical habitat on WMAs would only be triggered if there was a Federal nexus, such review would add little benefit, and it would require the use of resources to ensure regulatory compliance that could otherwise be used for on-the-ground management of targeted listed or sensitive species. Therefore, the benefits of exclusion include the reduction of administrative costs of section 7 compliance in the event that the MTFWP is conducting management actions on WMAs that have a Federal nexus that would trigger section 7 consultation, eliminating the need for a separate analysis of the effects of an action on lynx habitat.

Benefits of Exclusion Outweigh the Benefits of Inclusion—

We have evaluated the exclusion of approximately 43 mi^2 (113 km^2) of lands managed by the MTFWP as WMAs. We have determined that it is unlikely that including these areas in the final designation would lead to any changes in MTFWP management, as they manage these lands to conserve fish, wildlife, and plants and their habitats. Exclusion of these lands will not increase the likelihood that management activities would be proposed which would appreciably diminish the value of the habitat for the conservation of the species. Designation of critical habitat on WMAs would provide redundant, but no additional increment of conservation value for lynx in terms of management emphasis or public recognition or education by the MTFWP beyond what currently exists. We find that few, if any, additional conservation benefits would be realized through section 7 of the Act, because activities with a Federal nexus are infrequent on these State lands.

Therefore, we have determined that the benefits of excluding MTFWP WMAs outweigh the benefits of including these lands as critical habitat. Based on the above considerations, and consistent with the direction provided in section 4(b)(2) of the Act, we find that greater benefits to lynx are likely to be achieved by excluding MTFWP WMAs from the final designation rather than by including them.

Exclusion Will Not Result in Extinction of the Species—

The MTFWP WMAs represent a fraction of a percent of the lands with the PBFs necessary to support the lynx DPS. MTFWP's wildlife-focused management assures long-term certainty of adaptive management that benefits wildlife habitat by the state wildlife management agency. Therefore, it is our determination that the exclusion of MTFWP WMAs from critical habitat will not result in the extinction of the lynx DPS. We therefore exclude 43 mi^2 (113 km^2) of MTFWP WMAs from this final revised lynx critical habitat designation.

WDNR Lynx Habitat Management Plan for DNR-Managed Lands (WDNR LHMP)

The WDNR LHMP encompasses 197 mi^2 (510 km^2) of WDNR-managed lands distributed throughout north-central and northeastern Washington in areas delineated as Lynx Management Zones in the Washington State Lynx Recovery Plan (Stinson 2001, p. 39; WDNR 2006, pp. 5–13). Of the area covered by the plan, 166 mi^2 (430 km^2) overlaps the area proposed as critical habitat. The WDNR LHMP was finalized in 2006 and is a revision of the 1996 WDNR lynx plan. The 1996 plan was developed as a substitute for a species-specific state critical habitat designation required by Washington Forest Practices rules in response to the lynx being State-listed as threatened (WDNR 2006, p. 5). The 2006 WDNR LHMP included further provisions to avoid the incidental take of lynx (WDNR 2006, p. 6). WDNR is committed to following the LHMP until 2076, or until the lynx is delisted (WDNR 2006, p. 6). WDNR requested that lands subject to the LHMP be excluded from critical habitat.

The WDNR LHMP contains measures to guide WDNR in creating and preserving quality lynx habitat through its forest management activities. The objectives and strategies of the LHMP are developed for multiple planning scales (ecoprovince and ecodivision, Lynx Management Zone, Lynx Analysis Unit (LAU), and ecological community), and include:

(1) Encouraging genetic integrity at the species level by preventing bottlenecks between British Columbia and Washington by limiting size and shape of temporary non-habitat along the border and maintaining major routes of dispersal between British Columbia and Washington;

(2) Maintaining connectivity between subpopulations by maintaining

dispersal routes between and within zones and arranging timber harvest activities that result in temporary non-habitat patches among watersheds so that connectivity is maintained within each zone;

(3) Maintaining the integrity of requisite habitat types within individual home ranges by prolonging the persistence of snowshoe hare habitat that provides lynx forage and retaining coarse woody debris that provides denning habitat; and

(4) Maintaining connectivity between and integrity within home ranges used by individuals and/or family groups by providing a diversity of successional stages within each LAU and connecting denning sites and foraging sites with forested cover without isolating them with open areas by prolonging the persistence of snowshoe hare habitat and retaining coarse woody debris for denning sites (WDNR 2006, p. 29).

The LHMP identifies specific guidelines to achieve the objectives and strategies at each scale; it also describes how WDNR will monitor and evaluate the implementation and effectiveness of the LHMP (WDNR 2006, pp. 29–63). In response to several wildfires that reduced the availability of suitable lynx habitat in the Okanogan Lynx Management Zone, WDNR developed the Okanogan Lynx Management Zone Interim Management Guidelines and Recommendations (WDNR 2008, entire) to protect the remaining lynx habitat and assure no net loss of quality foraging habitat as a result of timber management activities. The Okanogan guidelines are considered a modification of the 2006 LHMP that will be implemented until WDNR, in conjunction with the Service and WDFW, have determined they are no longer necessary as additional conservation measures. WDNR has been managing for lynx for almost three decades, and lynx continue to be detected on and around the WDNR lands. A review of the WDNR monitoring report sent to the Service in March of 2025 demonstrates the WDNR has been following the LHMP (WDNR 2025, entire). The Service has concluded that the management strategies implemented are effective but could potentially be updated to incorporate newer science. The WDNR has committed to working with the Service to review newer science and determine what, if any, changes need to be made to the LHMP. They have committed to completing any updates to the LHMP by 2028 (Crump, C. in litt. 2025).

In the 2014 final revised critical habitat designation, (79 FR 54782; September 12, 20214), we determined that the benefits of excluding lands managed in accordance with the WDNR LHMP outweighed the benefits of including them in the designation, and that doing so would not result in extinction of the species. We reaffirm that determination in this rule based on the analysis below.

Benefits of Inclusion—

On WDNR State lands, it is uncommon for an action with a Federal nexus that triggers consultation under section 7 of the Act to occur; therefore, little benefit would be realized through section 7 consultation if these lands were included in the designation. Some educational benefits to designating critical habitat for lynx on WDNR-managed lands may exist; however, we believe there is already substantial awareness of lynx conservation issues because lynx are listed both under the Act and Washington State law; the public review process for the WDNR LHMP and the Washington State Lynx Recovery Plan (Stinson 2001, entire); lynx and snowshoe hare research that has been or is being conducted by the USFS Pacific Northwest Research Station, Washington State University, University of Washington, University of Montana, and Home Range Wildlife Research; and surveys that have been or are being conducted by WDNR, WDFW and the USFS.

Benefits of Exclusion—

The WDNR LHMP has provided substantial protection of features essential to the conservation of lynx on WDNR lands and has provided a greater level of lynx management on these State lands than would be achieved with the designation of critical habitat. Because the LHMP provides lynx-specific objectives and strategies for different planning scales, guidelines to meet the objectives, and monitoring to evaluate implementation and effectiveness, the measures contained in the WDNR LHMP exceed any measures that might result from critical habitat designation. As a result, we do not anticipate any actions on these lands that would destroy or adversely modify habitats essential to the conservation of the lynx DPS. The exclusion of WDNR lands from critical habitat would help preserve the partnerships that we have developed with the State of Washington through development and implementation of the 2006 LHMP and the original 1996 lynx plan, both of which provide for long-term lynx conservation.

Benefits of Exclusion Outweigh the Benefits of Inclusion—

We evaluated the exclusion of approximately 166 mi^2 (430 km^2) of lands managed by the WDNR. Including WDNR lands managed in accordance with the LHMP in the final designation would not lead to additional conservation measures being implemented because WDNR already manages in a way that provides benefits for lynx and snowshoe hare habitat; therefore, the benefits of inclusion are low. We find that few additional conservation benefits would be realized through section 7 of the Act because actions on these State lands rarely have a Federal nexus. The habitat conservation measures addressing the features essential to the conservation of lynx are already being implemented on WDNR lands under the WDNR LHMP, have a proven record of effectiveness, will be in place until at least 2076, and are providing for those PBFs essential to the conservation of lynx.

Therefore, we have determined that the benefits of excluding lands managed in accordance with the WDNR LHMP in Unit 4 outweigh the benefits of including these lands as critical habitat. Based on the above considerations, and consistent with the direction provided in section 4(b)(2) of the Act, we find that greater benefits to lynx are likely to be achieved by excluding WDNR LHMP lands from the final designation rather than by including them.

Exclusion Will Not Result in Extinction of the Species—

We have determined that the exclusion of lands managed in accordance with the WDNR LHMP from Unit 4 of this final revised critical habitat designation for the lynx DPS will not result in the extinction of the species because the WDNR LHMP provides for the conservation of lynx and the PBFs essential to the conservation of lynx. The jeopardy standard of section 7(a)(2) of the Act and routine implementation of conservation measures through the section 7 process also provide assurances that the subspecies will not go extinct. The protections afforded to the lynx under the jeopardy standard will remain in place for the areas excluded from revised critical habitat. We therefore exclude 166 mi^2 (430 km^2) of lands managed in accordance with the WDNR LHMP from Unit 4 of this final revised lynx critical habitat designation.

Green Diamond Resource Company Lands

The Green Diamond Resource Company (hereafter Green Diamond) is a family-owned business that owns and manages over 2,500 mi^2 (6,475 km^2) of land in California, Oregon, Washington, and Montana. Approximately 7 mi^2 (18

km²) of the proposed critical habitat overlaps Green Diamond lands in Montana in Unit 3. Green Diamond has a long history of developing and implementing long-term habitat and species conservation plans to guide its forest management practices. Green Diamond lands in northwestern Montana that overlap the tier 1 polygon are all under a permanent conservation easement that precludes development and protects wildlife habitat in perpetuity. The easement was completed in early 2025 through the Montana Great Outdoors Conservation Easement with MTFWP. This preclusion of development is particularly beneficial for maintaining the integrity of ecosystems that support lynx prey and other ecological functions. In the event the lands are sold, the easement stays with the land, ensuring conservation in perpetuity. The easement allows landowners to sustainably harvest wood products from the timberlands, and Green Diamond's lands are independently certified as sustainably managed under Sustainable Forestry Initiative (SFI) standards. The SFI mission is to promote sustainable forest management and conserve water quality, biodiversity, wildlife habitat, species at risk, and forests with exceptional conservation value. Green Diamond also manages its lands under an HCP designed to conserve native fishes until 2030. While not lynx-specific, the HCP provides incidental benefits for lynx by ensuring considerable riparian protection that provides dense forest for foraging and travel. Additionally, the HCP, conservation easement, and SFI certification demonstrate Green Diamond's commitment to conservation and offer incidental protections for lynx and their habitat.

Benefits of Inclusion—

The principal benefit of including an area in a critical habitat designation is the requirement of Federal agencies to ensure that actions they fund, authorize, or carry out are not likely to result in the destruction or adverse modification of any designated critical habitat, which is one of the regulatory standards of section 7(a)(2) of the Act, under which consultation is completed. A critical habitat designation may provide a regulatory benefit for lynx when there is a Federal nexus present for a project that may affect critical habitat; however, as Green Diamond lands are private property and consultations are expected to be rare, critical habitat is expected to have little effect due to the lack of a Federal nexus. Thus, the regulatory benefit is limited and dependence on private conservation actions is more important.

Another important benefit of including lands in a critical habitat designation is that it can serve to educate landowners, agencies, Tribes, and the public regarding the potential conservation value of an area and may help focus conservation efforts on areas of high value for certain species. Some educational benefits to designating critical habitat for lynx on Green Diamond lands may exist; however, we believe there is already substantial awareness of lynx conservation issues since lynx have been listed under the Act since 2000 and through the past critical habitat rules that designated critical habitat for the species on the lands now owned by Green Diamond, who purchased the lands knowing they were designated critical habitat. As a result, the educational value of the designation is minimal.

Benefits of Exclusion—

The benefits of excluding Green Diamond lands from the designation of critical habitat are substantial. The area will continue to provide conservation value to the species by continuing and strengthening our effective working relationship with Green Diamond to promote voluntary, proactive conservation and recovery of the lynx and its habitat on their lands. Green Diamond has indicated to the Service a desire to renew and expand the HCP that currently covers native fish and is valid until 2030, including an interest in adding lynx and other listed species to the HCP, which would cover roughly 453 mi² (1,173 km²) of Green Diamond lands in Montana. Excluding the Green Diamond lands from the critical habitat designation would minimize any additional review of future projects if there is a Federal nexus, and encourage voluntary conservation measures such as the HCP, conservation easement, and SFI certification. The exclusion may also serve to encourage other private landowners to pursue voluntary conservation measures that benefit lynx and other listed species in the future.

Benefits of Exclusion Outweigh the Benefits of Inclusion—

We evaluated the exclusion of approximately 7 mi² (18 km²) of Green Diamond lands. Including Green Diamond lands in the final designation would likely not lead to any changes in Green Diamond management (to further avoid destroying or adversely modifying that habitat), and therefore, the benefits of inclusion are low. We find that few additional conservation benefits would be realized through section 7 of the Act, because actions on these private lands rarely have a Federal nexus. Recognizing the contributions of private landowners committed to sustainable forest management, and the substantial value of conservation easements that benefit wildlife species and their habitat, not only aligns with the conservation goals of the Service but also strengthens partnerships with private stakeholders. The Green Diamond lands, managed under voluntary conservation efforts, are providing for those PBFs essential to the conservation of the species.

Therefore, we have determined that the benefits of excluding lands owned and managed by Green Diamond in Unit 3 outweigh the benefits of including these lands as critical habitat. Based on the above considerations, and consistent with the direction provided in section 4(b)(2) of the Act, we find that greater benefits to lynx are likely to be achieved by excluding Green Diamond lands from the final designation rather than by including them.

Exclusion Will Not Result in Extinction of the Species—

We have determined that the exclusion of Green Diamond lands from Unit 3 of this final revised critical habitat designation for the lynx DPS will not result in the extinction of the species because the voluntary conservation easement and Green Diamond's conservation-focused management provide for the conservation of the species and the PBFs essential to it and because the amount of land excluded is a fraction of a percent of the overall area identified as critical habitat for the lynx DPS. The jeopardy standard of section 7(a)(2) of the Act, and routine implementation of conservation measures through the section 7 process, also provide assurances that the species will not go extinct. The protections afforded to the lynx under the jeopardy standard will remain in place for the areas excluded from revised critical habitat. We therefore exclude 7 mi² (18 km²) of lands owned by Green Diamond Resource Company in Unit 3 of this final revised lynx critical habitat designation.

Tribal Lands

Several E.O.s, Secretary's Orders (S.O.s), and policies concern working with Tribes. These guidance documents generally confirm our trust responsibilities to Tribes, recognize that Tribes have sovereign authority to control Tribal lands, emphasize the importance of developing partnerships with Tribal governments, and direct the Service to consult with Tribes on a government-to-government basis.

A joint S.O. that applies to both the Service and the NMFS—S.O. 3206, *American Indian Tribal Rights, Federal–Tribal Trust Responsibilities, and the Endangered Species Act* (June 5, 1997)—is the most comprehensive of the various guidance documents related to Tribal relationships and Act implementation, and it provides the most detail directly relevant to the designation of critical habitat. In addition to the general direction discussed above, the appendix to S.O. 3206 explicitly recognizes the right of Tribes to participate fully in any listing process that may affect Tribal rights or Tribal trust resources; this includes the designation of critical habitat. Section 3(B)(4) of the Appendix requires us to consult with affected Tribes ''when considering the designation of critical habitat in an area that may impact Tribal trust resources, Tribally owned fee lands, or the exercise of Tribal rights.'' That provision also instructs the Service to avoid including Tribal lands within a critical habitat designation unless the area is essential to conserve a listed species, and it requires the Service to ''evaluate and document the extent to which the conservation needs of the listed species can be achieved by limiting the designation to other lands.''

Our implementing regulations at 50 CFR 424.19 and the 2016 Policy are consistent with S.O. 3206. When we undertake a discretionary exclusion analysis, in accordance with S.O. 3206, we consult with any Tribe whose Tribal trust resources, Tribally-owned fee lands, or Tribal rights may be affected by including any particular areas in the designation, and we evaluate the extent to which the conservation needs of the species can be achieved by limiting the designation to other areas. When we undertake a discretionary 4(b)(2) exclusion analysis, we always consider exclusion of Tribal lands, and give great weight to Tribal concerns in analyzing the benefits of exclusion.

However, S.O. 3206 does not override the Act's statutory requirement of designation of critical habitat. As stated above, we must consult with any Tribe when a designation of critical habitat may affect Tribal lands or resources. The Act requires us to identify areas that meet the definition of ''critical habitat'' (*i.e.,* areas occupied at the time of listing that contain the essential physical or biological features that may require special management considerations or protection and unoccupied areas that are essential to the conservation of a species), without regard to land ownership. While S.O. 3206 provides important direction, it expressly states that it does not modify the Secretaries' statutory authority under the Act or other statutes.

Flathead Indian Reservation and Blackfeet Reservation Lands

Areas proposed for critical habitat designation overlap with Tribal lands in Unit 3 including 186 mi² (482 km²) of lands on the Flathead Indian Reservation and 44 mi² (113 km²) on the Blackfeet Indian Reservation. We communicated with representatives for the Confederated Salish and Kootenai Tribes (CSKT) of the Flathead Nation and the Blackfeet Tribe, all of whom expressed a desire for their lands to be excluded from the final critical habitat designation.

In the previous final rules designating revised critical habitat for lynx, published in the **Federal Register** on February 25, 2009 (74 FR 8616) and September 12, 2014 (79 FR 54782), we determined that the benefits of excluding Flathead Indian Reservation Lands outweighed the benefits of including them. We determined that exclusion of these Tribal lands from the designation of critical habitat for the lynx will not result in the extinction of the species because the CSKT implement programs for the conservation of the species, and physical and biological features essential to it, in occupied areas. The protections afforded to the lynx under the jeopardy standard will remain in place for the areas considered for exclusion from revised critical habitat. Therefore, and in light of S.O. 3206 and Tribal management of lynx and their habitat, we are excluding 186 mi² (482 km²) of Flathead Indian Reservation Lands from the revised lynx critical habitat designation. Previous rules did not consider excluding any Blackfeet Reservation lands, as these were only identified as meeting the definition of critical habitat in the more recent habitat models (Olson et al. 2021, entire; Squires et al. 2024, entire) and identified as part of the tier 1 areas by the WLBT (WLBT 2022, entire).

Benefits of Inclusion—

The principal benefit of including an area in a critical habitat designation is the requirement of Federal agencies to ensure that actions that they fund, authorize, or carry out are not likely to result in the destruction or adverse modification of any designated critical habitat, which is one of the regulatory standards of section 7(a)(2) of the Act under which consultation is completed. Although the CSKT and Blackfeet Tribes are not Federal agencies, some actions taken by the Tribes may have a Federal nexus if they fall under the jurisdiction of the Bureau of Indian Affairs (BIA) due to Federal funding or authorization or because actions are occurring on lands held in trust for the Tribe.

We have provided the Tribes and the BIA with technical assistance on project implementation and conducted informal consultations with agencies implementing, funding, or authorizing actions on Tribal lands. We have conducted one formal consultation with the BIA related to lynx, a framework programmatic consultation for the Blackfeet Forest Management Plan that concluded some future forest management activities on the Blackfeet lands may result in short-term adverse effects to lynx due to habitat modifications, but they will not likely jeopardize the continued existence of the species. In fact, the forest management actions may provide benefits to lynx habitats by reducing the risk of catastrophic wildfire and creating a mosaic of forest structural stages. Because both tribes practice land management and prioritize conservation, we do not anticipate an increase in section 7 consultations in the future and, as a result, the regulatory benefit of critical habitat would be minimal.

Another potential benefit of critical habitat designation would be to signal the importance of these lands to Tribal governments, Federal agencies, scientific organizations, State and local governments, and the public to encourage conservation efforts, funding, or research to benefit the lynx and its habitat. By publication of the proposed rule and this final rule, we are educating the public of the location of core lynx habitat and areas most important for the conservation and recovery of the lynx DPS. Given that lynx have been listed and researched in these areas for over two decades and given that the habitat mapping efforts have already informed the public and Tribes about the value of these areas and helped to focus potential conservation actions, the educational benefits from designating critical habitat on Tribal-owned or -managed Lands would be small.

Benefits of Exclusion—

Under self-governance, the CSKT and Blackfeet Nation Tribes maintain their own high conservation standards and their own Wildlife Management divisions. According to their mission statement, the CSKT's Wildlife Management Program is charged with the protection, enhancement and management of terrestrial wildlife species and habitats to provide for viable populations of all wildlife species, and the Program actively engages in partnerships and research to benefit wildlife species and their

habitats. Additionally, most of the high-quality lynx habitat on the Flathead Reservation occurs in areas with formal protective status, including (1) The long-designated Mission Mountains and Rattlesnake Tribal Wilderness Areas, which are largely roadless and managed for wilderness qualities; (2) the South Fork/Jocko Primitive Area, which is open to use only by Tribal members and in which commercial timber harvest is prohibited. The Blackfeet Tribe's Fish and Wildlife Department has proven to be a model of professional wildlife management in the region through a variety of programs, services, research, meaningful collaborations and projects. The Forest Management Plan includes considerations for mapped lynx habitat for the next 15 years, including a variety of forestry practices to promote a mosaic of structural stages, and the Tribe recognizes the conservation measures from the Canada Lynx Conservation Assessment and Strategy (ILBT 2013, entire) to incorporate into planned forest management activities.

Tribal lands that fall within the proposed critical habitat are small in size relative to the large landscape required to sustain the lynx populations in these areas. Although these Tribal lands support lynx habitat and the PBFs, they have a smaller role in lynx conservation compared to the extensive National Forest lands in the western United States. Due to Tribal natural resource management philosophies, plans, and practices that are already in place on Tribal lands (*e.g.,* Blackfeet Forest Management Plan 2024, Confederated Salish and Kootenai Forest Management Plans 1999 and 2005), it is highly unlikely that activities approaching the threshold of adverse modification would occur.

The Tribes have a long history of professional wildlife management and conservation. The designation of critical habitat on their lands would be considered an unwanted intrusion into Tribal self-governance, thus compromising the government-to-government relationship essential to achieving our mutual goal of managing for healthy ecosystems upon which the viability of threatened and endangered species populations depend. It is unlikely that additional benefits to lynx would result from designating these lands as critical habitat.

S.O. 3206, ''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act'' (June 5, 1997) states that, ''critical habitat shall not be designated in such areas unless it is determined essential to conserve a listed species.'' The President's memorandum of April 29, 1994, ''Government-to- Government Relations with Native American Tribal Governments'' (59 FR 22951); E.O. 13175 (''Consultation and Coordination with Indian Tribal Governments''), and the relevant provision of the Departmental Manual of the Department of the Interior (512 DM 2) also emphasize that Tribal lands should be evaluated to determine whether their inclusion in a critical habitat designation is essential to the species. Therefore, we believe that fish, wildlife, and other natural resources on Tribal lands are better managed under Tribal authorities, policies, and programs than through Federal regulation wherever possible and practicable.

Benefits of Exclusion Outweigh the Benefits of Inclusion—

Exclusion of Tribal lands is warranted because affected Tribes already take actions to avoid negative impacts to lynx and to conserve habitat. In discussions with each of the Tribes, we heard them voicing their commitment to ensuring that lynx remain a viable part of the ecosystem.

We have determined that conservation of lynx can be achieved on Tribal lands within the critical habitat units through the continuation of the cooperative partnerships between the Service and the Tribes, and without designating them as critical habitat. The management plans, activities, and land-use designations being implemented on Tribal lands described above are likely to ensure continued conservation of lynx on Tribal lands. Given the importance of government-to-government relationship with Tribes, the benefit of maintaining our commitment to the E.O. by excluding these lands outweighs the benefit of including them in critical habitat. Therefore, pursuant to section 4(b)(2) of the Act, we have excluded Tribal lands in Unit 3 in this final rule from critical habitat for the lynx DPS.

Exclusion Will Not Result in Extinction of the Species—

We have determined that exclusion of Tribal lands from the designation of critical habitat for the lynx will not result in the extinction of the species because the Confederated Salish and Kootenai Tribes and Blackfeet Tribe implement natural resource and wildlife management programs that ensure conservation of the species, and the physical and biological features essential to it, in occupied areas. Additively, the Tribal lands excluded from critical habitat comprise 230 mi^2 (595 km^2), which is approximately 1 percent of the total critical habitat proposed in the western United States (Units 3, 4, 5, and 6). The protections afforded to lynx under the jeopardy standard will remain in place for the areas considered for exclusion from revised critical habitat. Therefore, in light of S.O. 3206 and Tribal management of lynx and their habitat, 186 mi^2 (482 km^2) of lands on the Flathead Indian Reservation and 44 mi^2 (113 km^2) on the Blackfeet Indian Reservation lands have been excluded from lynx critical habitat designation in this final rule.

Summary of Exclusions

As discussed above, based on the information provided by entities seeking exclusion, as well as any additional public comments received, we evaluated whether certain lands in the proposed critical habitat were appropriate for exclusion from this final designation pursuant to section 4(b)(2) of the Act. We are excluding the following areas from critical habitat designation for the Canada lynx: lands covered by the Montana DNRC HCP, lands covered by the Washington DNR Lynx Habitat Management Plan, Green Diamond Resource lands, and Tribal lands of the Flathead Reservation and Blackfeet Reservation.

TABLE 2—AREAS EXCLUDED FROM CRITICAL HABITAT DESIGNATION BY CRITICAL HABITAT UNIT

Unit	Specific area	Areas meeting the definition of critical habitat excluded, in square miles (mi^2) (square kilometers (km^2))
3. Northern Rockies ..	Tribal Lands: Flathead Reservation, MT	186 (482)
3. Northern Rockies ..	Tribal Lands: Blackfeet Reservation, MT	44 (113)
3. Northern Rockies ..	Montana DNRC Multi-species HCP	179 (463)
3. Northern Rockies ..	Montana Fish Wildlife & Parks Wildlife Management Areas	43 (113)
3. Northern Rockies ..	Green Diamond Resources	7 (18)

TABLE 2—AREAS EXCLUDED FROM CRITICAL HABITAT DESIGNATION BY CRITICAL HABITAT UNIT—Continued

Unit	Specific area	Areas meeting the definition of critical habitat excluded, in square miles (mi^2) (square kilometers (km^2))
4. North Cascades	Washington DNR Lynx Habitat Management Plan	166 (430)
Total	.....	625 (1,619)

Required Determinations

Regulatory Planning and Review (E.O.s 12866, 13563, 14192)

E.O. 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the OMB will review all significant rules as defined by section 3(f) of E.O. 12866. OIRA has determined that this final rule is significant under E.O. 12866.

E.O. 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the Nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. E.O. 13563 directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements This final rule is considered an E.O. 14192 deregulatory action.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA; title II of Pub. L. 104–121, March 29, 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the RFA to require Federal agencies to provide a certification statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities.

According to the Small Business Administration, small entities include small organizations such as independent nonprofit organizations; small governmental jurisdictions, including school boards and city and town governments that serve fewer than 50,000 residents; and small businesses (13 CFR 121.201). Small businesses include manufacturing and mining concerns with fewer than 500 employees, wholesale trade entities with fewer than 100 employees, retail and service businesses with less than $5 million in annual sales, general and heavy construction businesses with less than $27.5 million in annual business, special trade contractors doing less than $11.5 million in annual business, and agricultural businesses with annual sales less than $750,000. To determine whether potential economic impacts to these small entities are significant, we considered the types of activities that might trigger regulatory impacts under this designation as well as types of project modifications that may result. In general, the term ''significant economic impact'' is meant to apply to a typical small business firm's business operations.

Under the RFA, as amended, and as understood in light of recent court decisions, Federal agencies are required to evaluate the potential incremental impacts of rulemaking on those entities directly regulated by the rulemaking itself; in other words, the RFA does not require agencies to evaluate the potential impacts to indirectly regulated entities. The regulatory mechanism through which critical habitat protections are realized is section 7 of the Act, which requires Federal agencies, in consultation with the Service, to ensure that any action authorized, funded, or carried out by the agency is not likely to destroy or adversely modify critical habitat. Therefore, under section 7, only Federal action agencies are directly subject to the specific regulatory requirement (avoiding destruction and adverse modification) imposed by critical habitat designation. Consequently, only Federal action agencies will be directly regulated by this designation. The RFA does not require evaluation of the potential impacts to entities not directly regulated. Moreover, Federal agencies are not small entities. Therefore, because no small entities will be directly regulated by this rulemaking, we certify that this critical habitat designation will not have a significant economic impact on a substantial number of small entities.

During the development of this final rule, we reviewed and evaluated all information submitted during the comment period on the proposed rule (89 FR 94656; November 29, 2024) that may pertain to our consideration of the probable incremental economic impacts of this critical habitat designation. Based on this information, we affirm our certification that this critical habitat designation will not have a significant economic impact on a substantial number of small entities, and a regulatory flexibility analysis is not required.

Energy Supply, Distribution, or Use (E.O. 13211)

E.O. 13211 (''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'') requires agencies to prepare statements of energy effects ''to the extent permitted by law'' when undertaking actions identified as significant energy actions (66 FR 28355; May 22, 2001). E.O. 13211 defines a ''significant energy action'' as an action that (i) is a significant regulatory action under E.O. 12866; and (ii) is likely to have a significant adverse effect on the supply, distribution, or use of energy. This rule is a significant regulatory action under E.O. 12866. In our economic analysis, we did not find that this proposed critical habitat designation revision would significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action, and no statement of energy effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following finding:

(1) This rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' These terms are defined in 2 U.S.C. 658(5)–(7). ''Federal intergovernmental mandates'' include a regulation that ''would impose an enforceable duty upon State, local, or Tribal governments'' with two exceptions. It excludes ''a condition of Federal assistance.'' It also excludes ''a duty arising from participation in a voluntary Federal program,'' unless the regulation ''relates to a then-existing Federal program under which $500,000,000 or more is provided annually to State, local, and Tribal governments under entitlement authority,'' if the provision would ''increase the stringency of conditions of assistance'' or ''place caps upon, or otherwise decrease, the Federal Government's responsibility to provide funding,'' and the State, local, or Tribal governments ''lack authority'' to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; Aid to Families with Dependent Children work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. ''Federal private sector mandate'' includes a regulation that ''would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.''

The designation of critical habitat does not impose a legally binding duty on non-Federal Government entities or private parties. Under the Act, the only regulatory effect is that Federal agencies must ensure that their actions are not likely to destroy or adversely modify critical habitat under section 7. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply, nor would critical habitat shift the costs of the large entitlement programs listed above onto State governments.

(2) This rule will not significantly or uniquely affect small governments, because much of the designation (99 percent) occurs on Federal lands. Furthermore, based on an analysis conducted for the previous designation of critical habitat in 2014 and extrapolated to this designation, we do not expect this rule to significantly or uniquely affect small governments. Small governments will be affected only to the extent that any programs having Federal funds, permits, or other authorized activities must ensure that their actions will not adversely affect the critical habitat. Therefore, a small government agency plan is not required.

Takings (E.O. 12630)

In accordance with E.O. 12630 (''Governmental Actions and Interference with Constitutionally Protected Property Rights''), we have analyzed the potential takings implications of designating critical habitat for the Canada lynx in a takings implications assessment. The Act does not authorize the Services to regulate private actions on private lands or confiscate private property as a result of critical habitat designation. Designation of critical habitat does not affect land ownership, or establish any closures, or restrictions on use of or access to the designated areas. Furthermore, the designation of critical habitat does not affect landowner actions that do not require Federal funding or permits, nor does it preclude development of habitat conservation programs or issuance of incidental take permits to permit actions that do require Federal funding or permits to go forward. However, Federal agencies are prohibited from carrying out, funding, or authorizing actions that would destroy or adversely modify critical habitat. A takings implications assessment has been completed and concludes that this designation of critical habitat for the Canada lynx DPS does not pose significant takings implications for lands within or affected by the designation.

Federalism (E.O. 13132)

In accordance with E.O. 13132 (''Federalism''), this rule does not have significant federalism effects. A federalism summary impact statement is not required. In keeping with Department of the Interior and Department of Commerce policy, we requested information from, and coordinated development of this critical habitat designation with, the appropriate State resource agencies. From a federalism perspective, the designation of critical habitat directly affects only the responsibilities of Federal agencies. The Act imposes no other duties with respect to critical habitat, either for States and local governments, or for anyone else. As a result, the proposed rule does not have substantial direct effects either on the States, or on the relationship between the Federal Government and the States, or on the distribution of powers and responsibilities among the various levels of government.

The designation may have some benefit to these governments because the areas that contain the features essential to the conservation of the species are more clearly defined, and the physical or biological features of the habitat necessary for the conservation of the species are specifically identified. This information does not alter where and what federally sponsored activities may occur. However, it may assist State and local governments in long-range planning because they no longer have to wait for case-by-case section 7 consultations to occur.

Where State and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) of the Act would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency.

Civil Justice Reform (E.O. 12988)

In accordance with E.O. 12988 (''Civil Justice Reform''), the Office of the Solicitor has determined that the rule will not unduly burden the judicial system and that it meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are designating critical habitat in accordance with the provisions of the Act. To assist the public in understanding the habitat needs of the species, this rule identifies the physical or biological features essential to the conservation of the species. The proposed areas of critical habitat are presented on maps, and the

rule provides several options for the interested public to obtain more detailed location information, if desired.

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rule does not contain information collection requirements, and a submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) is not required. We may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

Regulations adopted pursuant to section 4(a) of the Act are exempt from the NEPA (42 U.S.C. 4321 *et seq.*) and do not require an environmental analysis under NEPA. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This includes listing, delisting, and reclassification rules, as well as critical habitat designations. In a line of cases starting with *Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), the courts have upheld this position. The Department has determined that this agency action does not require an environmental analysis under NEPA.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (''Government-to-Government Relations With Native American Tribal Governments;'' 59 FR 22951, May 4, 1994), E.O. 13175 (''Consultation and Coordination with Indian Tribal Governments''), the President's memorandum of November 30, 2022 (''Uniform Standards for Tribal Consultation;'' 87 FR 74479, December 5, 2022), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes and Alaska Native Corporations on a government-to-government basis. In accordance with S.O. 3206 of June 5, 1997 (''American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act''), we readily acknowledge our responsibilities to work directly with Tribes in developing programs for healthy ecosystems, to acknowledge that Tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to Tribes.

On October 13, 2022, the Service sent a letter to federally recognized Tribal partners across the range of the Canada lynx in the western United States, indicating that we would be updating the SSA, explaining why it was necessary to revise the SSA to inform this critical habitat revision, and requesting additional information. During development of the proposed rule and this final critical habitat rule, we coordinated with Tribes that have lands within the boundary of the proposed critical habitat revision to determine eligibility for exclusion of those lands from the final designation of critical habitat. As described above, we are excluding Flathead Indian Reservation and Blackfeet Reservation lands from the final critical habitat designation for the Canada lynx DPS. As a result, no Tribal lands fall within the boundaries of the final critical habitat for the Canada lynx, so no Tribal lands are be affected by the designation.

References Cited

A complete list of references cited in this rulemaking is available on the internet at *https://www.regulations.gov* and upon request from the Montana Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are the staff members of the Fish and Wildlife Service's Species Assessment Team and the Montana Ecological Services Field Office.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

Proposed Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

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

Authority: 16 U.S.C. 1361–1407; 1531–1544; and 4201–4245, unless otherwise noted.

■ 2. In § 17.95, in paragraph (a), amend the entry for ''Canada Lynx *(Lynx canadensis)*'' by:
■ a. Revising paragraphs (1) through (5);
■ b. Adding figure captions to paragraphs (6) and (7);
■ c. Revising paragraphs (8) through (10); and
■ d. Adding paragraph (11).

The revisions and additions read as follows

§ 17.95 Critical habitat—fish and wildlife.

* * * * *

(a) *Mammals.*

* * * * *

Canada Lynx *(Lynx canadensis)*

(1) Critical habitat units are depicted for States and Counties on the maps in this entry.

(2) Within these areas, the physical or biological features essential to the conservation of Canada lynx consist of the following components:

(i) Presence of snowshoe hares that support lynx residency and reproduction over time within a mosaic of boreal/subalpine forest structural stages that includes snowshoe hare habitat with dense horizontal cover at ground- or snow-level.

(ii) Winter conditions that provide and maintain deep persistent unconsolidated (fluffy) snow.

(iii) Presence of denning structures, including downed trees, root wads, and accumulations of coarse woody debris.

(iv) Habitat types, such as dry forest or meadows, that are between boreal forest patches and are likely to be used by lynx traveling between those patches within and among home ranges.

(v) Landscapes with suitable habitat large enough (483 mi^2 (greater than or equal to 1,250 km^2)) to support breeding populations.

(3) Critical habitat does not include manmade structures (lands covered by buildings, houses, pavement, and other structures; paved highways and roads; active mines and existing mining infrastructure; existing developed ski runs and tree islands, ski lifts, and associated ski area infrastructure and buildings; and irrigation infrastructure) and the land on which they are located existing within the legal boundaries on August 17, 2026.

(4) Critical habitat units were delineated using a combination of datasets, including the Interagency Western Lynx Biology Team (WLBT) tier 1 polygons and multiple lynx habitat predictive models developed by lynx researchers. The WLBT polygons were based on the aforementioned habitat models that identified high probability lynx habitat, while accounting for minimum patch size necessary to support multiple home ranges and high-quality habitat metrics to support persistent occupancy and reproduction. These areas were then verified by species experts to contain

the physical and biological features essential to the conservation of the species. For purposes of designating critical habitat under the Act, the Service made adjustments to the *critical habitat boundaries*—not to the WLBT polygons themselves—based on information received during public comment and interagency review, including additions, removals, and refinements where warranted to better reflect the best available information. Additional processing information is available in our files.

Critical habitat units were mapped and analyzed using Environmental Systems Research Institute (ESRI) ArcGIS Pro 3.5 Geographic Information System (GIS) program. Area calculations were done in ArcGIS Pro using the North American Datum (NAD) 1983 USA Contiguous Albers Equal Area Conic USGS projection. The maps in this entry, as modified by any accompanying regulatory text, establish the boundaries of the critical habitat designation. The coordinates or plot points or both on which each map is based are available to the public at the Service's internet site, *https://www.fws.gov/species/canada-lynx-lynx-canadensis,* at *https://www.regulations.gov* at Docket No. FWS–R6–ES–2024–0142 and Docket No. FWS–R6–ES–2013–0101, and at the field office responsible for this designation. You may obtain field office location information by contacting one of the Service regional offices, the addresses of which are listed at 50 CFR 2.2.

(5) Index map follows:

Figure 1 to Canada Lynx (*Lynx canadensis*) paragraph (5)

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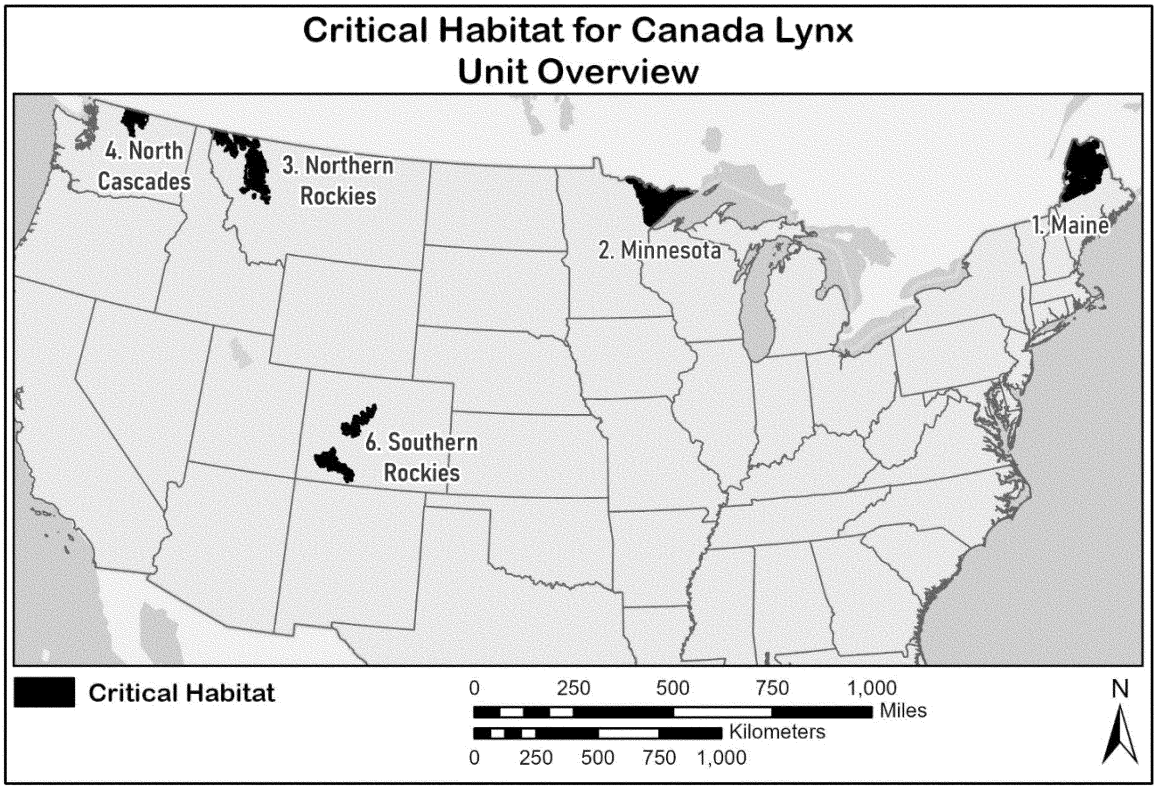


(6) * * *

Figure 2 to Canada Lynx (*Lynx canadensis*) paragraph (6)

* * * * *

(7) * * *

Figure 3 to Canada Lynx (*Lynx canadensis*) paragraph (7)

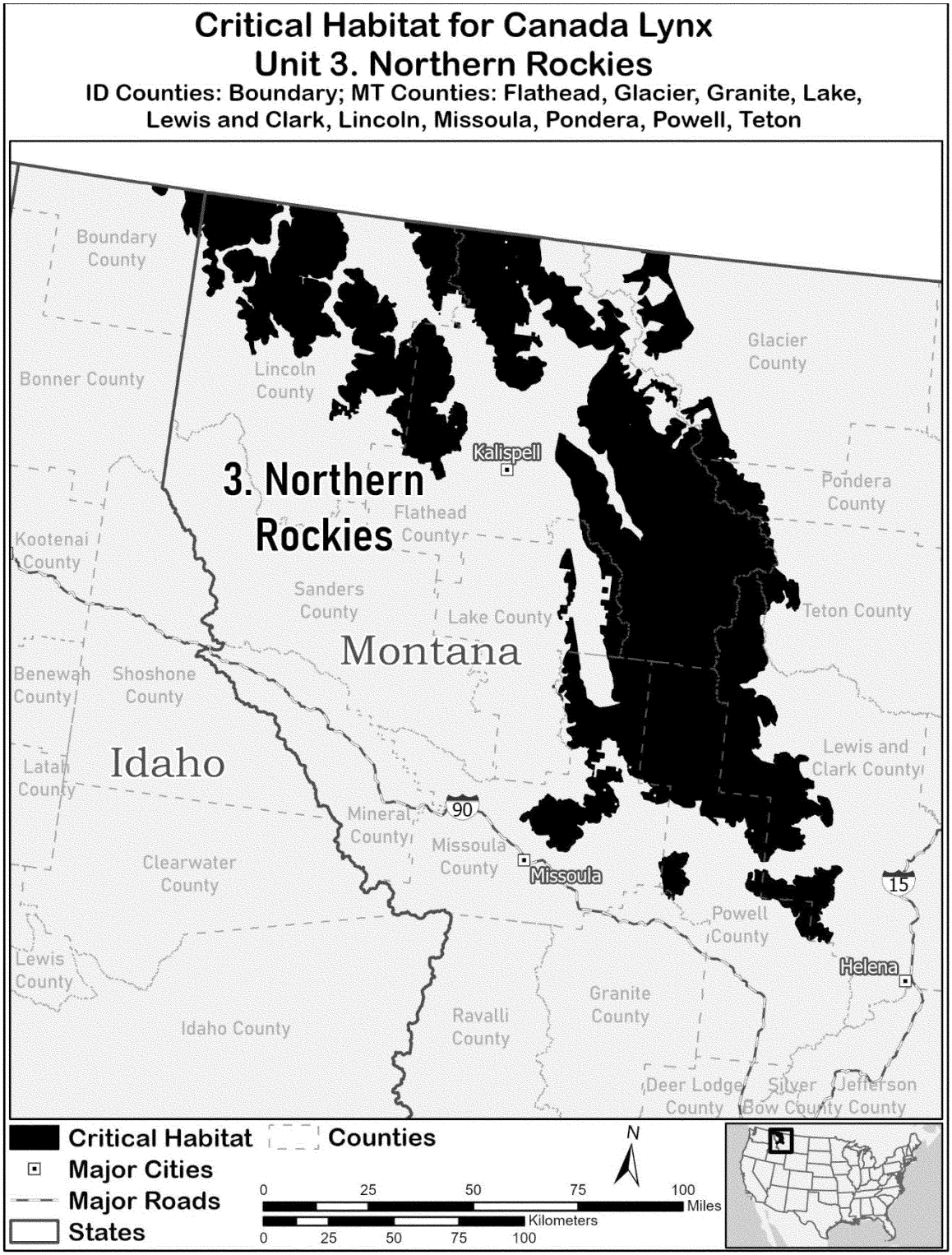
* * * * *

(8) Unit 3: Northern Rockies—The entirety or portions of Boundary County, ID, and Flathead, Glacier, Granite, Lake, Lewis and Clark, Lincoln, Missoula, Pondera, Powell, and Teton Counties, MT.

(i) Unit 3 consists of 6,918 mi^2 (17,918 km^2) located in northwestern Montana and northern Idaho. Land ownership within the unit is more than 99 percent Federal, with small parcels of State and private lands that represent less than one-half of 1 percent of the unit (total of 7 mi^2/18 km^2 State and private).

(ii) Map of Unit 3 follows:

Figure 4 to Canada Lynx (*Lynx canadensis*) paragraph (8)(ii)



(9) Unit 4: North Cascades—The entirety or portions of Chelan, Okanogan, Skagit, and Whatcom Counties, WA.

(i) Unit 4 consists of 2,075 mi² (5,375 km²) located in north-central Washington. Land ownership within the unit is over 99 percent Federal, with small parcels of private lands and one parcel of State land that represent less than one-half of 1 percent of the unit (less than 4 mi²/8 km²).

(ii) Map of Unit 4 follows:

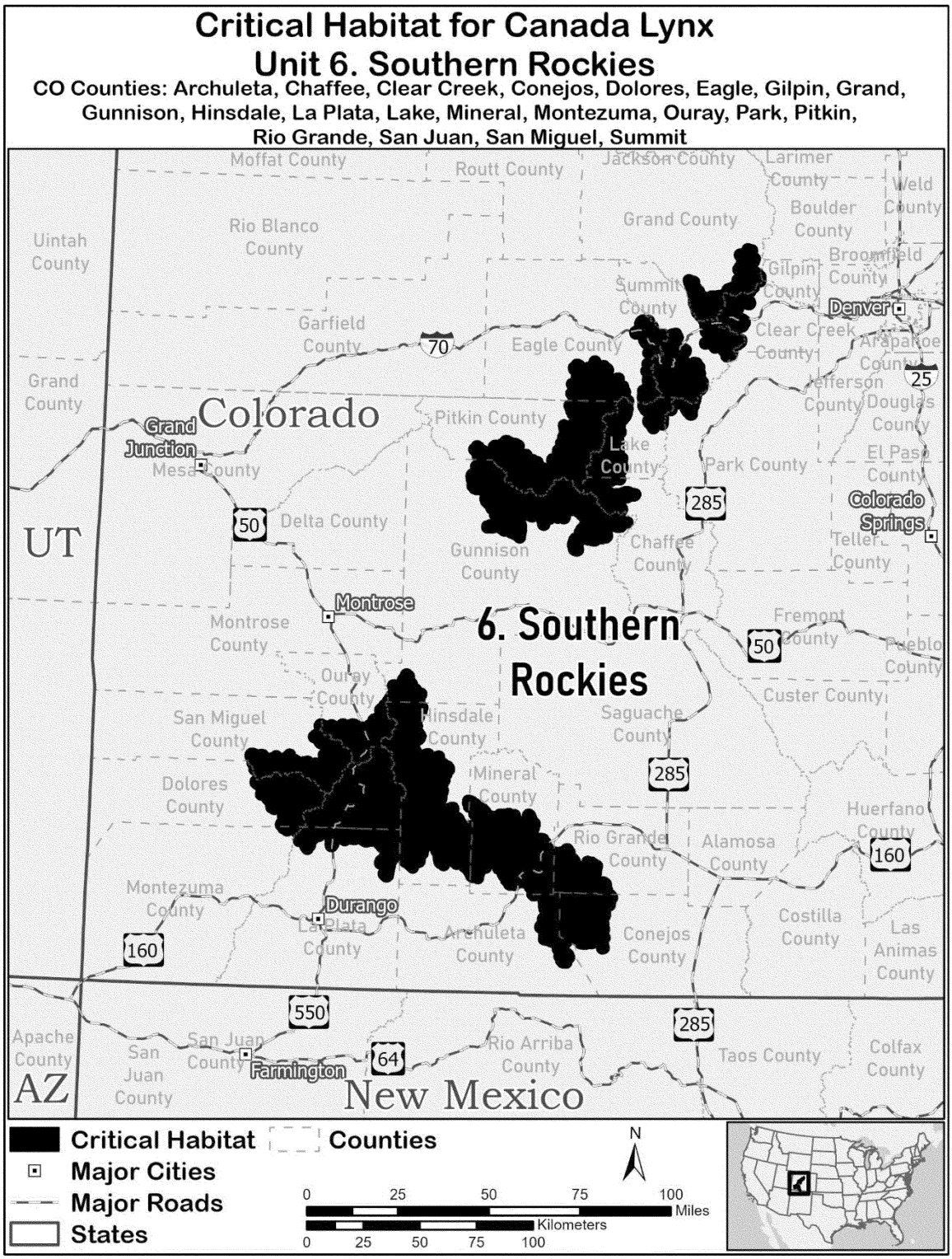
Figure 5 to Canada Lynx (*Lynx canadensis*) paragraph (9)(ii).

(10) Unit 6: Southern Rockies—The entirety or portions of Archuleta, Chaffee, Clear Creek, Conejos, Dolores, Eagle, Gilpin, Grand, Gunnison, Hinsdale, La Plata, Lake, Mineral, Montezuma, Ouray, Park, Pitkin, Rio Grande, San Juan, San Miguel, and Summit Counties, CO.

(i) Unit 6 consists of 5,037 mi^2 (13,047 km^2) located in west-central and southwestern Colorado. Land ownership within the unit is approximately 97 percent Federal, 3 percent private, and less than 1 percent State and other.

(ii) Map of Unit 6 follows:

Figure 7 to Canada Lynx (*Lynx canadensis*) paragraph (11)(ii)



* * * * *

Brian Nesvik,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2026–14299 Filed 7–15–26; 8:45 am]

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Part III

Department of Justice

Antitrust Division

United States of America, et al. v. RealPage, Inc., et al.; Proposed Final Judgment and Competitive Impact Statement

DEPARTMENT OF JUSTICE

Antitrust Division

United States of America, et al. v. RealPage, Inc., et al.; Proposed Final Judgment and Competitive Impact Statement

Notice is hereby given pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), that a proposed Final Judgment, Stipulation, and Competitive Impact Statement have been filed with the United States District Court for the Middle District of North Carolina in *United States of America et al.* v. *RealPage, Inc. et al.,* Civil Action No. 1:24–cv–00710. On January 7, 2025, the United States filed a Complaint alleging that Willow Bridge Property Company, LLC's agreements with RealPage, Inc. and other landlords to share information and align pricing violate Section 1 of the Sherman Act, 15 U.S.C. 1. The proposed Final Judgment, filed on July 6, 2026, bars Willow Bridge from licensing or using a revenue management software that relies on competitively sensitive data and prohibits Willow Bridge from sharing competitively sensitive information with other landlords. Willow Bridge must also establish an antitrust compliance policy and cooperate with the United States in this litigation.

Copies of the Complaint, proposed Final Judgment, and Competitive Impact Statement are available for inspection on the Antitrust Division's website at *http://www.justice.gov/atr* and at the Office of the Clerk of the United States District Court for the Middle District of North Carolina. Copies of these materials may be obtained from the Antitrust Division upon request and payment of the copying fee set by Department of Justice regulations.

Public comment is invited within 60 days of the date of this notice. Such comments, including the name of the submitter, and responses thereto, will be posted on the Antitrust Division's website, filed with the Court, and, under certain circumstances, published in the **Federal Register**. Comments should be submitted in English and directed to Danielle Hauck, Acting Chief, Technology and Digital Platforms Section, Antitrust Division, Department of Justice, 450 Fifth Street NW, Suite 7100, Washington, DC 20530 (email address: *ATR.Public-Comments-Tunney-Act-MB@usdoj.gov*).

Suzanne Morris,

Deputy Director Civil Enforcement Operations, Antitrust Division.

In the United States District Court for the Middle District of North Carolina

United States of America, U.S. Department of Justice, Antitrust Division, 950 Pennsylvania Avenue NW, Washington, DC 20530, State Of North Carolina, 114 W Edenton Street, Raleigh, NC 27603, State of California, 300 South Spring Street, Suite 1702, Los Angeles, CA 90013, State of Colorado, 1300 Broadway, 7th Floor, Denver, CO 80203, State of Connecticut, 165 Capitol Avenue, Hartford, CT 06106, State of Illinois, 115 S LaSalle St., Floor 23, Chicago, IL 60603, Commonwealth of Massachusetts, One Ashburton Place, 18th Floor, Boston, MA 02108, State of Minnesota, 445 Minnesota Street, St. Paul, MN 55101, State of Oregon, 100 SW Market St., Portland, OR 97201, State of Tennessee, P.O. Box 20207, Nashville, TN 37202, and State of Washington, 800 Fifth Avenue, Suite 2000, Seattle, WA 98104–3188, Plaintiffs, v. *RealPage, Inc., 2201 Lakeside Blvd., Richardson, TX 75082, Camden Property Trust, 11 Greenway Plaza, Ste. 2400, Houston, TX 77046, Cortland Management, LLC, 3424 Peachtree Rd., Ste. 300, Atlanta, GA 30326, Cushman & Wakefield, Inc., 225 W Wacker Dr., Ste. 3000, Chicago, IL 60606, Greystar Real Estate Partners, LLC, 465 Meeting St., Ste. 500, Charleston, SC 29403, Livcor, LLC, 233 South Wacker Dr., Ste. 4700, Chicago, IL 60606, Pinnacle Property Management Services, LLC, 2401 Internet Blvd., Ste. 110, Frisco, TX 75034, and Willow Bridge Property Company, LLC, 2000 McKinney Ave., Ste. 1100, Dallas, TX 75201,* Defendants.

Amended Complaint
Case No. 1:24–cv–00710–LCB–JLW
JURY TRIAL DEMANDED

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I. Introduction

1. Renters are entitled to the benefits of vigorous competition among landlords. In prosperous times, that competition should limit rent hikes; in harder times, competition should bring down rent, making housing more affordable. RealPage has built a business out of frustrating the natural forces of competition. In its own words, ''a rising tide raises all ships.'' This is more than a marketing mantra. RealPage sells software to landlords that collects nonpublic information from competing landlords and uses that combined information to make pricing recommendations. In its own words, RealPage ''*helps curb [landlords'] instincts to respond to down-market conditions by either dramatically lowering price* or by holding price when they are losing velocity and/or occupancy. . . . *Our tool [] ensures that [landlords] are driving every possible opportunity to increase price even in the most downward trending or unexpected conditions*'' (emphases added).

2. In fact, as RealPage's Vice President of Revenue Management Advisory Services described, ''*there is greater good in everybody succeeding versus essentially trying to compete against one another* in a way that actually keeps the entire industry down'' (emphasis added). As he put it, if enough landlords used RealPage's software, they would ''*likely move in unison versus against each other*'' (emphasis added). To RealPage, the ''greater good'' is served by ensuring that otherwise competing landlords rob Americans of the fruits of competition—lower rental prices, better leasing terms, more concessions. At the same time, the landlords enjoy the benefits of coordinated pricing among competitors.

3. RealPage replaces competition with coordination. It substitutes unity for rivalry. It subverts competition and the competitive process. It does so openly and directly—and American renters are left paying the price.

* * * * *

4. Americans spend more money on housing than any other expense. On average, American households allocate more than one-third of their monthly income to housing. Some purchase a home, while others choose to, or must, rent. A family's selection of an apartment reflects a complex set of values and criteria including comfort, safety, access to schools, convenience, and critically, affordability. To ensure they secure the greatest value for their needs, renters rely on robust and fierce competition between landlords.

5. RealPage distorts that competition. Across America, RealPage sells landlords commercial revenue management software. RealPage develops, markets, and sells this software to enable landlords to sidestep vigorous competition to win renters' business. Many of the largest landlords in the United States, including Greystar, Camden, Cortland, Cushman & Wakefield and Pinnacle, LivCor, and Willow Bridge (collectively, Defendant Landlords), which would otherwise be competing with each other, submit or have submitted on a daily basis their competitively sensitive information to RealPage.[1] This nonpublic, material, and granular rental data includes, among other information, a landlord's rental prices from executed leases, lease terms, and future occupancy. RealPage collects a broad swath of such data from competing landlords, combines it, and feeds it to an algorithm.

6. Based on this process and algorithm, RealPage provides daily, near real-time pricing ''recommendations'' back to competing landlords. These recommendations are based on the sensitive information of their rivals. But these are more than just ''recommendations.'' Because, in its own words, a ''rising tide raises all ships,'' RealPage monitors compliance by landlords to its recommendations. RealPage also reviews and weighs in on landlords' other policies, including trying to—and often succeeding in—ending renter-friendly concessions (like a free month's rent or waived fees) to attract or retain renters. A significant number of landlords then effectively agree to outsource their pricing function to RealPage with auto acceptance or other settings such that RealPage as a middleman, and not the free market, determines the price that a renter will pay. Competing landlords choose to share their information with RealPage to ''eliminate the guessing game'' about what their competitors are doing and ultimately take instructions from RealPage on how to make business decisions to ''optimize''—or in reality, maximize—rents.

7. Each landlord pays steep fees to license RealPage's software. RealPage's stated goals and value proposition are not a secret. Its executives are blunt: They want landlords to ''avoid the race to the bottom in down markets.'' Sometimes RealPage is even more direct, acknowledging that its software is aimed at ''driving every possible opportunity to increase price'' or observing that among landlords, ''there is a greater good in everybody succeeding versus essentially trying to compete against one another in a way that actually keeps the entire industry down.''

8. But that is not how the free market works. A free market requires that landlords compete on the merits, not coordinate pricing. Landlords should win renters by offering whatever combination of price and quality they think is most attractive. For example, landlords could lower rents or provide other financial concessions, like free months of rent, or with investments in amenities like gyms, grilling areas, or pools. Put differently, the fear of losing a renter to a competitor should motivate rival landlords to compete vigorously.

9. RealPage's revenue management software ingests on a daily basis nonpublic rental rates, future apartment availability, and changes in competitors' rates and occupancy. As competitor-landlords increase their rents, RealPage's software nudges other competing landlords to increase their rents as well. RealPage calls this ''maximiz[ing] opportunity[.]'' As RealPage explained to one landlord, by using competitors' data, they can identify situations where ''we may have a $50 increase instead of a $10 increase for that day.'' This is what RealPage encourages as ''stretch and pull pricing.''

10. RealPage allows landlords to manipulate, distort, and subvert market forces. One landlord observed that

[1] As used in this Complaint, the term ''landlord'' refers to a variety of entities that are responsible for setting rents and other lease terms at multifamily properties, including owners, operators, and managers.

RealPage's software ''can eliminate the guessing game'' for landlords' pricing decisions. Discussing a different RealPage product, another landlord said: ''I always liked this product because your algorithm uses proprietary data from other subscribers to suggest rents and term. That's classic price fixing . . . .'' A third landlord explained, ''Our very first goal we came out with immediately out of the gate is that we will not be the reason any particular sub-market takes a rate dive. So for us our strategy was to hold steady and to keep an eye on the communities around us and our competitors.''

11. RealPage's scheme not only distorts competition to the detriment of renters, but also allows it to reinforce its dominant position in the market for commercial revenue management software. By its own account, RealPage controls at least 80 percent of that market. Its dominant position is protected by substantial data advantages due to its massive reservoir of ill-gotten competitively sensitive information from competing landlords. No other revenue management company can match RealPage's access to landlords' nonpublic, competitively sensitive rental data. This is why RealPage acknowledges that it ''does not have any true competitors, mainly because our data is based on real lease transaction data.'' RealPage's conduct is predatory and exclusionary, which has allowed it to distort the market opportunities for honest providers of revenue management software.

12. At bottom, RealPage is an algorithmic intermediary that collects, combines, and exploits landlords' competitively sensitive information. And in so doing, it enriches itself and compliant landlords, including Defendant Landlords, at the expense of renters who pay inflated prices and honest businesses that would otherwise compete.

13. The United States, and the States of North Carolina, California, Colorado, Connecticut, Illinois, Minnesota, Oregon, Tennessee, and Washington, and the Commonwealth of Massachusetts, acting by and through their respective Attorneys General, bring this action pursuant to Sections 1 and 2 of the Sherman Act to rid markets of (i) RealPage's and Defendant Landlords' unlawful information-sharing and pricing alignment schemes, and (ii) RealPage's illegal monopoly in commercial revenue management software. In so doing, Plaintiffs seek to restore the free market to deserving individuals, families, and honest businesses.

II. RealPages's Revenue Management Software Is Fueled by Nonpublic, Competitively Sensitive Information Shared by Landlords

14. RealPage dominates the market for commercial revenue management software that landlords use to price apartments, controlling at least 80 percent of that market, according to its own estimates. RealPage currently offers three revenue management systems to landlords: YieldStar, AI Revenue Management (AIRM), and Lease Rent Options (LRO). The company's main legacy software, YieldStar, is the product of three acquisitions and subsequent internal development. Its successor, AIRM, uses much of the same codebase as YieldStar, but RealPage claims that AIRM's refined models and forecasting are more precise. RealPage acquired its other revenue management software, LRO, in 2017. RealPage has made plans to sunset both YieldStar and LRO by the end of 2024.

15. Competitively sensitive data collected from competing landlords is a critical input to RealPage's revenue management software. AIRM and YieldStar collect this data, such as rental applications, executed new leases, renewal offers and acceptances, and forward-looking occupancy, and use it to generate price recommendations for the competing landlords. This information is among the most competitively sensitive data a landlord maintains.

16. The exploitation of sensitive data from competing landlords is central to RealPage's approach. As part of pitching its software to landlords, RealPage highlights that its pricing algorithms use their competitors' data sourced directly from ''lease transaction data.'' RealPage describes this nonpublic data from competitors as one of three ''building blocks of price'' in AIRM and YieldStar. Landlords thus share their competitively sensitive information with RealPage with the understanding that RealPage's software will use the data to generate recommendations for rivals (and vice versa).

A. Landlords Agree To Share Nonpublic, Competitively Sensitive Transactional Data With RealPage for Use in Generating Competitors' Pricing Recommendations

17. RealPage amasses nonpublic, competitively sensitive data from competing landlords through use of its pricing algorithms, other rental property software, and thousands of monthly phone calls. The combined troves of nonpublic, competitively sensitive data are much more granular, sensitive, timely, and comprehensive than alternatives—and far more detailed than any data publicly available to potential renters. RealPage then uses this data in generating competitors' pricing recommendations.

18. *Data shared through YieldStar and AIRM.* Each AIRM and YieldStar client agrees to share detailed data with RealPage that are private, updated nightly, and granular. The data includes lease-level information on each unit's effective rent (rent net of discounts), rent discounts, rent term, and lease status, as well as unit characteristics such as layout and amenities. It also includes the number of potential future renters who have visited a property or submitted a rental application.

19. Landlords understand that AIRM and YieldStar use their data to recommend prices not just for their own units, but also for competitors. For example, a revenue management director at Greystar testified that she understood that Greystar, and other competing landlords who used AIRM or YieldStar, agreed with RealPage to share their data, which was combined in a single data pool for use by YieldStar and AIRM. An executive at Willow Bridge noted the advantages to using YieldStar at a property if others in the property's submarket—the small geographic area around the property—also used YieldStar because ''the shared data between the models at different communities can be a benefit in getting accurate transactional data on a timely basis.''

20. Landlords agree to provide this information for use by their competitors because they understand they will be able to leverage the sensitive information of their rivals in turn. In its pitch to prospective clients, RealPage describes AIRM's and YieldStar's access to competitors' granular, transactional data as a meaningful tool that it claims enables landlords to outperform their properties' competitors by 2–7%. RealPage clients receive training that highlights the role of competitors' transactional data in the price recommendation process.

21. *Data Shared Through Other RealPage Products.* AIRM and YieldStar are not the only ways that RealPage shares nonpublic, competitively sensitive information among landlords. RealPage obtains the same confidential transactional data from landlords that license at least three other programs: OneSite, Performance Analytics with Benchmarking, and Business Intelligence.

22. *OneSite* is RealPage's property management software, which operates as the central source of data for

landlords' leasing activity. *Performance Analytics with Benchmarking* allows landlords to compare the performance of their properties and floor plans (*e.g.,* a one-bedroom, one-bathroom unit) to their competitors. *Business Intelligence* is a data analytics tool that pulls data from a landlord's property management software and other products.

23. Each landlord using RealPage's OneSite, Business Intelligence, and Performance Analytics with Benchmarking products agrees to share its proprietary data with RealPage and agrees that RealPage's revenue management software can use the data to generate pricing recommendations. The license agreements for these products specifically identify the shared data, such as pricing information, as confidential, nonpublic information. RealPage takes this deeply confidential information and uses it to provide rent recommendations to competitors of these clients.

24. These agreements grant RealPage access to confidential information from over 16 million units across the country, including many that do not use its revenue management products. With respect to Performance Analytics with Benchmarking alone, a RealPage sales representative told a prospective client that ''we have over 16 million units of data coming from various source operating systems (PMS) [property management software] into the PAB platform,'' making RealPage the top choice for ''transactional data benchmarking.'' With properties containing approximately 3 million units using AIRM and YieldStar, these additional agreements meaningfully multiply the scale of the transactional data used by AIRM and YieldStar. This gives RealPage greater visibility, including into markets with less penetration by AIRM and YieldStar, granting even initial AIRM and YieldStar adopters in a new market the benefit of access to a significant amount of nonpublic, competitively sensitive information.

25. Landlords understand that AIRM and YieldStar will use data from these products. A revenue management director at Greystar explained that RealPage ingests transactional data from several RealPage products, besides AIRM and YieldStar, for use in revenue management. A property owner requested information from Greystar on which competing properties used revenue management software. In an internal response, the Greystar director noted that RealPage has ''access to more transactional history than anyone and [is] pulling data from anyone using RealPage products which includes companies who manually price or use other revenue management firms but leveraging their BI [Business Intelligence] products.''

26. A revenue management executive at Willow Bridge asked RealPage if other specific landlords were using RealPage's non-revenue management products. The landlord's owner client was concerned about the data available to YieldStar because competing properties were unsophisticated and did not use revenue management. This executive wanted to confirm that ''YieldStar will be able to leverage actual transactional data behind the scenes and not just look at offered rents for their comps.'' RealPage reminded the Willow Bridge executive that RealPage collected transactional data for *all* users of OneSite, Business Intelligence, and Performance Analytics with Benchmarking, and reassured the executive that YieldStar had ample transactional and survey data for that area.

27. *Calling Landlords.* RealPage has an additional, complementary product called Market Analytics. Market Analytics compiles data from over 50,000 monthly phone calls that RealPage makes to landlords across the country. On these calls RealPage collects nonpublic, competitively sensitive information by floor plan on occupancy rates, effective rents, and concessions, as well as information on the owner, management company, and any revenue management software used at the property. These market surveys cover over 11 million units and approximately 52,000 properties. Landlords, including but not limited to those that use AIRM, YieldStar, or other RealPage products, knowingly share this nonpublic information with RealPage.

B. AIRM and YieldStar Users Agree With RealPage To Use the Software To Align Pricing

28. In addition to agreeing to share nonpublic, competitively sensitive data with RealPage, each AIRM and YieldStar licensee agrees with RealPage to use the AIRM or YieldStar pricing software as RealPage designed it.[2] Landlords are expected to review daily AIRM or YieldStar floor plan price recommendations and use the programs to set scheduled floor plan rents or even unit-level prices.

29. While landlords may not accept every price recommendation, they use AIRM or YieldStar as their pricing software, regularly review AIRM or YieldStar floor plan recommendations, use AIRM or YieldStar to set a scheduled floor plan rent, and use AIRM or YieldStar to set unit-level prices.

30. Landlords who use AIRM and YieldStar know that others are using the same software. Some landlords track which revenue management software their competitors use, including by contacting competing properties directly and exchanging nonpublic information. Other landlords, including prospective AIRM and YieldStar users, ask RealPage whether there are existing AIRM and YieldStar users nearby before they themselves license the products.

31. An executive at Willow Bridge, for example, explained to her team how she would learn from RealPage data or from a property's website whether a property used revenue management. This information is important because properties that use revenue management tend to update prices much more frequently, and so a landlord will react differently to those price changes if it knows the competitor is using revenue management.

32. RealPage frequently tells prospective and current clients that a ''rising tide raises all ships.'' A RealPage revenue management vice president explained that this phrase means that ''there is greater good in everybody succeeding versus essentially trying to compete against one another in a way that actually keeps the industry down.'' This rising tide lifts all landlords, including but not limited to AIRM and YieldStar users.

33. In using AIRM and YieldStar, landlords expect this pricing alignment and use RealPage software in part for this reason. One landlord echoed the RealPage executive, using the phrase ''a rising tide rises [sic] all ships'' to explain that AIRM would move prices in a ''similar manner'' to how the top and bottom of the market move. Elsewhere that same landlord noted that ''if everyone in the market is doing well and everyone in the market has [sic] is having the rates go up, so should ours, right?'' An employee at Willow Bridge referenced RealPage's use of the phrase ''a rising tide raises all ships'' to explain how AIRM would provide price recommendations that amplify market trends. Multiple landlords have expressed their preference that their competitors use YieldStar and AIRM because widespread use would benefit them all. An executive of one landlord (which itself uses YieldStar and AIRM) said in a 2021 earnings call that more sophisticated, ''high-quality competition'' was better for that

[2] Defendants Camden, Cushman & Wakefield and Pinnacle, Greystar, LivCor, and Willow Bridge were active beta testers for AIRM and provided feedback to RealPage during the AIRM design process.

landlord when ''they all use revenue management. They are all smart. They raised rents when they should.'' RealPage highlighted in promotional materials the sentiments of another landlord who noted, ''It actually gives me chills to think about what a disadvantage we'd be at if we hadn't adopted YieldStar, knowing others are using it.''

C. RealPage's Transactional Data Is Fundamentally Different From Other Data Available to Landlords

34. The data that RealPage uses and supplies is unique relative to public data available to landlords on listing or property websites. As compared to public data, RealPage data is much more granular, covers a broader array of business information, and includes competitively sensitive data across several dimensions. For example:

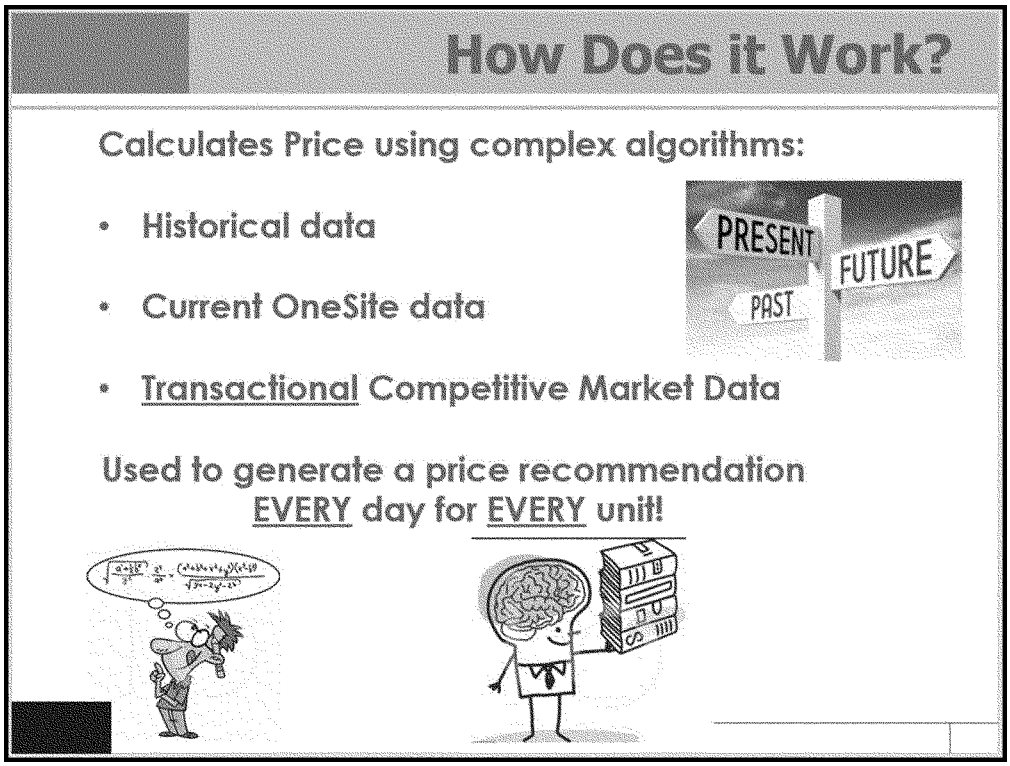
- *Information on Actual Transactions.* RealPage's data include, for each lease, the unit, floor plan, listed rent, final transacted lease price (including any discounts), and lease term.
- *Renewals.* RealPage's data include the same information for lease renewals. Information on renewals is not listed publicly—not even asking rents—leaving a significant blind spot for landlords not using RealPage.
- *Time Span.* AIRM and YieldStar have access to current and historical lease data, from the previous day and going back two to three years.
- *Future Demand.* The shared data further includes information on tenant demand, including detailed information on inquiries and applications by potential future tenants.
- *Accuracy.* Landlords have greater assurance of the accuracy of the data because it comes directly from the landlords' own databases.
- *Coverage.* The RealPage data covers millions of units from users of its revenue management software and other products.

35. RealPage touts how its data is different. As one RealPage pitch deck put it, ''we have [the] most data and the best data.'' And the ''[q]uality of data is best in class given that it is 'lease transaction data'—this provides insight into performance data from actual signed leases, both new and renewal, net effective of concessions.'' Another noted that without YieldStar ''you'll be pricing your renewals in the dark without insight into actual lease transaction data that YS uses to help you make pricing decisions. This is critical to price renewals right[,] especially in a downturn.''

36. Access to this data proves important in winning over revenue management clients, including skeptical ones. One RealPage senior manager noted that a ''highly suspicious CFO'' was won over in part by YieldStar's ''lease transaction data'' that allowed his company to ''achieve what his people couldn't achieve on their own.''

37. One landlord explained the benefits of YieldStar to its owner clients by calling the use of competitors' transactional data a ''game changer! We have 100% truth on [competitors'] activity powering YieldStar recommendations.''

38. Another landlord's internal training presentation on YieldStar highlighted the importance of having access to competitors' transactional data:



D. RealPage Revenue Management Software Uses Nonpublic, Competitively Sensitive Data To Recommend Prices

39. AIRM and YieldStar are built upon similar code and leverage competitive data in similar ways. LRO, on the other hand, was originally developed outside of RealPage and takes a different approach.

1. AIRM and YieldStar Leverage Competitively Sensitive Data To Generate Price Recommendations

40. AIRM uses competitors' nonpublic, transactional data in three

separate stages of the pricing process: (1) model training, (2) floor plan price recommendations, and (3) unit-level prices. YieldStar uses competitors' nonpublic, transactional data in stages two and three of its process.

(a) AIRM Model Training Relies on Competitively Sensitive Data To Generate Learned Parameters

41. In the first stage, RealPage trains its AIRM models using nonpublic data from OneSite and other property management software, totaling millions of executed lease transactions, new lead applications, renewal applications, and guest cards filled out by visiting potential tenants. This data is run through a machine learning model to generate learned parameters for supply and demand models that are then used for all AIRM clients across the country. Like the coefficients in a regression model, the learned parameters are applied to the data of a landlord's specific property, and to the data of its competitors, when AIRM makes pricing recommendations. RealPage generally retrains the models three to four times per year using updated nonpublic data.

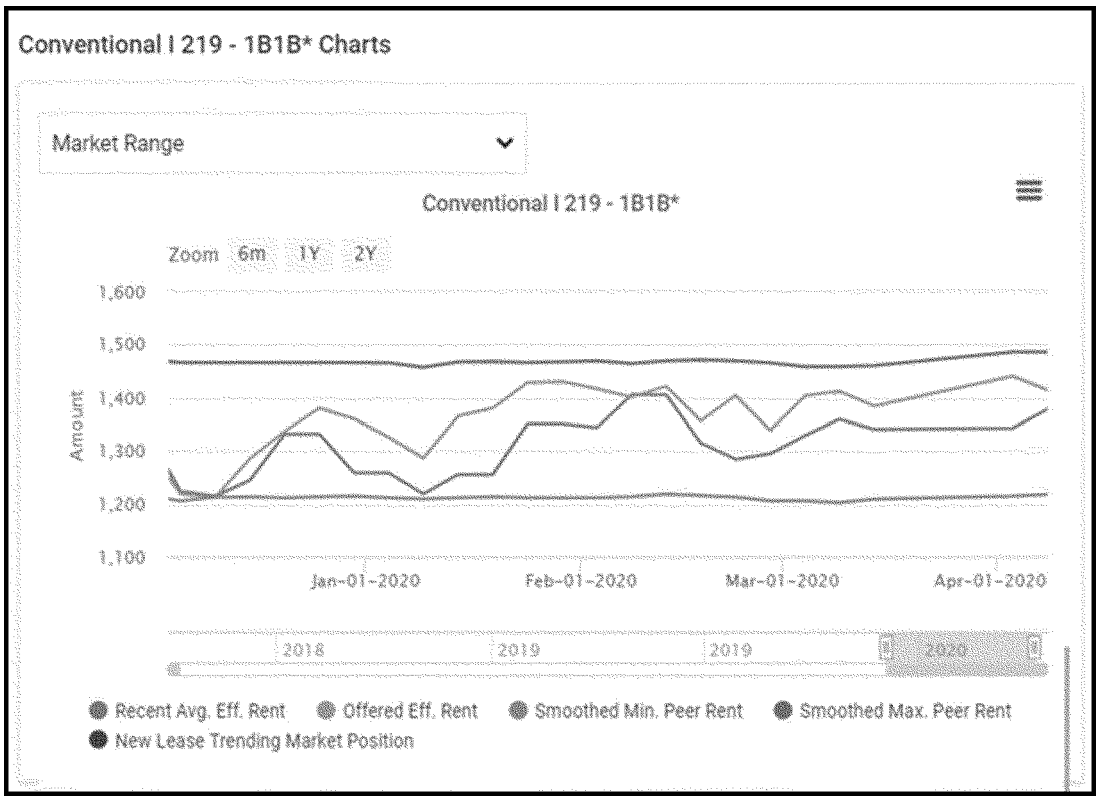
(b) AIRM and YieldStar Incorporate Competitors' Nonpublic Data To Generate Floor Plan Price Recommendations

42. In the second stage AIRM or YieldStar provides a price recommendation for every floor plan of a given property. A floor plan is a grouping of units that share similar characteristics, such as the number of bedrooms and bathrooms and square footage. Landlords define the floor plans in their buildings—for example, a large apartment building might have separate sets of floor plans for studios, one-bedroom, and two-bedroom apartments. As discussed below, AIRM and YieldStar use competitors' nonpublic, transactional data in nearly every step of setting a recommended floor plan price, including identifying peer properties, forecasting occupancy and leasing, increasing rents to match competitors' changes, and determining the magnitude of price changes.

43. *Identifying Peers.* First, AIRM and YieldStar use confidential transaction data to identify a property's peer properties, which include close competitors. In selecting peer properties, RealPage's algorithm generally looks for properties with similar floor plans, within close geographic proximity, and with similar effective rents over time. AIRM or YieldStar clients may review the list of peer properties and request that RealPage add or remove specific properties.

44. AIRM or YieldStar then uses the nonpublic data from competitors' executed leases to generate a market range chart for each floor plan. This chart identifies a ''smoothed'' market minimum effective rent and market maximum effective rent. The market minimum is a hard floor. AIRM and YieldStar will not recommend a rent below the market minimum. On the other hand, the market maximum is a ''soft ceiling,'' and the programs will recommend prices above the ceiling.

45. The client has access to the market range chart within the AIRM and YieldStar interfaces. As shown below, for each floor plan the client can see the smoothed market minimum and market maximum and where the client's own floor plan sits within the market range.



46. *Forecasting Occupancy and Leasing.* Every night, for each participating property, AIRM applies the model's learned parameters to that property's internal transactional data to forecast the number of expected vacancies and expected lease applications for a certain period into the future. AIRM may also use competitors' data to adjust the projected supply.

47. AIRM or YieldStar then determines whether actual leasing for a floor plan is on track to meet predicted

leasing. To do so, it creates a forecast of the number of leases over time, using nonpublic lease and application data from the subject property, and potentially from so-called surrogate properties (similar properties in the surrounding area).[3] When there is an imbalance between a property's actual and forecasted leasing, it recommends a price change.

48. *Changing Rents to Match Competitors.* Even when a property's supply and demand are balanced, RealPage's software will still recommend a price change, based on competitors' nonpublic data, when it determines that the market is moving. For example, if the minimum and maximum of the competing floor plans' effective rents increase, it will recommend a price increase to maintain the floor plan's market position (its price position relative to its competitors).

49. *Determining Magnitude of Price Changes.* Once AIRM or YieldStar has determined that it will recommend a price increase or a price decrease, it again uses competitors' transactional data to determine *how much* the price should move and provide a floor plan price recommendation. It uses nonpublic transactional data from peer properties, in addition to data from the subject property and surrogate properties, to generate a market response curve—analogous to a market demand curve—for every floor plan. This demand curve provides an estimate of how demand for particular apartments would change in response to changes in rents, a measure that RealPage calls elasticity. In other words, it uses competitors' nonpublic transactional data to calculate how many leases the property will likely gain or lose for a particular floor plan, for every price point along the curve. Using this data, AIRM or YieldStar can determine how much the price can increase and still achieve the target number of leases, or by how little price can decrease to maintain a target occupancy.

50. RealPage describes elasticity as a pivotal input into balancing supply and demand and, therefore, price.

51. The use of surrogate properties in this pricing process has the potential to push convergence on price even further. As two properties' surrogate sets become closer—and therefore their respective demand curves become more similar—AIRM and YieldStar will generate increasingly similar prices for the two properties. And the use of surrogates is common. One of the largest landlords in the country, for example, uses surrogates at over 80% of its properties.

52. This process repeats for every floor plan in the client's property, every night. A new floor plan price recommendation is generated daily.

(c) AIRM and YieldStar Use Competitors' Nonpublic Data—Including Data on Future Occupancy—To Determine Unit-Level Prices

53. A property manager at the landlord reviews each floor plan recommendation daily and enters the floor plan price. AIRM and YieldStar then use the floor plan price to generate prices for every unit within the floor plan. The unit price is shown in a pricing matrix, which provides the price for each combination of start date and lease term. To generate the price for an individual unit, the floor plan price is adjusted to account for unit-specific factors such as amenities (*e.g.,* a desirable view, the floor level, or an in-unit washer and dryer), staleness (*i.e.,* how long that specific unit has been vacant), and the timing of lease expirations. AIRM and YieldStar again use competitors' nonpublic data during this step in at least two ways.

54. First, AIRM and YieldStar use data on competitors' supply of multifamily housing to adjust recommendations to limit ''exposure'' with a feature called lease expiration management. Exposure refers to the number of units that are available for lease. Managing lease expirations is an important element of revenue management software. If too many leases expire and the corresponding units become available at the same time, supply increases and rents for those units will tend to drop. This process will also tend to repeat itself as the same units will become available at the same time a year later for leases with a standard twelve-month term.

55. The objective of expiration management is to smooth out this exposure so that landlords, as explained by one RealPage employee, ''remain in a position of pricing power.'' For example, if AIRM or YieldStar sees that a large number of units will likely be available in twelve months, it will increase the price recommendation for a twelve-month lease relative to price recommendations for leases of other terms, such as 11 months or 13 months, in order to nudge potential renters to accept those terms. Expiration management can only raise prices—AIRM does not lower a unit's price if the lease term would fall in an underexposed period.

56. This calculation does not rely *only* on the predicted future supply for the client's property. For any landlord who uses a ''market seasonality'' setting, AIRM and YieldStar *also* rely on competitors' transactional data and the supply for those competitors—including the supply of competitors' existing leases that expire in the future. AIRM and YieldStar thus work to manage lease expirations for the client's units based on how competitors' supply will change. RealPage strongly recommends to landlords that they use market seasonality.

57. The use of competitors' nonpublic data in expiration management to fill out the pricing matrix occurs regardless of whether the landlord accepts the AIRM or YieldStar recommendation. Thus, even if a landlord were to override every price recommendation, its rental prices would still be influenced by nonpublic information about its competitors' supply.

58. Second, AIRM and YieldStar include an amenity optimization feature. By pricing specific amenities within units, landlords can avoid making wholesale pricing changes to a floor plan if a specific unit fails to lease. Within the amenity analysis, AIRM and YieldStar provide market values for specific amenities to landlords, allowing them to compare their perceived value of an amenity with the nonpublic valuation of their competitors. The peer data include the market minimum and maximum value for specific amenities.

2. LRO Relies Primarily on Landlords To Input Data on Competitors

59. RealPage's LRO also provides pricing recommendations to users. Each week, LRO users manually input competitor information into the system that they have obtained from public websites or more questionable means, such as communicating directly with their competitors.

60. A small number of LRO users subscribe to a feature called AutoComp. With this feature, RealPage provides information on competitors' rents, traffic, and occupancy. This information comes from market surveys that RealPage compiles using call centers to call competitor properties. Landlords may use LRO without using AutoComp.

E. RealPage Uses Multiple Mechanisms To Increase Compliance With Price Recommendations

61. AIRM and YieldStar provide daily price recommendations. RealPage has taken multiple steps to increase

[3] If there is insufficient historical data for a particular building, or floor plan within that building, RealPage will use data from what it calls a ''surrogate property,'' which is the confidential transactional data from another property with characteristics similar to the subject property.

compliance with AIRM and YieldStar price recommendations. It designed AIRM and YieldStar to make it much easier to accept recommendations than to decline them. It built an auto-accept function and pushes clients to adopt it and increase its role. And its pricing advisors encourage landlords to follow AIRM and YieldStar pricing recommendations. Among their duties, pricing advisors review any request to override a price recommendation.

1. AIRM and YieldStar Make it Easy To Accept Recommendations and More Difficult and Time-Consuming To Decline

62. Every morning, the landlord's property manager chooses whether to accept the floor plan price recommendation, keep the previous day's rent, or override the recommendation. These options are the same for new leases and renewal leases. RealPage makes it easier and faster for a client to accept a recommendation than to decline it. When accepting recommendations, the manager can choose to do a bulk acceptance—she can accept all or multiple floor plan recommendations at once. But she cannot do the same when overriding, or rejecting, the recommendation.

63. Instead, for every recommendation that she does not accept—whether overriding or keeping the previous day's rent—the property manager must provide ''specific business commentary'' for diverging from the recommendation. This justification, RealPage instructs, should not be a mere preference for another price but must be based on a factor that the model cannot account for, such as local construction or renovations occurring in the building. It must be a ''strong sound business minded approach.''

64. The property manager knows that these recommendation rejections and accompanying justifications will be sent to a RealPage pricing advisor.[4] If the pricing advisor disagrees with the rejection or justification, the disagreement is escalated for resolution to a landlord's regional manager, who typically supervises the property manager.

65. As one client who complained to RealPage explained, RealPage's design is ''trying to persuade [clients] to take the recommendations (almost like we made it hard to do anything but).''

2. RealPage Pushes Clients To Adopt Auto-Accept Settings That Automatically Approve Recommendations

66. AIRM and YieldStar each include auto-accept functions. This functionality automatically accepts price recommendations falling within certain parameters. By default, AIRM and YieldStar set auto-accept parameters of a 3% daily change and an 8% weekly change. The landlord can change these parameters, disable or enable auto-accept, and even enable partial auto-accept. With partial auto-accept, if the recommendation exceeds the auto-accept parameters, the recommendation is accepted as far as the parameter permits. For example, if the auto-accept daily change limit is 4% and the price recommendation is 5%, using partial auto-accept will result in an increase of 4%. By enabling auto-accept, a landlord functionally delegates pricing authority to RealPage (within the bounds of the daily and weekly limits).

67. As part of the onboarding process, internal RealPage guidance states, ''AUTO ACCEPT should be confirmed as 'on' with parameters in place.'' Internal AIRM training explained that RealPage wanted to ''widen auto accept parameters'' by introducing the feature and then ''creating enough trust so that over time we have client[s] that are willing to let auto accept run with very wide parameters. . . AKA—accept all recommendations.'' RealPage trains pricing advisors to have an ''accountability conversation'' or a ''refresher on short term vs long term goals'' for clients that show less tolerance for increasing auto-accept parameters.

68. Even if a landlord does not want to use auto-accept, RealPage trains its advisors to convince the landlord to turn it on with 0% limits—a setting whereby auto-accept will never accept price changes. The reason? So that it is no longer a question of whether the client turns on auto-accept, but only a matter of convincing them to widen the parameters and further delegate pricing decisions. RealPage instructs its advisors on best practices: ''[I]f a partner is not ready to use auto acceptance, are they ready to use revenue management?''

3. RealPage Pricing Advisors Provide a ''Check and Balance'' on Property Managers To Increase Acceptance of Recommendations

69. RealPage offers landlords pricing advisory services. Landlords typically have an assigned pricing advisor, unless the client has internal revenue managers that were certified by RealPage. Pricing advisors play an important role in the daily review of pricing recommendations. Landlords' property managers are asked to review recommendations every morning by 9:30 a.m. After their review, a pricing advisor accepts agreed-upon pricing within an hour and escalates any disputes to the landlord's regional manager.

70. If a property manager disagrees with the direction of a recommended price change—*e.g.,* the manager wants to implement a price decrease when the model recommends a price increase—the RealPage pricing advisor escalates the dispute to the manager's superior. As a pricing advisor manager explained in a client training, the advisor would ''stop the process and reach out to our partners''—the property manager's supervisors—to ''talk about this further.'' The advisors, the manager elaborated, are part of a system of ''checks and balances.'' The client confirmed the value of this system to stop property managers from acting on emotions, which could limit RealPage's influence on their pricing.

71. Beyond the daily interactions between pricing advisors and their own property managers, clients agree to make meaningful changes when they use RealPage's pricing advisory services. Under the specifications for this service, clients agree to use AIRM or YieldStar exclusively to give quotes to potential renters, further tying landlords' pricing decisions to RealPage's software. Clients also agree to change their commission programs for leasing agents to ''ensure these programs motivate sales behavior that is consistent with the objectives of revenue growth.'' And clients further agree to revenue growth as the official metric to evaluate AIRM and YieldStar, as opposed to occupancy rates.

72. RealPage imposes additional requirements on landlords who want to use internal or in-house revenue management advisors with YieldStar or AIRM (rather than use RealPage pricing advisors). RealPage requires these landlords' employees go through RealPage certification. Certification is a multiday course in which landlords are trained—at times in the same session—on AIRM and YieldStar use and best practices, according to RealPage. Certification includes observing and leading pricing calls with property managers and passing a written exam. This certification program facilitates the landlords' agreements with RealPage to align pricing by ensuring that landlords' internal revenue managers are trained

[4] Some clients have internal revenue managers that are certified by RealPage. For those clients who have internalized the revenue management function, recommendation rejections may be routed to the internal revenue manager rather than a RealPage pricing advisor.

and tested to use AIRM and YieldStar in the same way.

4. Pricing Recommendations Heavily Influence Landlords' Behavior

73. RealPage defines an acceptance as where the final floor plan price is within 1% of the recommended floor plan price. According to that definition, the average acceptance rate across all landlords nationally for new leases between January 2017 and June 2023 is between 40–50%. But RealPage itself recognizes that acceptance rates are not necessarily the best measure of its influence; one employee explained that the spread between a floor plan recommendation and the final scheduled floor plan price is more useful for measuring model adoption—and therefore influence—than the binary accept/reject decision that the RealPage-defined acceptance rate reflects. Widening the definition of acceptance even slightly to account for partial acceptances illustrates the influence of recommendations: nearly 60% of final floor plan prices are within 2.5% of RealPage's recommendation, and more than 85% are within 5% of RealPage's recommendation.

74. RealPage's preferred measure of acceptance understates the influence of RealPage's price recommendations and the effect of competitors' data. AIRM and YieldStar use competitors' nonpublic transactional data to adjust unit-level pricing, after a floor plan recommendation has been accepted or rejected. RealPage's metric does not capture the cumulative effect of rate acceptances over time. Nor do they capture when a client is influenced by and partially accepts a recommendation.

III. Coordination Among Competing Landlords Is a Feature of This Industry

75. Several characteristics of apartment-rental markets make it easier for landlords to coordinate with, or accommodate, each other. Rental housing is a necessity for many Americans, meaning that demand is inelastic—that is, changes in rent produce relatively small changes in the number of renters. There is significant concentration among landlords in local markets, and these landlords engage in widespread, regular communications with one another. And RealPage makes rental units more comparable to each other in AIRM and YieldStar, allowing landlords to track one another more easily. These industry characteristics exacerbate the harm to the competitive process—and ultimately to renters—from the exchange of nonpublic, competitively sensitive data through RealPage and the use of the AIRM and YieldStar models.

A. Rental Housing Is a Necessity for Millions of Americans

76. Shelter is a basic, foundational necessity of life. And for tens of millions of Americans, conventional multifamily apartment buildings are the only reasonable option for much of their lives. Many renters cannot afford the significant down payment needed to purchase a single-family home, among other requirements.

77. Demand for apartments is relatively inelastic. Rising rents have disproportionately affected low-income residents: The percentage of income spent on rent for Americans without a college degree increased from 30% in 2000 to 42% in 2017. In 2021, the proportion of severely burdened households—households spending more than half of their income on gross rent—was 25%, or approximately 10.4 million households, an increase in approximately 1 million households since 2019. By 2022, this number increased to 12.1 million households. For college graduates, the percentage of income spent on rent increased from 26% to 34% from 2000 to 2017.

B. The Multifamily Property Industry Is Rife With Cooperation Among Ostensible Competitors

78. Within particular metropolitan areas and neighborhoods, the multifamily property industry is concentrated and replete with competitively sensitive discussions among ostensible competitors. Landlords have agreed with one another to share nonpublic, sensitive information, both indirectly through RealPage software and directly outside of RealPage's software. RealPage facilitates some of these discussions, while others are made directly between competing landlords. These discussions supplement and reinforce the indirect information sharing among landlords that occurs through AIRM and YieldStar. As a result of this coordination, RealPage's pricing algorithms are even more likely to restrain, rather than promote, competition.

1. At the Local Level, the Multifamily Property Industry Comprises a Small Number of Large Landlords Managing Buildings With Different Owners

79. In 595 zip codes with at least 1,000 total multifamily units across 125 core-based statistical areas, five or fewer landlords manage more than 50% of the multifamily units. Within the submarkets alleged in this complaint, there are at least 214 zip codes, each with at least 1,000 total multifamily units, in which five or fewer landlords manage more than half of those units. Similarly, within the ten core-based statistical areas alleged in the complaint, there are 144 zip codes, each with at least 1,000 total multifamily units, in which five or fewer landlords manage more than half of those units.

80. The same landlord often oversees nearby properties with different owners. In at least 502 zip codes, at least one landlord using AIRM or YieldStar oversees properties with different owners.

81. There is also overlap among RealPage pricing advisor assignments. In at least 683 zip codes, within 96 core-based statistical areas, a RealPage pricing advisor has responsibility for properties managed by different landlords. RealPage takes no steps to avoid assigning the same pricing advisor to properties with different owners, even if those properties compete with each other or are RealPage-mapped competitors.

2. Landlords Regularly Discuss Competitively Sensitive Topics With Their Competitors and Swap Information

82. Landlords regularly solicit and obtain nonpublic information about inquiries by prospective renters, occupancy, and rents from their direct competitors. Although this information is not as accurate or thorough as the transactional-level data shared with AIRM and YieldStar, it is nonetheless sensitive competitive information.

83. Landlords collect this information through a variety of means, including weekly phone calls, emails, and in-person visits. Some landlords also share information on their local geographic markets through shared Google Drive documents. One RealPage employee explained to his colleagues, reflecting on his former time working at a landlord, that these weekly inquiries ''required cooperation among the comp[etitor]s but wasn't hard to get that.'' In June 2023, a senior director at Cushman & Wakefield admitted that ''this practice has been prevalent in our industry for a long time.''

84. Landlords not only knew of these so-called ''market surveys,'' but expected their property managers to participate. As a manager of Cushman & Wakefield's revenue management department explained, ''we have always expected our properties to continue doing a traditional market survey[,]'' which ''gives us insight into the very specific handful of competitors closest to the subject property.''

85. At a February 2020 industry event, representatives from Cushman & Wakefield and two other landlords shared tips on collecting information on concessions and net effective rents from competitors. The suggestions included bi-weekly and monthly meetings with competitors, sponsored ''cocktail hours for regional competitors to share info and build relationships and rapport,'' and using Google Drive documents to share information on a weekly basis. Building relationships with competitors to get accurate data was ''critical.'' The representatives cautioned that the collected data was used to make ''major decisions about pricing,'' so the landlord employees collecting data should be trained accordingly to ask such questions as ''are you seeing a slow down?'' and ''are you adjusting pricing?''

86. Some landlords engage in even more sensitive communications about price, demand, and market conditions. These communications are not isolated instances at a specific property. Rather, they are conversations at the corporate revenue management level about strategies and approaches to market conditions that apply to the landlords' business across all markets.

87. For example, in January 2018, Willow Bridge's director of revenue management reached out to Greystar's director of revenue management and asked about Greystar's use of auto accept in YieldStar. In response, Greystar's director provided Greystar's standard auto-accept settings, including daily and weekly limits and for which days of the week auto accept was used. The Greystar director, explaining why she provided this information, testified that the Willow Bridge director was a ''colleague,'' even though Willow Bridge was a competitor to Greystar.

88. In March 2020, Cushman & Wakefield's director of revenue management reached out to Willow Bridge's director of revenue management. The Cushman & Wakefield director wanted to hold a call among revenue management executives at multiple landlords to discuss market conditions, use of YieldStar, and strategy plans. The Willow Bridge director agreed and suggested a small number of landlords to invite to keep the group ''tight.'' The directors agreed to reach out to Greystar, as well as several other landlords.

89. Also in March 2020, a senior executive at Greystar obtained a copy of Willow Bridge's sensitive strategic plans regarding the COVID–19 pandemic. The plans included Willow Bridge's corporate protocols for concessions, rent increases, and lease terms. The plans recommended that property managers work closely with YieldStar and LRO to preserve rent integrity. The Greystar executive forwarded Willow Bridge's plans to executives at Cushman & Wakefield and another landlord. All four landlords compete with one another.

90. In September 2020, Camden's director of revenue management reached out to Greystar's director of its internal revenue management team. Camden asked Greystar—a direct competitor—what increases on renewal pricing Greystar had seen in August and offered what it had seen. Greystar's director replied with information not only on August renewals, but also on how Greystar planned to approach pricing in the upcoming quarter. Greystar's director further disclosed its practices on accepting YieldStar rates and use of concessions. As the conversation continued, the two competitors shared additional highly-sensitive information on occupancy—including in specific markets—demand, and the strategic use of concessions.

91. At the same time, Camden's director emailed a revenue management executive at LivCor and asked how LivCor was faring on raising renewal rates. He explained his request by noting that Performance Analytics provided some good data, but it was ''hard to see what our competitors are signing today.'' The two executives shared information about their respective renewal increases. After the Camden executive passed this information along internally, he continued his outreach with several other landlords and with the LivCor executive—who in the meantime had reached out to three other landlords about their renewal rates. Camden's internal team decided to raise a renewal cap to get to the same renewal gains as LivCor.

92. Camden's director received competitively sensitive information from at least four competitors. Another senior executive at Camden asked him to compile the information so it could be shared internally. That executive noted the usefulness of the competitors' information and the need to take advantage of the shared information while it was fresh.

93. In June 2021, Willow Bridge's head of revenue management emailed Greystar's revenue management director. She proposed collaborating with Greystar to convince a client to move all of its properties, including those managed by Willow Bridge and those managed by Greystar, to AIRM. But she also noted that, in thinking about ''the larger picture as well,'' it could be useful to ''coordinate with the other companies that we often share business with'' to prepare to move their clients to AIRM as well. Greystar responded favorably to transitioning the joint client to AIRM.

94. In November 2021, a revenue management executive at LivCor emailed an executive at Camden to propose a call to discuss Camden's ''renewal philosophy,'' for the purpose of informing how LivCor calculated renewal increases. The two spoke that day. The following day, another LivCor executive—who was included on the call—thanked the Camden executive for the opportunity to ''connect on industry best practices'' and asked another ''operational question'' about implementing ''larger renewal increases.'' The executives exchanged emails over the next few months, including discussing their respective strategies on maximum increases to lease renewal prices. They shared not only their increase limits in specific markets but also what price increases they were able to achieve. For example, in April 2022, the executive at LivCor reached out to Camden to share that ''my current thinking (not sure it's right, just where my mind is at) is. . . prices for almost everything are up 20%. Therefore, unless there is a good reason not to, should we be increasing rates on rentable items by 20%?'' The Camden executive responded, ''I like your thinking.'' He continued, ''Typically, we lean into the demand signals to inspire a price increase. . . . I'm divided on whether the default increase should be 20% or closer to the 10% . . . . Curious what your thoughts are!?''

95. In September 2021, a property manager at Cortland explained to a colleague that the manager had called two competitors and received from them pricing information on two-bedroom and three-bedroom units. The property manager asked for the information to decide how to act on YieldStar's price recommendations.

96. Landlords also engage in group discussions with local and national competitors about sensitive topics. For example, for a number of months in 2020, dozens of ''high-level participants'' from competing landlords participated in weekly ''multifamily leadership huddle'' videoconferences. The organizer informed participants that ''the goal of the call is to share information about what our companies are doing, share some collateral and resources,'' and then—perhaps recognizing the problematic nature of these calls—he claimed that ''then we hang up and make our own decisions.''

97. In one such call in April 2020 with over 100 attendees, participants discussed a number of topics, including ''pricing and renewal strategies.'' Several senior landlord executives, including a Greystar senior managing director and a CEO of another landlord, participated and shared their practices on new leases and renewals, use of renter payment plans, and use of YieldStar and other revenue management software. On a similar call in October 2020, participants discussed current and forecast rent prices, renewal strategies, and use of concessions. A Willow Bridge employee forwarded a colleague notes from the call, and he specifically highlighted information about a competitor's use of concessions.

98. These conversations among competing landlords have extended from the national level to local markets across the country. For example, in Minnesota, property managers from Cushman & Wakefield, Greystar, and other landlords regularly discussed competitively sensitive topics, including their future pricing. When a property manager from Greystar remarked that another property manager had declined to fully participate due to ''price fixing laws,'' the Cushman & Wakefield property manager replied to Greystar, ''Hmm . . . Price fixing laws huh? That's a new one! Well, I'm happy to keep sharing so ask away. Hoping we can kick these concessions soon or at least only have you guys be the only ones with big concessions! It's so frustrating to have to offer so much.'' The property managers from Greystar and Cushman & Wakefield continued to discuss competitively sensitive topics. For example, in response to Greystar's tipoff that it had reduced concessions and ''hop[ed] the Spring/Summer market allow us to pull further back on concessions,'' the Cushman & Wakefield property manager replied, ''That's great news and I love hearing about the concessions being pulled back. We have done the same and hoping the rest of the market follows suit.'' These communications between RealPage users that are ostensibly competitors are examples of the industry-wide coordination that magnifies the anticompetitive effects of RealPage's software.

99. In addition to contacting each other directly, many landlords also exchange information through other intermediaries. One vendor offers a tool for landlords to exchange with one another nonpublic information on concessions, net effective rents, inquiries and visits by prospective renters, and occupancy that is pulled from each landlord's property management software. Over 150 landlords nationally have used this service, including Greystar, LivCor, and some of the other largest landlords across the country. The vendor's CEO described this as a ''quid pro quo or give to get'' arrangement among landlords where ''if you share this data with me, I'll share the same data.'' A RealPage employee noted that this vendor makes it ''quicker and easier to get your market surveys.''

100. Some landlords use this direct exchange of competitively sensitive information to update competitor rents within LRO—a practice that RealPage is aware of and accepts.

101. Recently, under the scrutiny of antitrust lawsuits, some landlords have adopted internal policies prohibiting ''call arounds'' and other direct sharing of competitively sensitive information with direct competitors. But even assuming that their property managers fully comply with these legally unenforceable internal policies, these landlords continue to use RealPage's revenue management software.

3. At RealPage User Group Meetings, Landlords Discuss Competitively Sensitive Topics

102. RealPage holds monthly ''user group'' meetings attended by competing landlords that use RealPage's software. There are separate user group meetings for LRO and for YieldStar and AIRM.[5] One of RealPage's stated purposes for the user groups is to ''to promote communications between users.'' Attendees include a wide mix of competing landlords. For example, the June 2022 YieldStar user group included representatives from five of the largest property management companies in the country, among a larger group.

103. Recurring topics at the user group meetings include product enhancements and an ''idea exchange'' on potential changes to the products. The user group participants often vote on the proposals discussed in the idea exchange. But discussions have covered competitively sensitive topics, including managing lease expirations, pricing amenities, the use of concessions, pricing strategies, and how to manage properties during the COVID–19 pandemic. RealPage encouraged landlords to use the user group meetings to discuss such topics in their industry and set agendas for these meetings to aid them in doing just that, remarking that ''[t]he user group is meant to be self-governed to a degree and the clients should be leading it.'' These RealPage-fostered discussions among competitors enhance and facilitate the landlords' agreement with RealPage to use AIRM and YieldStar to align pricing.

104. At an April 2020 YieldStar user group meeting, the participants discussed strategies for handling the COVID–19 pandemic. In the presentation, two RealPage employees and a landlord led a group discussion of trends in rent payments and collections and provided five strategic tips. One tip encouraged landlords to ''push for occupancy but don't give away the farm (pricing).'' Another counseled landlords to ''balance internal and external dynamics'' and, referring to the nonpublic information used by YieldStar, to ''use transactional market data for decision support and to know when you can be more aggressive'' in pushing higher rents. Invited attendees included representatives from at least twelve landlords. At this meeting, Greystar and another landlord shared information on their usage of payment plans with tenants.

105. In May 2020, RealPage started a YieldStar user group meeting by surveying them on concessions. RealPage asked landlords how many of their properties offered concessions, whether concessions applied to new leases or renewals, and the types of concessions offered (such as discounts, gift cards, or other benefits). Invited attendees included representatives of thirteen landlords.

106. In March 2021, the user group meeting included a discussion on possible adjustments to how YieldStar calculated lease expiration premiums. A RealPage executive shared that she liked the idea of adding weekend premiums to incentivize prospective renters to move in during the week, and commented that ''the rev[enue] potential would then scale up.'' The LivCor representative responded in favor of weekend premiums, and another user group member suggested adding the proposal to the user group idea exchange. RealPage agreed to do so.

107. RealPage began its agenda for an April 2021 YieldStar user group meeting with ''strategic insights'' from a RealPage economist. This employee shared ''21 key strategic insights,'' including ''focus on renewals,'' ''be cautious with concessions,'' and ''drive up revenues—not just base rent.'' Specifically, he urged the group to ''push up new and renewal pricing where demand [is] solid'' and warned against over-relying on concessions. They were instead to ''trust the science'' of YieldStar.

[5] RealPage previously held separate AIRM and YieldStar user groups but combined them in 2023.

108. In May 2021, RealPage included a ''Back to Basics'' discussion in a YieldStar user group meeting. This discussion covered ''returning to renewal increases post-COVID'' and ''declining concessions,'' as well as eviction moratoria and areas where acceptance rates were ''seeing significant uptick in past 6 months.'' The meeting group chat is even more revealing. Over a period of approximately fifteen minutes, representatives from fifteen landlords shared their plans for renewal increases and their use of concessions. The questions were posed, ''At what point do we go back to normal? I[f] we go back to normal[,] [i]s it now? Is anyone seeing that the model is raising rent and are you doing it?'' In response, these representatives made statements on renewal increases such as ''increasing, back to normal,'' ''major rent growth on the west coast,'' ''increasing the renewals,'' ''almost all markets we are raising rents,'' ''actually raising more than before covid at some,'' ''raising,'' and ''we are pushing to get back to normal. Sending increases.'' A representative from LivCor stated, ''increasing renewals and pushing new lease rents.''

109. The user group members were similarly open about their disinterest in concessions, signaling to each other that they do not intend to offer them or would offer them less frequently. Their pronouncements included ''no consessions [sic],'' ''no concessions,'' ''considerably less concessions,'' ''less frequent and less aggressive,'' ''no concessions except in markets with a lot of lease-ups,'' and ''almost no concessions currently.'' A representative from Willow Bridge noted concessions had ''gone away a LOT. People asking for a free month on renewals and being denied, but still signing the renewal.''

110. When the discussion turned to acceptance rates, a RealPage employee stated that rates had ''pretty much gone back to pre-COVID. Rate Acceptance has grown 11% over the past 6 months.'' A landlord responded that they had ''seen our acceptance rate increase tremendously.'' Another user group member explained to the group, for ''about ⅓ of the communities I manage the [YieldStar] model was too slow to respond, and we are pushing rates above market and above YS rec[ommendation].'' A representative from Willow Bridge concluded, ''Are we deciding as a group to remove hesitation?:).''

111. The LivCor representative who attended this May 2021 meeting testified that similar discussions happened numerous times during the COVID–19 pandemic—specifically, the beginning of 2020 through the middle of 2022. In these meetings, user group members discussed new and renewal rent increases, concessions, and renewal strategies, as well as other sensitive topics.

112. RealPage claims that this and other user group meetings were not recorded.

113. The July 2021 YieldStar user group meeting, held at RealWorld (a RealPage-hosted industry event), included a roundtable discussion among competitors. One of the discussion topics? ''What is the one thing you consistently consider outside of the model when accepting or changing price and why?''

114. At the October 2021 YieldStar user group meeting, a RealPage economist gave a presentation regarding the 2022 market outlook. RealPage presented analyses on current occupancy and pricing, and on expected occupancy and rent growth in 2022 by geographic regions.

115. At the July 2022 RealWorld YieldStar user group meeting, RealPage hosted a ''roundtable discussion'' on market volatility and its impact on how to use revenue management, unit amenities and their impact on tenant rents, and best practices for conducting lease ups.[6]

116. RealPage recognized the sensitive nature of the information shared at these meetings. Beginning in late 2022, after public reporting about AIRM and YieldStar, RealPage added an antitrust compliance statement in the user group presentations. Among other directions, the statement instructed participants not to discuss ''confidential or competitively sensitive information,'' and then noted that this included ''you or your competitors' prices or anything that may affect prices, such as current or future pricing strategies, costs, discounts, concessions or profit margins.'' But these were the very topics of previous user group meetings, as described above, that RealPage encouraged its users to discuss. And these are the very types of nonpublic information that AIRM and YieldStar use to recommend and determine prices.

117. Landlords frequently take advantage of RealPage user group meeting invites to email each other directly. In August 2020, for example, an employee of Cortland emailed a user group invitee list and asked them to support a change to how YieldStar calculated the number of leases needed. In response, an employee of a different landlord agreed, adding that ''I also rely on comparing available units to adj[usted] leases needed, to forecast leases, to gut check the pricing recs. These data points are always a factor in my pricing decisions.''

C. RealPage Uses Nonpublic Information To Allow Landlords to More Easily Compare Units on an Apples-to-Apples Basis

118. Renters typically search for a rental unit using certain key criteria, including the number of bedrooms and the location. Recognizing this market reality, RealPage enables landlords to more easily compare unit prices. When picking a property's ''peer set,'' RealPage matches floorplans with the same number of bedrooms that are geographically proximate. This makes it easier for landlords, through AIRM and YieldStar, to track and respond to competitors' movements at the floor plan level.

119. To account for amenities, RealPage instructs landlords to identify amenities using standardized naming conventions so that RealPage can use machine learning to group amenities together. RealPage then provides the market value for specific amenities, allowing landlords to more accurately identify and track how their competitors value these amenities and adjust their own pricing accordingly. The peer data include the market minimum and maximum value, as well as market quartile values, for specific amenities.

IV. Realpage Harms the Competitive Process and Renters by Entereing Into Unlawful Agreements With Landlords To Share and Exploit Competitively Sensitive Data

120. AIRM's and YieldStar's use of nonpublic, competitively sensitive data is likely to harm, and has harmed, the competitive process and renters. AIRM and YieldStar distort the competitive process by using nonpublic data to maximize pricing increases and minimize pricing decreases. AIRM and YieldStar incorporate special rules, called ''guardrails,'' that override the ordinary functioning of the algorithms in ways that tend to push rival landlords' rental prices higher than would occur in a competitive market. RealPage presses landlords to curtail ''concessions'' to renters. And AIRM and YieldStar's ''lease expiration management'' features aim to sequence vacancies to maximize landlords' pricing power.

[6] A lease up is typically a pre-leasing period (such as with a newly constructed property) where a landlord is seeking to reach a certain, initial occupancy threshold.

A. AIRM and YieldStar Have the Purpose and Effect of Distorting the Competitive Pricing of Apartments

121. As RealPage frequently trumpets to landlords, ''a rising tide raises all ships.'' AIRM and YieldStar ensure that the 'tide' flows primarily one way—higher rental prices. In a hot market, AIRM and YieldStar will recommend price increases to test what the market will bear, while in a down market AIRM and YieldStar will, to the extent possible, still increase or hold prices and minimize price decreases to reach the target occupancy rate.

122. AIRM and YieldStar are designed to help landlords press pricing beyond what they could otherwise achieve while reducing the risk that other landlords would undercut them. A revenue manager at Willow Bridge explained it succinctly: YieldStar is ''designed to always test the top of the market whenever it feels it's safe to.'' By using competitors' sensitive nonpublic data to generate elasticity estimates, among other things, AIRM and YieldStar can recommend higher price increases to extract more money from renters without losing an additional lease. As RealPage explained to a YieldStar client in training, this pricing elasticity measurement informs ''how far do we stretch and pull pricing within the market.'' That, in turn, means that ''we may have a $50 increase instead of a $10 increase for that day.''

123. That insight, gleaned from competitors sharing sensitive, transactional data with RealPage, which is in turn shared with landlords through pricing recommendations, removes uncertainty and competitive pressure that benefits renters. As one landlord put it, these products ''eliminate the guessing game'' on rent.

124. As RealPage explains to its clients, AIRM and YieldStar reveal ''hidden yield.'' This extra yield or revenue is hidden in a competitive market—a market in which competitors do not share sensitive information with each other—because landlords ''can't see the opportunity'' and ''fail to capture [the] full opportunity.''

125. AIRM and YieldStar disrupt the normal competitive bargaining process between landlords and renters. They place landlords in a better negotiating position vis-à-vis renters. Landlords using AIRM and YieldStar know that these models recommend floor plan prices and price units incorporating nonpublic data of their competitors, including effective rents and occupancy rates, all of which allow landlords to raise price with more certainty.

126. As landlords appreciate, AIRM and YieldStar use competitors' nonpublic data to predict with more certainty the highest price that the market will bear for a particular unit. A landlord is therefore less likely to negotiate on price. Any potential negotiation instead turns on lease term and move-in date, which AIRM and YieldStar adjust the pricing for to avoid overexposure for the landlord in the future.

127. AIRM and YieldStar also encourage landlords to follow each other in raising rents. When transactional data reveal that peers are raising effective rents—particularly the highest and lowest competitors for a given floor plan—AIRM and YieldStar follow with recommendations to increase rental prices. This movement with the market is ingrained in the AIRM and YieldStar models; AIRM and YieldStar will not recommend a floor plan price that falls below the market minimum.

128. Accordingly, as adoption of AIRM and YieldStar increases among peer competitors, the use of AIRM and YieldStar can push prices up through a feedback effect. As peers move up, other AIRM or YieldStar users may move up accordingly. This phenomenon, where participating landlords ''likely move in unison versus against each other,'' a RealPage executive testified, explains ''the rising tide.'' The same executive saw evidence of this ''rising tide'' in 2020: When looking at multiple peer sites using YieldStar, ''we started to see the trajectory of performance and trends be eerily similar when comparing subject sites and comp sets, thus showing that we are in fact 'r[a]ising the entire tide.' '' He acknowledged that YieldStar contributed to market prices rising as a tide.

129. Landlords rely on competitors' data within AIRM and YieldStar to determine their prices and how hard they need to try to be competitive. A revenue management director at Greystar noted in an internal AIRM deck that competitors' data is ''like the boundaries of the street you are driving on.'' The director elaborated that ''the competitive market range are [sic] the edges of the road, staying in those boundaries are [sic] necessary to get you to the destination.''

130. Another landlord that used YieldStar told RealPage that within a week of adopting YieldStar they started increasing their rents, and within eleven months had raised rents more than 25% and eliminated concessions. The landlord added that they were now pricing at the top of their peers and, importantly, had ''brought the rest of the Comps rents up with us.'' A RealPage executive responded internally that this was a ''great case study that highlights performance before, during, and a result of YS [YieldStar].''

131. A landlord explained in an internal presentation that because YieldStar recommends floor plan pricing that moves with the market—a market position—YieldStar would use competitors' data to inform ''how competitive we need to be [e]ach [d]ay.''

132. AIRM uses machine learning to train models on competing landlords' sensitive data. The parameters learned in this training are then applied to each AIRM client.[7] As a result, the model uses the same method and learned parameters to generate price recommendations from the relevant data for each landlord.

133. This aligns and stabilizes prices in at least two ways. First, it reduces volatility in *how* prices change, compared to a situation in which each client sets prices independently. No longer do competitors react in distinctive ways to changing market conditions as they would in a market without access to competitors' transactional data. Instead, AIRM price recommendations tend to standardize those reactions. This leads to the second result: pricing recommendations, and consequently pricing decisions, become more predictable and aligned among competitors as each is using the same set of learned model parameters.

134. RealPage has even manipulated competitor mappings to increase the likelihood that AIRM or YieldStar would recommend price increases. For example, a prominent client asked why a subject property had mapped peers located more than 100 miles away, in a different metropolitan area, when there were satisfactory mapped competitors within five miles. RealPage's response was that if these distant properties were not mapped, the client's property would be at the top of the market and it would be more difficult for AIRM to recommend price increases. RealPage had originally mapped these distant properties to give the model more room to recommend price increases for the client's property.

135. This dynamic exists not only in markets with growing demand, but also so-called ''down markets,'' where demand is decreasing. In a competitive market with a fixed supply (at least in the short run) of housing units, a demand decrease would result in prices falling. But AIRM and YieldStar resist price decreases in down markets as much as possible while achieving targeted occupancy rates. RealPage told one prospective AIRM client that the combination of ''AI and the robust data in the RealPage ecosystem'' would allow the landlord to ''avoid the race to the bottom in down markets.''

136. Using competitors' transactional data to calibrate and set the bounds of its model enables YieldStar and AIRM to decrease prices as little as possible in a down market. As one example, in 2023 a landlord reached out to RealPage with concerns about price recommendations at a property. Despite the property having too many vacancies and peer properties decreasing in price, AIRM was recommending price increases, frustrating the property owner. A senior RealPage executive responded that the model was not lowering prices because ''there isn't much elasticity between the recommended position and the current one'' and ''the model would recommend the highest possible position [*i.e.,* price] without affecting demand.''

137. RealPage succinctly summarized for landlords the effect of using AIRM and YieldStar in down markets: it ''curbs [clients'] instincts to respond to down-market conditions by either dramatically lowering price or by holding price when they are losing velocity and/or occupancy.'' These tools instill pricing discipline in landlords, curbing normal fully independent competitive reactions by substituting them with interdependent decision-making (*i.e.,* through the use of pricing recommendations based on shared, competitively sensitive information). These products ensure that clients are ''driving *every possible opportunity to increase price* even in the most

[7] There are separate AI Supply models, and therefore potentially different learned model parameters, for clients using Yardi's property management software and clients using other property management software. But within these two categories the learned model parameters for the AI Supply models are the same.

downward trending or unexpected conditions.''

138. When one client wanted to cancel YieldStar, a RealPage executive noted to colleagues that with cancelation the client would lose ''our helping them mitigate damage during rent control and covid.'' In particular, the client would lose ''us helping them rise with the tide given their strategy.''

139. Landlords understand the sensitivity of the information being shared and the likely anticompetitive effects. One potential client put it succinctly to RealPage: ''I always liked this product [AIRM] because your algorithm uses proprietary data from other subscribers to suggest rents and term. That's classic price fixing . . . .''

140. Cushman & Wakefield recognized the anticompetitive potential of sharing this level of detailed competitor data. When a property owner asked for information on specific competitors, Cushman & Wakefield's director of revenue management replied that the requested tool, RealPage's Performance Analytics with Benchmarking, did not provide information on specific competitors. The reason? Performance Analytics with Benchmarking ''tracks transactional information therefore due [to] the potential pricing collusion, it's anonymize[d] by RealPage.'' Performance Analytics with Benchmarking draws from the same transactional database as AIRM and YieldStar. And while AIRM and YieldStar do not display the granular transactional data to the user, AIRM and YieldStar see and use that data. The price recommendations are based upon the very data that this client recognized could lead to collusion.

141. Even RealPage employees selling LRO recognized the anticompetitive harm from using competitors' transactional data to recommend prices. In a 2018 training deck provided to clients, RealPage explained, ''we often times get the question about if comps are on LRO, can we just update the rents for you? Unfortunately, no, we can't. That could be considered price collusion, and it's illegal.'' But this is precisely what AIRM and YieldStar do.

B. AIRM and YieldStar Impose Multiple Guardrails Intended to Artificially Keep Prices High or Minimize Price Decreases

142. Unsatisfied with relying merely on competitively sensitive data to advantage landlords, RealPage created ''guardrails'' within AIRM and YieldStar to force adjustments to the price recommendation. But these guardrails serve as one-way ratchets that help landlords, not renters, by increasing price recommendations or limiting a recommended decrease. And each of these guardrails makes use of competitively sensitive data that landlords agree to share with RealPage. These guardrails have even spurred multiple landlords to tell RealPage that AIRM and YieldStar are not dropping recommended rents as much as their individual conditions, or even market conditions, would warrant.

143. *Hard Floor.* AIRM and YieldStar will not recommend a floor plan price that falls below the smoothed market minimum effective rent. The market minimum is a hard floor. AIRM and YieldStar thus explicitly constrain floor plan price recommendations based on the prices of competitors, using shared nonpublic information.

144. *Revenue Protection Mode.* RealPage created a ''revenue protection'' mode that effectively lowers output to increase revenues. Revenue protection activates when AIRM or YieldStar predict—using calculations incorporating competitors' data—that demand is too low for a landlord to meet its target occupancy. Rather than lowering the price to stimulate demand, the algorithm reduces the target number of leases. AIRM and YieldStar then maximizes revenue for the *reduced* occupancy level, which tends to reduce price decreases or increase rental prices.

145. RealPage acknowledges that revenue protection ''may seem counterintuitive to leasing needs.'' In June 2023, a landlord complained to RealPage that ''something in your model is broken'' because ''the pricing model is not lowering rents dramatically'' despite the client's high exposure during a busy summer leasing season. RealPage explained that, with revenue protection, ''the model still sees the way to make more revenue is to lease fewer units at higher prices.'' In other words, the model seeks to ''raise rates to get the highest dollar value possible for the leases we can statistically achieve'' and ignore those leases that the client wants but the model predicts, using competitors' data, the client will not get.

146. The model's hard price floor can trigger revenue protection mode. In May 2022, for example, a landlord complained that AIRM was recommending price increases despite a projected shortfall in leases. Because revenue protection mode cannot be turned off, the RealPage pricing advisor recommended that the client reduce sustainable capacity. Sustainable capacity is a client-set parameter that imposes an inventory constraint and determines the number of leases AIRM and YieldStar will try to achieve. This is, of course, what revenue protection mode functionally does on its own: increase inventory constraints to reduce output.

147. This phenomenon, a RealPage employee explained internally, was ''true revenue protection mode.'' The client's floor plan was priced toward the bottom of its competitors. AIRM did not see any price decrease that would achieve the original target number of leases without dropping below the market floor (determined using competitors' data). Because AIRM never recommends prices below the market floor, AIRM instead reduced the number of leases and optimized against that new, lower occupancy rate.

148. Revenue protection mode interrupts AIRM's and YieldStar's normal revenue maximization process. As a RealPage data scientist explained, ''the model really wants to reduce rent but is prevented from doing so by the revenue protection restriction.'' Revenue protection leads to higher prices and lower occupancy.

149. *Sold-Out Mode.* Once a landlord reaches its targeted capacity for a particular floor plan, the model considers that floor plan ''sold out'' even though units may still be physically available. In that situation, AIRM and YieldStar recommends the maximum rent charged by a property's competitors, even if the floor plan's previous price was far lower.

150. RealPage intentionally designed sold-out mode to use competitively sensitive data to lift rents. In an earlier version of the software, sold-out mode pushed rents to 95% of that floor plan's highest recently achieved rent. But RealPage modified the algorithm in 2022 to go ''straight to 100% of comps,'' deliberately aligning rents with competitors' highest rents, rather than the property's own historical performance.[8]

151. *The Governor.* AIRM and YieldStar favor recommended price increases over price decreases. When the model calculates that the current day's ''optimal'' price will result in greater revenue than the previous day, a feature called the ''governor'' causes the model to recommend the current day's optimal price.[9] But when AIRM or YieldStar calculates that the current

[8] RealPage has at least considered changing this model logic because it introduced meaningful pricing volatility and significant price increases. Even if RealPage has implemented this proposed logic change, the new model logic still incorporates competitors' confidential rents because AIRM and YieldStar recommend a market position that is tied to the bottom and top of the market, as defined by mapped competitors.

[9] In some circumstances AIRM will cap the floor plan recommended price increase at a five percent increase.

day's optimal price will result in less revenue than the previous day, the governor recommends the recent average price *even though it is not optimal for the current day.* In other words, when market conditions weaken and the model calculates that a price decrease is warranted, this guardrail kicks in and recommends keeping the recent rent even though it is suboptimal. This asymmetry favors price increases over price decreases.

152. The effect of these guardrails is intentionally asymmetric. AIRM and YieldStar recommend price increases generated by the model. But the guardrails reduce or eliminate certain proposed price decreases even though the model has determined such deviations may contravene the landlord's individual economic interest.

C. AIRM and YieldStar Harm the Competitive Process by Discouraging the Use of Discounts and Price Negotiations

153. RealPage discourages landlords using AIRM and YieldStar from discounting rents. In the multifamily property industry, discounts typically consist of ''concessions,'' which are financial allowances (such as a free month's rent or waived fees) offered to incentivize renters. Concessions may be offered generally or negotiated individually with a potential tenant.

154. In a competitive marketplace, each landlord may independently decide to offer concessions so that it can better compete in enticing lessors. But, again, RealPage seeks to replace fully independent, competitive decision-making with collective action by ending concessions. AIRM and YieldStar do not work as well when landlords use one-off or lumpy concessions. In its ''best practices'' for revenue management to landlords, RealPage's guidance is simple: ''Eliminate concessions.'' Detailed ''best practices'' documents for both YieldStar and AIRM users explain that ''concessions will no longer be used in conjunction with'' YieldStar and AIRM.

155. When onboarding a new property, RealPage emphasizes the importance of accepting price recommendations without offering discounts, including ''no concessions.'' Concessions cause landlords to deviate from what RealPage determines is the maximum revenue-generating price.

156. Landlords have worked to implement RealPage's requests. In one YieldStar training, Greystar explained that ''Concessions are gone!'' In a client-facing FAQ document about its revenue management products, RealPage explained that ''the vast majority of our clients have discontinued the use of concessions.'' A 2023 RealPage client presentation showed that the number of units offering concessions generally trended downward from approximately 30% of units in 2013 to under 15% in 2023. A client's refusal to offer concessions is bolstered by its awareness of competing landlords receiving the same advice from RealPage. In addition to discouraging discounts, RealPage discourages negotiating prices with renters. RealPage trains landlords that ''YieldStar [or AIRM] is managing your Price,'' so the landlord's staff can focus on other things. The YieldStar or AIRM rent matrix is to be the source of prices that are given to a prospective renter. RealPage instructs leasing staff to provide prospective renters the specific price from the matrix that corresponds to the prospect's desired move-in date, unit, and lease term. RealPage cautions landlords not to show renters the matrix itself.

D. AIRM and YieldStar Increase and Maintain Landlords' Pricing Power by Using Competitors' Data to Manage Lease Expirations

157. Supply is a basic component of pricing. For this reason, information on a company's supply is highly sensitive, and its disclosure to competitors is particularly concerning. Yet AIRM and YieldStar use competitors' supply data precisely for the purpose of adjusting unit-level pricing, regardless of whether the landlord accepts the floor plan price recommendation. The goal of this ''lease expiration management'' is clear: As a RealPage senior manager explained for a client, using this data means that the client's property ''will remain in a position of pricing power.''

158. The purpose of lease expiration management is to avoid too many units becoming available in the market at the same time. Expiration management only increases unit-level prices. It never reduces the price.

159. Every landlord can choose to use ''market seasonality'' to inform its lease expiration management. As the name suggests, market seasonality adjusts the landlord's prices based on how many of its competitors' units will be vacant—that is, *future supply.* This feature is popular among landlords. For example, one of the largest landlords in the United States uses it in 98% of its properties. Every single property that uses market seasonality is leveraging RealPage's access to this highly sensitive, nonpublic data about its competitors' supply to inform pricing. RealPage trains landlords to turn on market seasonality as a best practice.

160. When activated, the market seasonality function changes unit-level prices across the different possible lease terms *regardless* of whether the landlord accepts the AIRM or YieldStar floor plan price recommendation.

161. RealPage determines for landlords an important input into lease expiration management: the expirations threshold. This threshold influences the point at which expiration premiums are added. The threshold calculation relies on nonpublic lease transaction data for the property's submarket and pulls from numerous RealPage products, including YieldStar, AIRM, OneSite, Business Intelligence, and Performance Analytics with Benchmarking. Landlords cannot adjust the expirations threshold.

162. Fueled by competitor data, expiration management results in ''increased stability'' and ''pricing power.'' Using competitors' data reduces the risk of overexposure that ''could erode rent roll growth.'' By adjusting price recommendations based on how much total supply is forecast in the market for a given time period, AIRM empowers landlords to charge higher prices than they could without access to competitors' nonpublic data.

E. No Procompetitive Benefit Justifies, Much Less Outweighs, RealPage's Use of Competitively Sensitive Data To Align Competing Landlords

163. AIRM and YieldStar do not benefit the competitive process or renters. Any legitimate benefits of revenue management software can be achieved through less anticompetitive means, and any theoretical additional benefits of AIRM and YieldStar are not cognizable and outweighed by harm to the competitive process and to renters.

V. Realpage Uses Landlords' Competitively Sensitive Data To Maintain its Monopoly and Exclude Commercial Revenue Management Software Competitors

164. Landlords are not the only ones that benefit from RealPage's rental pricing practices. RealPage benefits too through maintaining its monopoly over commercial revenue management software for conventional multifamily housing rentals. In that market, RealPage's internal documents reflect that it commands an 80% share.

165. RealPage's core value proposition creates a self-reinforcing feedback loop of data and scale advantages. The sharing of competitively sensitive information among rivals attracts more landlords that seek to maximize revenues and extract more money from renters. As a result of its exclusionary conduct, RealPage has been able to

obstruct rival software providers from competing on the merits via revenue management products that do not harm the competitive process.

166. Over time, RealPage has become more entrenched and has stymied alternatives unless they too enter into similar unlawful agreements with landlords to obtain and use nonpublic transactional data to price units. Even then, RealPage's unparalleled troves of competitively sensitive data provide an ill-gotten advantage.

A. Landlords Are Drawn to RealPage Because of Access to Nonpublic Transactional Data That Is Used to Increase Landlords' Revenue

167. Landlords prize RealPage's accumulation of nonpublic transactional data from competing landlords. For example, Greystar noted that ''RealPage supplies the best set of transactional data available via their millions of units of data—this becomes a valuable source of truth to our competitive landscape.'' In a training document for its employees, the same landlord explained that ''better data = better outcomes'' and that AIRM has ''over 15 million units of data available.'' From the perspective of Greystar, ''pricing decisions start with data'' and that precision in pricing ''comes from data driven decisions.'' Importantly, the landlord believed that AIRM's ability to ''examine data quality . . . each night'' via its property management software integrations, including guest card entry, ''plays an important role'' in pricing.

168. As another example, Cushman & Wakefield identified this data as especially helpful in a dense market because of insights into competitors' actions in the market. The same landlord also concluded that the more data points, the better confidence a landlord has in RealPage's rental recommendations. According to Cushman & Wakefield, more data—especially data about concessions—enabled the landlord to make better decisions because it showed the landlord where the market stood. Cushman & Wakefield's director of revenue management explained to a colleague that YieldStar ''collects about 14 MILLION transactional lease data across the US and has over 20 years of historical records.'' The director acknowledged that ''[t]his is huge! Essentially, this is a window into the market and the shifts we are going to experience . . . Having insight into this data, allows [landlords] to make changes with the dynamic changes in the market.''

169. Willow Bridge, who compared AIRM to another commercial revenue management software product, noted that the competing product ''is about half of the cost and does a good job in reviewing rents and making recommendations but does it without the additional reporting capabilities and market data that AIRM uses.'' Ultimately, this landlord decided to push their owner clients towards AIRM. The landlord's decision to use AIRM was in part based on receiving ''more accurate and time sensitive data'' and noted that, although revenue management is not changing, ''the amount of data and how that information is used to grow revenue is bigger and better than ever'' with AIRM.

170. Landlords want access to RealPage's transactional data because RealPage advertises, and landlords believe, that the use of this data will increase a landlord's revenue. ''Due to the amount of data RealPage possesses,'' Greystar explained, RealPage developed AIRM ''to leverage machine learning to improve both the supply and demand modeling and provide a tool to further customize to each asset's needs.'' The materials sent to the landlord's clients also included a flyer explaining that AIRM will ''outperform the market 2–7% year over year'' and that it provides ''[a]ctionable intelligence derived from the industry's largest lease transaction database of 13M+ units.''

171. Landlords view the lack of access to transactional data as a significant shortcoming in other commercial revenue management software. One landlord received a request from a property owner client for information on YieldStar and how it compared to another commercial revenue management product. A landlord executive explained that YieldStar was backed by robust data and ''millions of units of transactional data to support not only their demand and forecast modeling but also their market/competitive set information.'' She concluded that the other revenue management software was ''in a completely different class'' than YieldStar. More than two years later, the same executive again concluded that this company's new revenue management product was inferior to AIRM because AIRM had far more transactional data, supported by RealPage's Market Analytics survey data. In another example, a different landlord compared multiple commercial revenue management products to RealPage's YieldStar. He concluded that a major weakness of these alternatives was that they lacked access to transactional data on competitors' rents.

B. RealPage's Collection and Use of Competitively Sensitive Data Excludes Competition in Commercial Revenue Management Software

172. RealPage recognizes the barriers to competition on the merits that its data, scale, and business model provide. RealPage understands that ''pricing decisions start with data.'' RealPage explains to its clients that ''[t]he data entered into your [property management software] and collected each night, along with current market data (and lead data if OneSite) provides insight into advantageous demand drivers, identifies revenue risk and opportunity, and captures this competitive landscape for informed pricing.''

173. This data and scale advantage is significant and creates a feedback loop that further increases barriers to competition for commercial revenue management software. RealPage touts its access to an ''unmatched database.'' In one case from 2023, a RealPage sales representative noted that RealPage's ''revenue management is the most widely adopted solution in the industry'' and RealPage had ''approximately 4.8M units on revenue management.'' In a 2023 presentation for AIRM, RealPage advertised that the ''[a]mount of data we have (~17mm units) is unique to RealPage'' and that the ''[q]uality of data is best in class given that it is 'Lease Transaction Data.'" RealPage claimed this ''supports that fact that the industry views RealPage as the source of truth for performance data.''

174. RealPage has used this competitively sensitive data to develop an AI-driven revenue management solution that leverages the scale and scope of its data. RealPage's plan to use this database as fuel for its AI pricing model is spelled out in a Go-To-Market summary from 2019. In that document, RealPage describes that:

> RealPage can achieve $10 Million in organic ACV growth through delivery of the next generation of revenue management. Failure to do so reduces the opportunity to harvest gains from our $300M investment in LRO and places a portion of current $100M revenue management revenue at risk to emerging competitors, including Yardi and low-cost alternatives that say 'all revenue management is the same.' Over time we can sunset YieldStar and LRO reducing expense, and leverage LRO capabilities as a revenue management lite offering.

175. This plan came to fruition with the introduction of AIRM. In a RealPage training presentation from February 2020—right before the launch of AIRM—RealPage discusses a new optimization solution that is built on the ''RealPage Foundation'' which is

defined as ''13.5m units of lease transactional data informing our models with real actionable intelligence in near real time.'' As described earlier in the deck, RealPage's competitors ''lack the foundational capabilities on which to build upon'' leaving RealPage with the possibility ''to tie together each capability . . . in a single view.''

176. RealPage knows that its rivals do not have access to similar data sets. In one presentation from 2022, RealPage discussed competing revenue management products from Yardi and Entrata. Yardi and Entrata have fewer than 250,000 units, RealPage concluded, while RealPage had at least 4 million. Unlike RealPage, Yardi had a limited data set that used data only from Yardi's property management software. RealPage likewise explained that Entrata lacked much data outside of student housing and Entrata's revenue management software worked only with its own property management software, meaning Entrata could not pull data from RealPage's OneSite or other property management software products. RealPage further criticized manual in-house pricing options for having biased data, introducing errors through manual pricing, and being inefficient.

177. RealPage pitches prospective clients on its unique access to and use of nonpublic transactional data that is competitively sensitive. In 2021, RealPage discussed internally how to pitch AIRM to a prospective client who was considering an alternative revenue management solution. A RealPage employee pointed to the competitor's lack of ''AI driven competitor information derived from lease transaction data.'' Another employee added that the salesperson should amplify the prospective client's concerns about the competitor's lack of nonpublic transactional data, comparing it to buying a ''Ferrari without an engine.'' RealPage's chief economist concurred.

178. RealPage's use of competitors' nonpublic transactional data provides it an important advantage on pricing renewals. Information on renewals is not available publicly. Competing revenue management vendors who do not use nonpublic, competitively sensitive data are left partially blind to this important part of the rental market. In 2022, a RealPage salesperson stressed this advantage to a prospective client who was also considering a competing commercial revenue management solution. The salesperson noted the lease transaction data RealPage collected on a nightly basis and declared that RealPage had an ''unequaled ability to stress test renewals *nightly* and drive amenity optimization.''

179. RealPage recognizes that its use of competitively sensitive data minimizes any competitive pressure it faces. A RealPage senior vice president explained in a strategy document that RealPage's unique nonpublic data on leasing decisions was a ''data moat,'' protecting RealPage from competitors. In 2020 RealPage's chief economist noted that RealPage's access to this data was a ''major competitive advantage'' and a ''major reason we can do what we do.'' In 2021 a prospective client asked RealPage why AIRM cost three times the amount of a competing revenue management product. Internally, a RealPage employee pointed to AIRM leveraging daily transactional data of over 13 million units to collect competitors' rents and forecast demand. He noted that multiple large landlords had refused to adopt the competing revenue management product rather than AIRM even when the competitor offered it for free. The same RealPage employee explained to another client that RealPage's leveraging of lease transaction data—with access to confidential data for over 14 million units—was a key advantage over a competing commercial revenue management provider.

180. In June 2023 a landlord emailed RealPage and asked, ''who are your competitors?'' A RealPage sales executive responded, ''Our revenue management solution does not have any true competitors, mainly because our data is based on real lease transaction data from all kinds of third-party property management systems . . . .''

181. In addition, when discussing a potential entrant, a RealPage executive noted that the entrant needed ''to get the data to enable [revenue management].'' He further noted that [g]etting the data (and more modern methods) . . . will be hurdles for [the entrant].'' Another RealPage senior executive explained that shifting clients from LRO, which is less reliant on competitively sensitive information of rivals, to AIRM, which is very reliant on such information, reduced the threat from new entry when she noted that migrating LRO clients to AIRM was ''critical to reducing the risk that may come from this new [entrant's] offering.''

182. RealPage's power and conduct in connection with commercial revenue management software serves to exclude rivals and maintain its monopoly power. RealPage has ensured rivals cannot compete on the merits unless they enter into similar agreements with landlords, offer to share competitively sensitive information among rival landlords, and engage in actions to increase compliance. As a result of its exclusionary conduct, RealPage has been able to obstruct rival software providers from competing via revenue management products that do not harm the competitive process in addition to cementing its massive data and scale advantage that keeps increasing due to feedback effects.

VI. Relevant Markets

A. Conventional Multifamily Rental Housing Markets

1. Product Markets

183. Conventional multifamily rental housing is a relevant product market. Conventional multifamily rental housing includes apartments available to the general public in properties that have five or more living units. Conventional rental housing does not include student housing, affordable housing, age-restricted or senior housing, or military housing. This product market reflects consumer preferences, industry practice, and governmental policy.

184. In 2023, RealPage estimated the conventional multifamily rental market to cover approximately 14 million units. The 2021 American Housing Survey estimated a total of 21.1 million multifamily apartments—not limited to conventional—in the United States.

(a) Conventional Multifamily Rentals Are Distinct From Other Types of Multifamily Housing

185. Other types of multifamily apartment buildings are not good substitutes for conventional multifamily rentals. Some kinds of multifamily buildings are restricted to specific types of renters, such as student housing units, affordable housing units (*i.e.,* income-restricted housing), senior (*i.e.,* age-restricted) housing, and military housing. These housing units focused on different classes of renters are not reasonable substitutes for conventional multifamily rentals. RealPage distinguishes conventional multifamily as being in a different market segment from senior, affordable, and student housing in the ordinary course of business.

186. Non-conventional units are not widely available to all renters and can exhibit different buying patterns. For example, student housing serves individuals enrolled in higher education and is typically located on or near universities. Student housing is typically leased by the bed instead of by unit, and faces a significantly different leasing cycle and different patterns in

renewals and leasing practices. Recognizing these differences, RealPage will assign to student properties surrogates that are distant student assets rather than nearby conventional assets. RealPage in fact offers a different version of both AIRM and OneSite, its property management software, for the ''student market.''

187. Affordable housing units are available only to individuals or households whose income falls below certain thresholds. Multiple federal affordable housing regulations, for example, require participants in affordable housing programs to have incomes lower than a set percentage, such as 30%, of the median family income in the local area. Affordable housing units are also relatively scarce, with families seeking such housing often waiting years on a waitlist. These legal and practical restrictions prevent affordable housing from being a reasonable substitute to conventional multifamily housing for the typical renter.

188. Senior housing is typically restricted to individuals aged 55 and older. RealPage separates senior housing into four categories: independent living, assisted living, memory care, and nursing care. Independent living offers senior-focused amenities—such as transportation, meals, and social gatherings among community members—that materially increase housing costs and are less desirable to younger households. The other three categories of senior housing provide professional or special care to assist renters with basic tasks like eating, bathing, and dressing, and they are not reasonable substitutes for conventional multifamily rentals.

189. Military housing is also not a reasonable substitute to conventional multifamily rentals. It is typically geographically proximate to military installations, with roughly 95% of military housing found on-base. Although civilians may in some cases be able to live in military housing properties experiencing low occupancy rates, military regulations place them below five higher-priority categories of potential renters, including active and retired military personnel.

(b) Single-Family Housing Is Not A Reasonable Substitute to Multifamily Rentals

190. The multifamily industry, government regulators, and policy documents distinguish between properties with at least five units, which are classified as ''multifamily housing'' and those with fewer units, which are classified as ''single-family rentals.''

191. The purchase of single-family or other types of homes is not a reasonable substitute for conventional multifamily housing rentals. A former RealPage economist explained that ''the choice between renting and owning is first and foremost a life stage and lifestyle choice over a financial one.'' Single-family homes also generally require a substantial down payment. In March 2023, a RealPage economist estimated an ''entry premium'' of $800 per month to home ownership over rentals. According to a 2021 RealPage strategic planning guide, the ''myth'' that people were abandoning multifamily properties for single-family homes is false, stating that ''rising home sales do not hurt apartment demand.'' Single-family home sales are not reasonable substitutes for conventional multifamily housing.

192. More broadly, renters living in conventional multifamily apartments will not switch to single-family homes—purchases or rentals—because of a small increase in rent. The decision to move from an apartment building to a single-family home is primarily a life-stage and lifestyle choice. For example, the decision by a household to have children may spur a move to a single-family home. In many areas, relatively few children live in conventional multifamily apartments. Multifamily apartments typically offer community amenities and a different lifestyle, such as high walkability in an urban area, whereas single-family homes generally do not offer the same amenities and offer instead increased privacy, including private yards. A RealPage analyst explained in 2022 that because a move to a single-family home is a ''lifestyle choice,'' single-family home rentals were not direct competitors to multifamily rental housing. A 2022 RealPage deck, shared with a landlord, stated that multifamily rentals and single-family rentals were ''complementary, not competitive,'' and targeted different renters, with different floor plans, in different locations. Another RealPage analyst explained to a multifamily property owner that single-family rentals offer a different renter profile than multifamily rentals.

193. Industry participants agree that single-family rentals attract a different pool of renters from multifamily rentals. A managing director of a single-family rental property management company explained in 2021 that a renter's journey from multifamily apartment living to single-family rentals came as life stages evolved. The CEO of a single-family rental developer similarly explained that these single-family rental homes are for renters who age out of multifamily apartments.

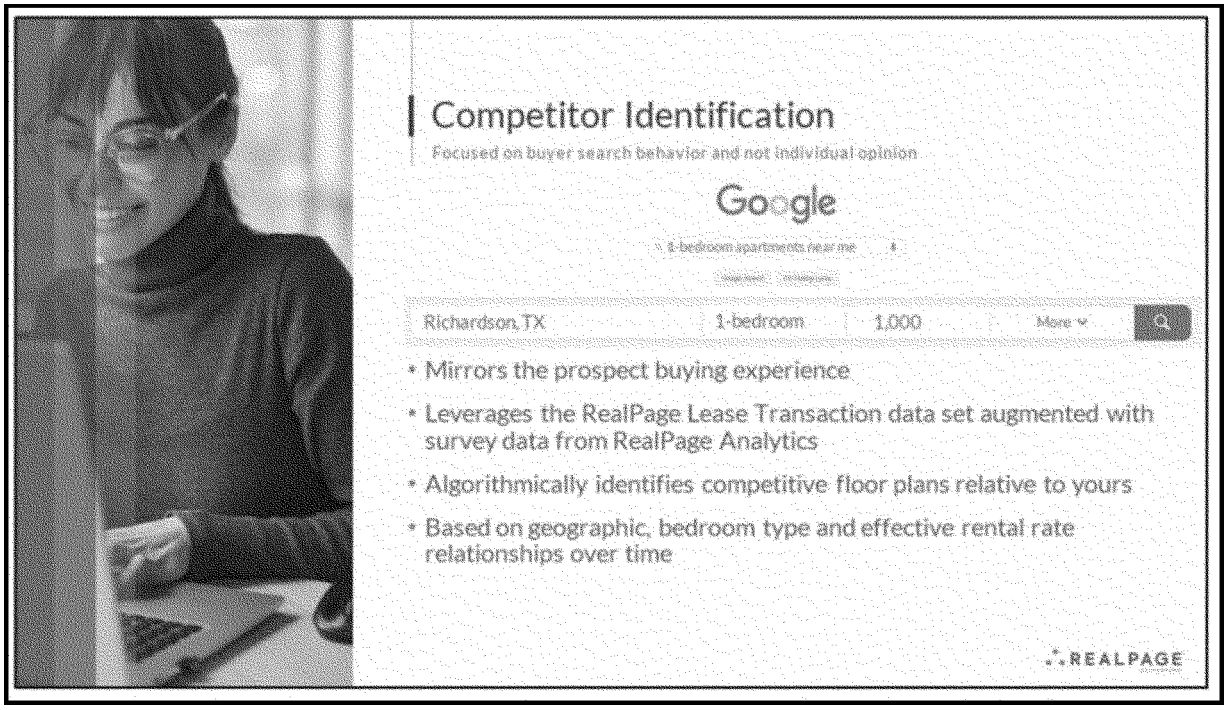
194. Single-family rentals are also typically priced higher than multifamily apartments, further reducing potential substitution between them. The chairman of one institutional multifamily property owner explained in a 2022 earnings call that multifamily housing was relatively affordable compared to single-family rentals. An industry price index showed that, in March 2024, single-family rent was approximately 18% higher than multifamily rent.

(c) Conventional Multifamily Rental Units With Different Bedroom Counts Are Relevant Product Markets

195. Different bedroom floor plans also constitute relevant product markets. A key criterion by which a current or prospective renter searches for a rental unit is the number of bedrooms. One-bedroom units are substitutes for other one-bedroom units, two-bedroom units are substitutes for other two-bedroom units, and so forth. Individual renters may change their desired numbers of bedrooms, but this is typically tied to changes in circumstance independent from price. For example, the birth of a new child may require a family to shift from a one-bedroom unit to a two-bedroom unit.

196. RealPage adopts this practical reality in the ordinary course of business. For every property using AIRM or YieldStar, RealPage maps peer floor plans. These mapped floor plans capture reasonable substitutes for the subject property floor plan and reflect the perceived market by a prospective renter.

197. To be selected as a peer, a floor plan must have the same number of bedrooms. A RealPage employee explained the mapping process to a client: ''we are looking specifically at the bedroom level. The tool will only map 2b[edroom] with 2b[edroom] or 1b[edroom] with 1b[edroom].'' The object of mapping peers is to mirror the prospect buying experience by identifying properties that a potential tenant will see in online searches when searching for a particular floor plan and price range.



198. AIRM and YieldStar price the different floor plans, which consist of different numbers of bedrooms, independently. RealPage testified that the model considers no cross-price elasticity between different floor plans: ''when you set up the different floor plans, a one bedroom, a two bedroom, or three bedroom, those are completely independent. . . . [T]here's no influence in what the pricing is for the two bedrooms, for example . . . has no influence on what the pricing is for the one bedrooms.'' Landlords also take steps to maintain a pricing spread between one- and two-bedroom units and avoid pricing one-bedrooms at a higher rate than two-bedroom units.

199. Landlords recognize that units with different bedroom counts face different demand from renters. For example, Greystar explained internally in 2022 that demand for studio apartments differs from demand for three-bedroom units. A separate 2023 training by Greystar reiterated that demand trends, and therefore pricing trends, differ by bedroom counts and that staff should not react to a downward trend in one category, such as two bedrooms, with discounts in one- or three-bedroom units. At another time, Greystar emphasized the benefit of RealPage's lease expiration management feature because it is managed at the bedroom level—not at the property level—so it could match seasonal demand for units with that specific number of bedrooms. A revenue manager at Willow Bridge similarly explained to colleagues that one-bedroom units have drastically different demand patterns from two-bedroom units and from three-bedroom units.

2. Geographic Markets

200. Defining relevant geographic markets help courts assess the potential anticompetitive impact of the agreements challenged. Here, the relevant geographic markets for the purposes of analyzing the anticompetitive effects of RealPage's agreements with landlords are the areas in which the sellers (the landlords) sell and in which the purchasers (potential renters) can practicably turn for alternatives. RealPage's agreements are alleged to have suppressed price competition in the markets for conventional multifamily housing. The relevant geographic markets to assess those agreements are those property locations close enough for their apartments to be considered reasonable substitutes. In delineating a geographic market for conventional multifamily housing, the focus is inherently local. Renters are typically tied to a particular location for work, family, or other needs.

201. RealPage recognizes the local nature of geographic markets. One RealPage former employee explained that under ''Real Estate 101 rules, real estate is local, local, local.'' Another RealPage former chief economist noted that an effective evaluation of a property's performance must be done in comparison to similar properties in the property's neighborhood because competitive conditions in the neighborhood could differ widely from the city at large. When training landlords on lease expiration management, two RealPage executives explained that market seasonality was based on the most accurate geographic level, such as zip code, neighborhood, or submarket. They further explained that renters typically move locally. Similarly, a former property manager explained that potential tenants will look at a small number of properties in the same neighborhood, and it is on that neighborhood level where competition occurs among multifamily properties. This individual testified, ''location really does matter in real estate.''

202. RealPage has created a tool called True Comps. Used in performance benchmarking products that provide decisional support to AIRM and YieldStar, True Comps provides a more accurate mapping of competitor properties. It uses an algorithm to find the properties most comparable to the subject property, as measured by characteristics including distance, effective rent, age, property height, and unit count and mix. By default, True Comps picks competitors within a 15-mile radius. In scoring distance, True Comps applies a ''highly-punitive model''—the distance score drops from 99% for a distance of 0.05 miles, to 56% for a distance of 2 miles, and to 10% for a distance of 8 miles. Thus, RealPage acknowledges and incorporates small geographic areas as the appropriate

location in which to find true competitive alternatives.

203. During a property's implementation process, AIRM and YieldStar require the mapping of peer properties, including competitors. RealPage starts by looking for competitors within a half-mile radius from the subject property and then expands as necessary. Geographic proximity is in fact so important that YieldStar has a default radius that limits its search for competing properties to no more than 5 miles in urban settings, and to no more than 10 miles in suburban settings. RealPage has an internal process for escalating any proposed peer property that is more than 15 miles away.

(a) RealPage-Defined Submarkets Identify Relevant Geographic Markets

204. RealPage defines geographic submarkets in the ordinary course of business. Each submarket reflects the geographic area, defined by a set of zip codes, that features similar properties that compete for the same pool of potential renters. In constructing submarkets, which are generally larger than its neighborhoods, RealPage considers major roads, city and county boundaries, and school districts. RealPage also considers socioeconomic factors and apartment market characteristics, such as the age of properties and rental rates.

205. Even within a city, apartment demand varies significantly based on factors such as employment. Supply may also vary widely as existing properties and new construction may be located in different parts of a city. A former RealPage chief economist explained that because ''real estate is very local . . . you typically want to take a . . . more narrow view if you can on what's going on in any given submarket.'' [10]

206. The multifamily industry recognizes submarkets as an important geographic area for analyzing competition and pools of renters. Multiple industry analysts offer data by submarkets. A revenue management director at Greystar testified about a submarket that ''everybody in our industry uses this term.'' She further stated that submarkets are a standard categorization system, used by RealPage and others, including to benchmark a subject property's performance with comparable properties. A revenue manager at Cushman & Wakefield circulated a scorecard comparing performance to the submarket, and exclaimed that ''we're perfectly aligned with the submarket'' on rent roll.

207. A revenue management executive at Willow Bridge testified that submarkets identify specific, smaller areas of a city where renters look to live to be close to schools or work. This executive testified that submarkets typically identify the area within which a renter is comparing apartment options. This landlord tracks other properties' rents in a subject property's submarket to make sure the subject property remains competitive, and if rents in a submarket increased, then the landlord expected that its property in that submarket would also raise its rents.

208. Appendix A lists RealPage-defined submarkets that identify relevant local markets in which the agreements among RealPage and landlords to share nonpublic, competitively sensitive information for use in pricing conventional multifamily rentals have harmed, or are likely to harm, competition and thus renters.

209. The RealPage-defined submarkets identified in Appendix A are relevant markets in which the agreements between RealPage and AIRM and YieldStar users to align pricing has harmed, or is likely to harm, competition and thus renters. In each of these markets, the penetration rate for AIRM and YieldStar ranges from at least around 26% to 69%, and for AIRM, YieldStar, and OneSite ranges from at least around 30% to 78%.[11] In each of these markets, the landlords using AIRM or YieldStar and/or sharing competitively sensitive information collectively have market power.

210. Appendix B identifies submarkets by bedroom count that are relevant markets in which the agreements between RealPage and landlords, and agreements among landlords, to share nonpublic, competitively sensitive information for use in pricing conventional multifamily rentals have harmed, or are likely to harm, competition and thus renters.

211. The markets identified in Appendix B are relevant markets in which the agreements between RealPage and AIRM and YieldStar users to align pricing collectively have harmed, or are likely to harm, competition and thus renters. In each of these markets, the penetration rate for AIRM and YieldStar ranges from at least around 26% to 79%, and for AIRM, YieldStar, and OneSite ranges from at least around 30% to over 80%. In each of these markets, the landlords using AIRM or YieldStar and/or sharing competitively sensitive information collectively have market power.

(b) Core-Based Statistical Areas (CBSAs) Are Relevant Geographic Markets

212. A core-based statistical area (CBSA) is also a relevant geographic market. A CBSA is a geographic area based on a county or group of counties. A CBSA has at least one core of at least 10,000 individuals. A CBSA includes adjacent counties that have a high degree of social and economic integration with the core, as measured by commuting ties. A CBSA includes both metropolitan statistical areas and micropolitan statistical areas. A CBSA includes the set of reasonable conventional multifamily rental alternatives to which a renter would turn in response to a small but significant, nontransitory price increase.

213. RealPage itself tracks CBSAs in the ordinary course of business and refers to them as ''markets.''

214. Table 1 identifies relevant markets in which the agreements between RealPage and landlords, and agreements among landlords, to share nonpublic, competitively sensitive information for use in pricing conventional multifamily rentals collectively have harmed, or are likely to harm, competition and/or consumers. In each of these markets, the penetration rate for AIRM and YieldStar ranges from at least around 26% to 37%, and for AIRM, YieldStar, and OneSite ranges from at least around 35% to 45%. Three of these markets are located in North Carolina.

[10] RealPage also tracks data at a more granular level than a submarket, called a neighborhood.

[11] Including penetration rates for RealPage's Business Intelligence and Performance Analytics with Benchmarking products, which landlord users agree to share nonpublic data with RealPage that RealPage then uses in AIRM and YieldStar, would increase the data penetration rates subject to unlawful agreements for these and all other relevant conventional multifamily rental housing markets identified in the Complaint.

Table 1: Core-Based Statistical Area (CBSA) Markets

Core-Based Statistical Area (CBSA) Markets	YS/AIRM 30% or More	YS/AIRM/OneSite 30% or More
Atlanta-Sandy Springs-Roswell, GA	Yes	Yes
Austin-Round Rock, TX	Yes	Yes
Charleston-North Charleston, SC		Yes
Charlotte-Concord-Gastonia, NC-SC	Yes	Yes
Dallas-Fort Worth-Arlington, TX	Yes	Yes
Denver-Aurora-Lakewood, CO	Yes	Yes
Durham-Chapel Hill, NC	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN		Yes
Orlando-Kissimmee-Sanford, FL	Yes	Yes
Raleigh, NC	Yes	Yes

215. The markets identified in Table 1 are relevant markets in which the agreements between RealPage and AIRM and YieldStar users to align pricing collectively have harmed, or are likely to harm, competition and thus renters.

216. Table 2 identifies relevant CBSAs by bedroom counts that are relevant markets in which the agreements between RealPage and landlords, and agreements among landlords, to share nonpublic, competitively sensitive information for use in pricing conventional multifamily rentals collectively have harmed, or are likely to harm, competition and/or consumers. In each of these markets, the penetration rate for AIRM and YieldStar ranges from at least around 27% to 42%, and for AIRM, YieldStar, and OneSite ranges from at least around 33% to 45%.

Table 2: Core-Based Statistical Area (CBSA) Markets by Bedroom Count

Core-Based Statistical Area (CBSA) Markets	No. of Beds.	YS/AIRM 30% or More	YS/AIRM/ OneSite 30% or More
Atlanta-Sandy Springs-Roswell, GA	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	2	Yes	Yes
Austin-Round Rock, TX	1	Yes	Yes
Austin-Round Rock, TX	2	Yes	Yes
Charleston-North Charleston, SC	1	Yes	Yes
Charleston-North Charleston, SC	2		Yes
Charlotte-Concord-Gastonia, NC-SC	1	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	2	Yes	Yes
Dallas-Fort Worth-Arlington, TX	1	Yes	Yes
Dallas-Fort Worth-Arlington, TX	2	Yes	Yes
Denver-Aurora-Lakewood, CO	1	Yes	Yes
Denver-Aurora-Lakewood, CO	2	Yes	Yes
Durham-Chapel Hill, NC	1	Yes	Yes
Durham-Chapel Hill, NC	2	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	1	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	2		Yes
Orlando-Kissimmee-Sanford, FL	1	Yes	Yes
Orlando-Kissimmee-Sanford, FL	2	Yes	Yes
Raleigh, NC	1	Yes	Yes
Raleigh, NC	2	Yes	Yes

217. The markets identified in Table 2 are relevant markets in which the agreements between RealPage and AIRM and YieldStar users to align pricing collectively have harmed, or are likely to harm, competition and thus renters.

218. Even assuming available land and no regulatory constrictions, local markets for conventional multifamily rental housing feature substantial barriers to entry. Landlords seeking to respond to rising rental prices by expanding supply, rather than simply acquiring an existing property, typically face substantial lead times to construct a new multifamily property. Additionally, there are significant upfront capital costs, including to fund expenditures on building material and labor, that are recuperated over time, which may require landlords to secure financing.

B. Commercial Revenue Management Software Market

219. RealPage has monopoly power in the market for commercial revenue management software for conventional multifamily housing rentals in the United States, with a durable market share over 80%, according to internal documents and other information.

1. Product Market

220. Commercial revenue management software for conventional multifamily housing rentals is a relevant antitrust product market.

221. Other methods for pricing conventional multifamily housing units are not reasonable substitutes for commercial revenue management software. RealPage and others in the industry recognize that revenue management software companies for multifamily housing units compete primarily against each other and not manual or do-it-yourself pricing methods.

222. Internal documents from RealPage refer specifically to commercial revenue management for multifamily housing and recognize RealPage's substantial market share. For example, a 2021 strategy presentation described RealPage as ''the market leader in commercial revenue management for multifamily [housing] with 45 of the 50 Top NMHC Owner and Operators'' all using RealPage's revenue management products.

223. A presentation to RealPage's board in 2022 noted that ''[RealPage] has gained [the] pole position in Revenue Management largely through the success of AI Revenue Management, which has become RealPage's leading differentiating product.'' Additionally, the presentation described how ''Revenue Management is experiencing strong growth driven by AIRM'' due to its ''PMS agnostic approach'' which gives RealPage the ability to aggregate data from its clients resulting in ''revenue management [that] has achieved a market share of 95% of the top 50 owners and operators.''

224. RealPage acknowledges its market power and durable market position. A 2023 RealPage presentation reviewing the use of artificial

intelligence in property technology noted that ''RealPage is already the de facto market leader in certain key areas at leveraging AI for multifamily proptech'' and shows ''revenue management'' as the area where it is the furthest ahead.'' Later, the same presentation noted that RealPage's current offer for revenue management is ''best-in-class'' and that ''[n]o other company is cross-pollinating their pricing tools with data in a way similar to [RealPage].'' As early as 2019, a RealPage presentation for clients stated that RealPage ''has around 80% of the Revenue Management market share.'' That share has proved durable over time. In 2023, during a sales pitch to a property owner, a RealPage representative noted that ''[RealPage] has 80% to 85% of the market share with the closest competitor around 12% (<750K units).''

225. In late 2021, a RealPage employee preparing competitor intelligence explained to RealPage's chief economist that RealPage ''dominate[d]'' revenue management. He added that RealPage ''dominate[d]'' Yardi and Entrata, which are the next two largest commercial revenue management competitors.

226. RealPage's monopoly power is protected by barriers to entry, including the unlawful collection and use of competitors' nonpublic transactional data on millions of multifamily units.

227. Landlords also recognize RealPage's substantial market share and market power over commercial revenue management software. In 2024, a landlord revenue management executive testified that manual pricing does not compete with AIRM. The same landlord pitched YieldStar to its owner clients by explaining that ''it's evident manual pricing cannot solve at the level a revenue management tool can.''

228. In a 2023 pricing dispute with a large landlord, RealPage refused to lower the price for its AIRM software. In response, an employee employed by the landlord noted that it was no surprise they would not decrease their price, remarking that ''[h]ere is the joy of a monopoly on a product category.'' In 2021, a different landlord commented that ''the entire industry is feeling the monopolizing effects of RealPage right now and everyone is hungry for a new product.'' A third landlord noted during AIRM renewal negotiations in 2022 that it had no options besides RealPage, with a senior executive stating about RealPage, ''too bad they have a monopoly going here!'' Also in 2022, a fourth landlord, in the face of RealPage pushing a 400% increase in annual revenue management costs over a five-year period, bemoaned the ''limited competition in the market around revenue management tools'' and how ''the industry desperately needs a solid competitor,'' and then discussed a plan to ''incubate a viable alternative to AIRM in the future.'' In 2024, that alternative had less than one half of one percent market share.

2. Geographic Market

229. The United States is a relevant geographic market for commercial revenue management software. RealPage sells its commercial revenue management software in the United States and tracks its business in the United States in the ordinary course of business. RealPage sets its subscription prices on a nationwide basis. Further, RealPage can deploy its commercial revenue management software, which may use inputs from properties located throughout the country, in any U.S. state. Landlords in the United States purchase commercial revenue management software from RealPage to set rental prices for renters in the United States. Many landlords have centralized revenue management teams that set nationwide revenue management policies and conduct revenue management trainings for their employees across the United States.

VII. Jurisdiction, Venue, and Commerce

230. The United States brings this action pursuant to Section 4 of the Sherman Act, 15 U.S.C. 4, to prevent and restrain RealPage's violations of Sections 1 and 2 of the Sherman Act, 15 U.S.C. 1, 2.

231. The Attorneys General assert these claims based on their independent authority to bring this action pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26, and common law, to obtain injunctive and other equitable relief based on RealPage's anticompetitive practices in violation of Sections 1 and 2 of the Sherman Act, 15 U.S.C. 1, 2.

232. The Attorneys General are the chief legal officers of their respective States. They have authority to bring actions to protect the economic well-being of their States and their residents, and to seek injunctive relief to remedy and protect against harm resulting from violations of the antitrust laws.

233. This Court has subject matter jurisdiction over this action under Section 4 of the Sherman Act, 15 U.S.C. 4, and 28 U.S.C. 1331, 1337(a), and 1345.

234. The Court has personal jurisdiction over RealPage, Inc. (''RealPage''); venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. 22, and under 28 U.S.C. 1391 because RealPage transacts business and resides within this District.

235. RealPage is a privately-owned company organized and existing under the laws of the State of Delaware and is headquartered in Richardson, Texas. It is registered to do business in the State of North Carolina as a foreign corporation offering software solutions for the multifamily housing industry and software as a service.

236. RealPage engages in, and its activities substantially affect, interstate trade and commerce. RealPage provides a range of products and services that are marketed, distributed, and offered to consumers throughout the United States and across state lines.

237. The Court has personal jurisdiction over Camden Property Trust (''Camden''); venue is proper in this District under Section 12 of the Clayton Act, 15. U.S.C. 22, and under 28 U.S.C. 1391 because Camden transacts business and resides within this District.

238. Camden is a publicly-traded multifamily company organized under the laws of the State of Delaware and is headquartered in Houston, Texas. Camden is registered to do business in the State of North Carolina. Camden owns or manages at least one multifamily rental property using AIRM within this District.

239. Camden engages in, and its activities substantially affect, interstate trade and commerce. Camden owns or manages multifamily rental units across the United States, including within this District. Camden's rental properties are marketed and offered to consumers throughout the United States and across state lines.

240. The Court has personal jurisdiction over Cortland Management, LLC (''Cortland''); venue is proper in this District under Section 12 of the Clayton Act, 15. U.S.C. 22, and under 28 U.S.C. 1391 because Cortland transacts business and resides within this District.

241. Cortland is a privately-owned company organized under the laws of the State of Delaware and is headquartered in Atlanta, Georgia. Cortland is responsible for the management of multifamily rental housing properties, either directly owned by an affiliated entity or other third-party owners of multifamily housing properties. Cortland is registered to do business in the State of North Carolina. Cortland owns or manages multiple multifamily rental properties within this District, which use (or recently used) AIRM. Cortland

has a registered agent for service of process in this District.

242. Cortland engages in, and its activities substantially affect, interstate trade and commerce. Cortland owns or manages multifamily rental units across the United States, including within this District. Cortland's rental properties are marketed and offered to consumers throughout the United States and across state lines.

243. The Court has personal jurisdiction over Cushman & Wakefield, Inc. (''Cushman & Wakefield'') and Pinnacle Property Management Services, LLC (''Pinnacle''); venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. 22, and under 28 U.S.C. 1391 because Cushman & Wakefield, including its subsidiary Pinnacle, transacts business and resides within this District.

244. Cushman & Wakefield is organized under the laws of the State of New York and is headquartered in Chicago, Illinois. Cushman & Wakefield's multifamily rental property business is operated through its subsidiary Pinnacle, and also under the Cushman & Wakefield name since acquiring Pinnacle in March 2020. Pinnacle is organized under the laws of the State of Delaware and is headquartered in Frisco, Texas. Pinnacle is registered to do business in the State of North Carolina. Cushman & Wakefield U.S., Inc. is also registered to do business in the State of North Carolina. Pinnacle owns or manages multiple multifamily rental properties using YieldStar within this District.

245. Cushman & Wakefield engages in, and its activities substantially affect, interstate trade and commerce. Through Pinnacle, Cushman & Wakefield owns or manages multifamily rental units across the United States, including within this District. Cushman & Wakefield provides a range of multifamily property and revenue management services that are marketed and offered to consumers throughout the United States and across state lines.

246. The Court has personal jurisdiction over Greystar Real Estate Partners, LLC (''Greystar''); venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. 22, and under 28 U.S.C. 1391 because Greystar transacts business and resides within the District.

247. Greystar is a privately-owned company organized under the laws of the State of Delaware and is headquartered in Charleston, South Carolina. A Greystar management services entity is registered to do business in the State of North Carolina. Greystar owns or manages multiple multifamily rental properties using AIRM within this District.

248. Greystar engages in, and its activities substantially affect, interstate trade and commerce. Through its subsidiaries, including Greystar Management Services, LLC, Greystar North America Holdings, LLC, and GREP Washington, LLC, Greystar owns or manages multifamily rental units across the United States, including within this District. Greystar provides a range of products and services that are marketed and offered to consumers throughout the United States and across state lines.

249. The Court has personal jurisdiction over LivCor, LLC (''LivCor''); venue is proper in this District under Section 12 of the Clayton Act, 15 U.S.C. 22, and under 28 U.S.C. 1391 because LivCor transacts business and resides within this District.

250. LivCor is a privately-owned company organized under the laws of the State of Delaware and is headquartered in Chicago, Illinois. It is registered to do business in the State of North Carolina as a foreign corporation engaging in ownership and investment in real property and related services. LivCor owns or provides asset management services at least one multifamily rental property using AIRM within this District.

251. LivCor engages in, and its activities substantially affect, interstate trade and commerce. LivCor owns or provides asset management services for multifamily rental units across the United States, including within this District. LivCor provides multifamily asset management services that are marketed and offered to consumers throughout the United States and across state lines.

252. The Court has personal jurisdiction over Willow Bridge Property Company LLC (''Willow Bridge''); venue is proper in this District under 28 U.S.C. 1391 and Section 12 of the Clayton Act, 15 U.S.C. 22 because Willow Bridge transacts business and resides within this District.

253. Willow Bridge is a privately-owned company organized under the laws of the State of Texas and is headquartered in Dallas, Texas. Willow Bridge is registered to do business in the State of North Carolina as a foreign corporation offering services for the multifamily real estate industry. Willow Bridge owns or manages multiple multifamily rental properties using AIRM within this District.

254. Willow Bridge engages in, and its activities substantially affect, interstate trade and commerce. Willow Bridge owns or manages multifamily rental units across the United States, including within this District. Willow Bridge's rental properties are marketed and offered to consumers throughout the United States and across state lines.

255. The Durham-Chapel Hill CBSA is partially or entirely within the Middle District of North Carolina.

256. RealPage tracks the number of rental housing units that use its commercial revenue management software products, including AIRM and YieldStar, by market (*i.e.,* a CBSA) and submarket, and several of these markets and submarkets are entirely or partially within North Carolina. These RealPage-defined markets include Raleigh/Durham, NC; Charlotte–Concord–Gastonia, NC–SC; Greensboro/Winston-Salem, NC; Wilmington, NC; Fayetteville, NC; and Asheville, NC. The submarkets include Southwest Durham, Northwest Durham/Downtown, East Durham, and Chapel Hill/Carrboro, all of which are located entirely or partially within this District.

257. Defendant Landlords each own or manage one or more properties in one or more relevant markets within the Middle District of North Carolina for which they, along with other landlords and RealPage, currently agree (or have in the past agreed) to share information and align pricing by using AIRM or YieldStar to generate rental pricing using pooled, competitively sensitive information.

258. A substantial part of the activities and conduct giving rise to the claims asserted in this Complaint occurred within this District. As alleged in paragraphs 208–211 above and Appendices A and B below, relevant local geographic markets in which competition and renters have been harmed by RealPage's anticompetitive conduct include the RealPage-defined submarkets in Raleigh/Durham. As alleged in paragraphs 214–217 above, relevant geographic markets in which competition and renters have been harmed by RealPage's anticompetitive conduct include the Durham–Chapel Hill CBSA.

VIII. Violations Alleged

First Claim for Relief: Violation of Section 1 of the Sherman Act by Unlawfully Sharing Information for Use in Competitors' Pricing

(By All Plaintiffs Against RealPage, Cushman & Wakefield, Greystar, LivCor, and Pinnacle; By All Plaintiffs Except Washington Against Camden and Willow Bridge; By the United States, Colorado, and North Carolina Against Cortland)

259. Plaintiffs incorporate the allegations of paragraphs 1 through 258 above.

260. Each landlord using AIRM and YieldStar, including each Defendant Landlord, has agreed with RealPage to provide RealPage daily nonpublic, competitively sensitive data. RealPage invites each landlord to share this information so that it can be pooled to generate pricing recommendations for the landlord and its competitors. Each of these landlords, including Defendant Landlords, uses (or has used) RealPage software, knowing or learning that RealPage will use this data to train its models and provide floor plan price recommendations and unit-level pricing not only for the landlord, but for the landlord's competitors (and vice versa). Landlords are therefore joining together in a way that deprives the market of fully independent centers of decision-making on pricing.

261. Each landlord using OneSite, Business Intelligence, or Performance Analytics with Benchmarking has agreed with RealPage to provide RealPage daily nonpublic, competitively sensitive data. RealPage invites each landlord to share this information, and each of these landlords understands that RealPage will use this data in RealPage's other products, including revenue management products that provide pricing recommendations and prices to competing landlords.

262. The transactional data these landlords agree to provide to RealPage, and indirectly to each other, includes current, forward-looking, granular, and highly competitively sensitive information. It includes information on effective rents, rent discounts, occupancy rates, availability, lease dates, lease terms, unit amenities, and unit layouts. Landlords also shared information on guest cards and lease applications.

263. Landlords, including Defendant Landlords and other landlords that compete with each other in the relevant markets alleged, have agreed with one another, through RealPage and directly, to exchange nonpublic, competitively sensitive data, both through RealPage's revenue management software and by other means. The other means include RealPage user groups, direct communications, market surveys, and other intermediaries. The information exchanged includes future pricing plans, current pricing and occupancy rates, pricing discounts, and guest traffic.

264. RealPage uses this nonpublic, competitively sensitive data to train its AIRM models and provide floor plan price recommendations and unit-level pricing to AIRM- and YieldStar-using landlords. AIRM and YieldStar are designed to increase prices as much as possible and minimize price decreases.

265. RealPage engages in a variety of conduct to increase compliance with the output of its products and the objectives it touts.

266. The sharing of nonpublic, competitively sensitive data with RealPage, and its use in AIRM and YieldStar, is anticompetitive. It harms or is likely to harm the competitive process and results, or is likely to result, in harm to renters and prospective renters in at least the relevant antitrust markets identified in this complaint.

267. In each relevant market, RealPage and participating landlords collectively have sufficient market power, including market and data penetration, to harm the competitive process and renters.

268. AIRM and YieldStar do not benefit the competitive process or renters. Any theoretical benefits are outweighed by harm to the competitive process and to renters.

269. Less restrictive alternatives are available to RealPage and the market. RealPage has recently altered AIRM or YieldStar for some clients to remove those clients' access to competitors' nonpublic data in at least certain portions of the software. RealPage has the ability to make changes to remove broader access to competitors' nonpublic data in AIRM and YieldStar. RealPage has the capability to modify its software products to eliminate competitive defects. LRO does not require the same type and quantity of nonpublic, transactional data pulled from competitors' property management software.[12] RealPage has stopped offering LRO to new clients and made plans to discontinue LRO for legacy clients by the end of 2024.

[12] Landlords may nevertheless use LRO in ways that may likely harm competition, as illustrated in paragraphs 59–60 and 100 above.

Second Claim for Relief: Violation of Section 1 of the Sherman Act Through Agreements to Align Pricing

(By All Plaintiffs Against RealPage, Cushman & Wakefield, Greystar, LivCor, and Pinnacle; By All Plaintiffs Except Washington Against Camden and Willow Bridge; By the United States, Colorado, and North Carolina Against Cortland)

270. Plaintiffs incorporate the allegations of paragraphs 1 through 268 above.

271. Each landlord, including Defendant Landlords, that licenses AIRM or YieldStar has agreed with RealPage to use the software as it has been designed. This includes providing nonpublic, competitively sensitive transactional data to RealPage, but more broadly is an agreement to use AIRM or YieldStar as the means to price the landlord's rental units. The landlord agrees to review AIRM or YieldStar floor plan price recommendations, use AIRM or YieldStar to set a scheduled floor plan rent, and use the AIRM or YieldStar pricing matrix to price units to renters.

272. AIRM and YieldStar are designed to ''raise the tide'' for all landlords, including AIRM- and YieldStar-using landlords. AIRM and YieldStar have the likely effect of aligning users' pricing processes, strategies, and pricing responses.

273. These landlords understand this effect, and it is a reason why they sign up for and use AIRM or YieldStar and discuss their usage with one another in user group meetings and other settings.

274. RealPage engages in a variety of conduct to increase compliance with the output of its products and the objectives it touts.

275. RealPage's user group meetings and its revenue management certification program facilitate landlords' agreements with RealPage to align pricing.

276. Taken together, the agreements between each AIRM or YieldStar landlord and RealPage to use AIRM or YieldStar, respectively, harm or are likely to harm the competitive process and renters.

277. The agreement by a landlord to use AIRM or YieldStar is an agreement to align users' pricing processes, strategies, and pricing responses. Collectively, these agreements between landlords using AIRM or YieldStar and RealPage are harmful to the competitive process and to renters.

278. In each relevant submarket and CBSA, RealPage and participating AIRM or YieldStar landlords collectively have sufficient market power, including

market and data penetration, to harm the competitive process and renters.

279. AIRM and YieldStar do not benefit the competitive process or renters. Any theoretical benefits are outweighed by harm to the competitive process and to renters, and less restrictive alternatives are available to RealPage and these landlords.

Third Claim for Relief: Violation of Section 2 of the Sherman Act Through Monopolization of the Commercial Revenue Management Software Market

(By All Plaintiffs Against RealPage)

280. Plaintiffs incorporate the allegations of paragraphs 1 through 279 above.

281. Commercial revenue management software for conventional multifamily housing rentals in the United States is a relevant antitrust market, and RealPage has monopoly power in that market.

282. RealPage has unlawfully monopolized the commercial revenue management market through unlawful exclusionary conduct. RealPage has amassed a massive reservoir of competitively sensitive data from competing landlords and used that data to sell AIRM and YieldStar. RealPage has ensured that rivals cannot compete on the merits unless they enter into similar agreements with landlords, offer to share competitively sensitive information among rival landlords, and engage in actions to increase compliance. As a result of its exclusionary conduct, RealPage has been able to obstruct rival software providers from competing via revenue management products that do not harm the competitive process in addition to cementing its massive data and scale advantage that keeps increasing due to self-reinforcing feedback effects.

283. RealPage's anticompetitive acts have harmed the competitive process and reduced feasible and less restrictive alternatives for landlords, which alternatives thereby pose less risk of competitive harm to renters.

284. RealPage's exclusionary conduct lacks a procompetitive justification that offsets the harm caused by RealPage's anticompetitive and unlawful conduct.

Fourth Claim for Relief, in the Alternative: Violation of Section 2 of the Sherman Act Through Attempted Monopolization of the Commercial Revenue Management Software Market

(By All Plaintiffs Against RealPage)

285. Plaintiffs incorporate the allegations of paragraphs 1 through 284 above.

286. Commercial revenue management software for conventional multifamily housing rentals in the United States is a relevant antitrust market.

287. RealPage has attempted to monopolize that market through unlawful exclusionary conduct enhanced by its self-reinforcing data and scale advantages. By amassing its massive reservoir of competitively sensitive data from competing landlords and the follow-on benefits that scale and its feedback effects provide in terms of blunting competition among landlords, RealPage's conduct excludes commercial revenue management rivals from competing on the merits in a lawful manner. As such, it has increased, maintained, or protected RealPage's power.

288. RealPage's anticompetitive acts have harmed the competitive process and reduced feasible and less restrictive alternatives for landlords, which alternatives thereby pose less risk of competitive harm to renters.

289. As inferred from the anticompetitive conduct described in Sections IV and V, *supra,* RealPage has acted with a specific intent to monopolize, and to eliminate effective competition in, the commercial revenue management software market in the United States. There is a dangerous probability that, unless restrained, RealPage will succeed in monopolizing the commercial revenue management software market in violation of Section 2 of the Sherman Act.

Fifth Claim for Relief: Violation of North Carolina Law

290. Plaintiff State of North Carolina incorporates the allegations of Paragraphs 1 through 289 above.

291. Defendants engaged in the conduct alleged above while operating their businesses in North Carolina markets, including, but not limited to, the markets alleged in paragraphs 214, 216, 256, and Appendices A and B. Defendants' anticompetitive conduct has affected commerce in North Carolina to a substantial degree by harming the competitive process and renters across the State including, but not limited to, in the North Carolina markets identified in paragraphs 214, 216, 256, and Appendices A and B.

292. Defendants' acts as alleged in the First and Second claims for reliefs stated in paragraphs 259–279 above, violate the North Carolina Unfair or Deceptive Trade Practices Act in that they constitute contracts in restraint of trade or commerce in North Carolina, and/or acts and contracts in restraint of trade or commerce which violate the principles of the common law. N.C.G.S. §§ 75–1, 75–2.

293. Defendant Real Page's acts as alleged in the Third and Fourth claims for relief stated in paragraphs 280–289, above, violate the North Carolina Unfair or Deceptive Trade Practices Act, N.C.G.S. § 75–1 *et seq.,* in that they constitute unlawful monopolization of a part of trade or commerce in North Carolina. N.C.G.S. § 75–2.1. Plaintiff State of North Carolina seeks the following remedies available for claims under federal law and claims under N.C.G.S. §§ 75–1, 75–2, and 75–2.1, without limitation:

a. Injunctive and other equitable relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26, N.C.G.S. § 75–14, and the common law of North Carolina;

b. Civil penalties pursuant to N.C.G.S. § 75–15.2, which provides a penalty of up to $5,000 per violation;

c. Costs of suit, including expert witness fees, costs of investigation, and attorney's fees pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26 and N.C.G.S. § 75–16.1; and

d. Other remedies as the court may deem appropriate under the facts and circumstances of the case.

Sixth Claim for Relief: Violation of California Law

295. The State of California incorporates the allegations of Paragraphs 1 through 289 above.

296. Defendants' practices, as alleged above, violate the Sherman Act sections 1 and 2 and therefore constitute unlawful business practices under California's Unfair Competition Law (''UCL''), Cal. Bus. & Prof. Code § 17200, *et seq.*

297. Plaintiff State of California seeks the following:

a. injunctive relief and penalties pursuant to sections 17203 and 17206 of the UCL,

b. costs of suit, including expert witness fees, costs of investigation, and attorney's fees pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26, and

c. other remedies as the court may deem appropriate under the facts and circumstances of the case.

Seventh Claim for Relief: Violation of Colorado Law

298. Plaintiff State of Colorado repeats and re-alleges and incorporates by reference Paragraphs 1 through 289 in this Complaint as if fully set forth herein.

299. The acts alleged in the Complaint violate the Colorado Antitrust Act, § 6–4–101 et. seq., including C.R.S. § 6–4–104 and C.R.S. § 6–4–105. These violations substantially affect the people

of Colorado and have impacts within the State of Colorado.

300. Each of the unlawful agreements, arrangements, or acts alleged herein constitute at least one distinct violation of the Colorado Antitrust Act within the meaning of C.R.S. § 6–4–113.

301. Defendants' acts alleged herein constitute a continuous pattern and practice of behavior within the meaning of C.R.S. § 6–4–113(2)(c).

302. Defendants' acts alleged herein were willful within the meaning of C.R.S. § 6–4–113(2)(d).

303. The State of Colorado seeks the following remedies under federal law and the Colorado Antitrust Act, including, without limitation:

a. Injunctive and other equitable relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26 and C.R.S. § 6–4–112;

b. Civil penalties pursuant to C.R.S. § 6–4–113 for each violation of the Colorado Antitrust Act;

c. Costs and attorneys' fees, pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26, and C.R.S. § 6–4–112(5); and

d. Other remedies as the Court may deem appropriate based on the facts properly alleged and proven.

Eighth Claim for Relief: Violation of Connecticut Law

304. Plaintiff State of Connecticut, acting by and through its Attorney General pursuant to Conn. Gen. Stat. § 35–44a, incorporates the allegations of paragraphs 1 through 289 above. The State of Connecticut brings its state and federal law claims for relief against all Defendants except Cortland.

305. The acts alleged in the Complaint also constitute violations of the Connecticut Antitrust Act, Conn. Gen. Stat. § 35–24 *et seq.* These violations had impacts within the State of Connecticut and substantially affected the citizens of Connecticut.

306. Plaintiff State of Connecticut seeks all remedies available under federal law and the Connecticut Antitrust Act, including, without limitation, the following:

a. Civil penalties pursuant to Conn. Gen. Stat. § 35–38, which provides that in any action instituted by the Attorney General, any person who has been held to have violated any of the provisions of the Connecticut Antitrust Act shall forfeit and pay to the state a civil penalty of not more than one million dollars for each violation;

b. Injunctive and other equitable relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26, Conn. Gen. Stat. §§ 35–34, 35–44a;

c. Costs and fees including, without limitation, costs of investigation, litigation, expert witness fees, and attorney's fees pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26, Conn. Gen. Stat. §§ 35–34, 35–44a; and

d. Other remedies as the Court may deem appropriate under the facts and circumstances of the case.

Ninth Claim for Relief: Violation of Illinois Law

307. Plaintiff State of Illinois, acting by and through its Attorney General, incorporates the allegations of paragraphs 1 through 289 above. The State of Illinois brings its state and federal law claims for relief against all Defendants except Cortland.

308. The acts alleged in the Complaint violate the Illinois Antitrust Act, 740 ILCS 10/1 et seq, including 740 ILCS 10/3(1), 740 ILCS 10/3(2), and 740 ILCS 10/3(3). These violations substantially affect the people of Illinois and have impacts within the State of Illinois.

309. The State of Illinois seeks all available remedies under federal law and the Illinois Antitrust Act, including, without limitation:

a. Injunctive and other equitable relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26; and 740 ILCS 10/7;

b. Civil penalties pursuant to 740 ILCS 10/7(4) for each violation of the Illinois Antitrust Act;

c. Disgorgement, damages, and/or other equitable or monetary relief pursuant to federal law including Section 4 of the Sherman Act, 15 U.S.C. 4, Section 4c of the Clayton Act, 15 U.S.C. 15c and state law including 740 ILCS 10/7, and treble damages for injuries sustained, directly or indirectly, by individuals residing in Illinois to their property, pursuant to the State of Illinois' parens patriae authority under 740 ILCS 10/7(2);

d. Costs and attorneys' fees, pursuant to Section 4c of the Clayton Act, 15 U.S.C. 15c, Section 16 of the Clayton Act, 15 U.S.C. 26, 740 ILCS 10/7(2); and

e. Other remedies as the Court may deem appropriate on the basis of the facts properly alleged and proven.

Tenth Claim for Relief: Violation of Massachusetts Law

310. Plaintiff Commonwealth of Massachusetts repeats, realleges, and incorporates the allegations of paragraphs 1 through 289 above as if fully set forth herein. The Commonwealth of Massachusetts brings its state and federal law claims for relief against all Defendants except Cortland.

311. The acts alleged in the aforementioned paragraphs of this Complaint, including but not limited to unlawful agreements in restraint of trade and unlawful monopolization, constitute unfair methods of competition and/or unfair or deceptive acts or practices in trade or commerce in violation of the Massachusetts Consumer Protection Act, M.G.L c. 93A § 2 *et seq.*

312. Defendants knew or should have known that their conduct violated the Massachusetts Consumer Protection Act, M.G.L c. 93A § 2 *et seq.*

313. Plaintiff Commonwealth of Massachusetts is entitled to and seeks the following relief under M.G.L. c. 93A § 4:

a. Injunctive and other equitable relief pursuant to M.G.L. c. 93A § 4;

b. Civil penalties of up to $5,000 per each violation committed by the Defendants pursuant to M.G.L. c. 93A § 4;

c. Costs and fees including, without limitation, costs of investigation, litigation, and attorneys' fees pursuant to M.G.L. c. 93A § 4; and

d. Other remedies as the court may deem appropriate under the facts and circumstances of the case.

314. The Commonwealth of Massachusetts notified the Defendants of this intended action at least five days prior to the commencement of this action and gave the Defendants an opportunity to confer in accordance with M.G. L. c. 93A § 4.

Eleventh Claim for Relief: Violation of Oregon Law

315. Plaintiff State of Oregon, acting by and through its Attorney General, incorporates the allegations of paragraphs 1 through 289 above. The State of Oregon brings its state and federal law claims for relief against all Defendants except Cortland.

316. The acts alleged in the Complaint also constitute violations of the Oregon Antitrust Law, Oregon Revised Statutes (''ORS'') 646.705 to ORS 646.836. These violations had impacts within the State of Oregon and substantially affected the people of Oregon.

317. The State of Oregon appears in its sovereign or quasi-sovereign capacities and under its statutory, common law, and equitable powers, and as parens patriae on behalf of natural persons residing in the State of Oregon pursuant to ORS 646.775(1). The State of Oregon seeks all remedies available under federal law and the Oregon Antitrust Law, including, without limitation, the following:

a. Disgorgement and/or other equitable relief pursuant to federal law including Section 4 of the Sherman Act, 15 U.S.C. 4, and state law pursuant to ORS 646.770, and ORS 646.775;

b. Injunctive and other equitable relief pursuant to Section 16 of the Clayton

Act, 15 U.S.C. 26, ORS 646.760, ORS 646.770, and ORS 646.775;

c. Civil penalties pursuant to ORS 646.760(1) which provides that a court may assess for the benefit of the state a civil penalty of not more than $1,000,000 for each violation of the Oregon Antitrust Law,

d. Costs of suit, including expert witness fees, costs of investigation, and attorney's fees pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26, ORS 646.760, ORS 646.770, ORS 646.775; and

e. Other remedies as the court may deem appropriate under the facts and circumstances of the case.

Twelfth Claim for Relief: Violation of Tennessee Law

318. Plaintiff State of Tennessee incorporates the allegations of paragraphs 1 through 289 above. The State of Tennessee brings its state and federal law claims for relief against all Defendants except Cortland.

319. Defendants engaged in the conduct described above, individually and collectively, to thwart competition for multifamily housing in Tennessee. This anticompetitive conduct in Tennessee harmed thousands of multifamily renters across the state.

320. Defendants' business practices have caused a reduction in competition in relevant Tennessee markets, including, but not limited to, in the markets identified in paragraphs 214 and 216 and Appendices A and B, and, as a result, Tennesseans have suffered anticompetitive harms.

321. Accordingly, Defendants' actions violate the Tennessee Trade Practices Act, Tenn. Code Ann. § 47–25–101, as amended.

322. Defendant RealPage engaged in the conduct described above to maintain its monopoly and exclude competing commercial revenue management software competitors.

323. Accordingly, Defendant RealPage's actions violate the Tennessee Trade Practices Act, Tenn. Code Ann. § 47–25–102, as amended.

324. This conduct has affected Tennessee trade and commerce to a substantial degree.

325. To remedy this anticompetitive conduct, the Tennessee Attorney General and Reporter seeks all remedies available to which it is entitled under federal law and claims under Tenn. Code Ann. §§ 47–25–101, 102, and 106, as amended, including, without limitation, the following:

a. injunctive or other equitable relief; reasonable attorney fees, costs, and expenses, pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26, Tenn. Code Ann. § 47–25–106(b), and the common law of Tennessee;

b. civil penalties pursuant to Tenn. Code Ann. § 47–25–106(g);

c. costs of suit, including expert witness fees, costs of investigation, and attorney's fees pursuant to Section 16 of the Clayton Act, 15 U.S.C. 26 and Tenn. Code Ann. § 47–25–106(b); and

d. other legal and equitable remedies as the court may deem appropriate and the interest of justice may require under the facts and circumstances of the case.

Thirteenth Claim for Relief: Violation of Washington Law

326. The State of Washington incorporates the allegations in Paragraphs 1 through 289, except for the portions of paragraphs 95, 96, 97, 117, 131, 171, and 228 that Washington was unable to review due to confidentiality redactions. Washington reserves the right to adopt the portions of those paragraphs which are later disclosed.

327. Washington brings its federal and state law claims for relief against Defendants RealPage, Cushman & Wakefield, Pinnacle, Greystar, and LivCor (''Washington Defendants'').

328. Washington Defendants engaged in the conduct alleged above while operating their businesses in Washington. This anticompetitive conduct in Washington harmed the competitive process and renters across the State including in, but not limited to, the markets identified in Appendices A and B.

329. The acts alleged in the paragraphs incorporated by the State of Washington also constitute antitrust violations of the Washington Consumer Protection Act under Wash. Rev. Code § 19.86.030, which declares unlawful every contract, combination, or conspiracy in restraint of trade or commerce.

330. The acts alleged in the paragraphs incorporated by the State of Washington also constitute antitrust violations of the Washington Consumer Protection Act under Wash. Rev. Code § 19.86.040, which declares monopolization or attempts to monopolize unlawful.

331. Washington seeks the following remedies available under the Washington Consumer Protection Act and federal law including, without limitation, the following:

a. That the Court adjudge and decree that conduct alleged in the complaint to be unlawful and in violation of the Washington Consumer Protection Act, Wash. Rev. Code § 19.86.030 and § 19.86.040;

b. Injunctive and other equitable relief pursuant to Wash. Rev. Code § 19.86.080;

c. Damages including treble damages; disgorgement; and/or restitution and any appropriate interest pursuant to federal law including Sherman Act, 15 U.S.C. 4, 15c and pursuant to state law including Wash. Rev. Code § 19.86.080;

d. Civil penalties pursuant to Wash. Rev. Code § 19.86.140;

e. Costs and attorney's fees and any appropriate interest on those fees and costs pursuant to Sherman Act, 15 U.S.C. 15c and/or pursuant to Wash. Rev. Code § 19.86.080; and

f. Other remedies, including pre-judgement interest, as the court may deem appropriate under the facts and circumstances of the case.

IX. Request for Relief

332. To remedy these illegal acts, Plaintiffs request that the Court:

a. Adjudge and decree that Defendants have acted unlawfully to restrain trade in conventional multifamily rental housing markets across the United States in violation of Section 1 of the Sherman Act, 15 U.S.C. 1;

b. Adjust and decree that RealPage has acted unlawfully to monopolize, or attempt to monopolize, the commercial revenue management software market in the United States in violation of Section 2 of the Sherman Act, 15 U.S.C. 2;

c. Enjoin Defendants from continuing to engage in the anticompetitive practices described herein and from engaging in any other practices with the same purpose and effect as the challenged practices;

d. Enter any other preliminary or permanent relief necessary and appropriate to restore competitive conditions in the markets affected by Defendants' unlawful conduct;

e. Enter any additional relief the Court finds just and proper; and

f. Award Plaintiffs an amount equal to their costs, including reasonable attorneys' fees, incurred in bringing this action.

X. Demand for a Jury Trial

333. Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs demand a trial by jury of all issues properly triable to a jury in this case.

Dated this 7th day of January, 2025.

Respectfully submitted,

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Appendix A: Submarkets

Area	Submarket	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Anaheim-Santa Ana-Irvine, CA	South Orange County	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Alpharetta/Cumming	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Briarcliff	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Buckhead	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Chamblee/Brookhaven	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Decatur	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Downtown Atlanta	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Duluth	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Dunwoody	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Kennesaw/Acworth	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Midtown Atlanta	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Norcross	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Northeast Atlanta	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Northeast Cobb/Woodstock	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Northeast Gwinnett County	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Roswell	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Sandy Springs	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Smyrna	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	South Cobb County/Douglasville	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Southeast Gwinnett County	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Southeast Marietta	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Southwest Atlanta	Yes	Yes

Area	Submarket	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Atlanta-Sandy Springs-Roswell, GA	Vinings	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	West Atlanta	Yes	Yes
Austin-Round Rock, TX	Arboretum	Yes	Yes
Austin-Round Rock, TX	Cedar Park	Yes	Yes
Austin-Round Rock, TX	Downtown/University	Yes	Yes
Austin-Round Rock, TX	East Austin	Yes	Yes
Austin-Round Rock, TX	Far South Austin	Yes	Yes
Austin-Round Rock, TX	Far West Austin	Yes	Yes
Austin-Round Rock, TX	Near North Austin	Yes	Yes
Austin-Round Rock, TX	North Central Austin	Yes	Yes
Austin-Round Rock, TX	Northwest Austin	Yes	Yes
Austin-Round Rock, TX	Pflugerville/Wells Branch	Yes	Yes
Austin-Round Rock, TX	Round Rock/Georgetown	Yes	Yes
Austin-Round Rock, TX	South Austin	Yes	Yes
Austin-Round Rock, TX	Southwest Austin	Yes	Yes
Baltimore-Columbia-Towson, MD	Columbia/North Laurel	Yes	Yes
Birmingham-Hoover, AL	Southeast Birmingham	Yes	Yes
Boston-Cambridge-Newton, MA-NH	Chelsea/Revere/Charlestown		Yes
Boston-Cambridge-Newton, MA-NH	East Middlesex County		Yes
Boston-Cambridge-Newton, MA-NH	Quincy		Yes
Boston-Cambridge-Newton, MA-NH	West Norfolk County		Yes
Charleston-North Charleston, SC	Downtown/Mount Pleasant/Islands	Yes	Yes
Charleston-North Charleston, SC	West Ashley	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Ballantyne	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Huntersville/Cornelius	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Matthews/Southeast Charlotte		Yes
Charlotte-Concord-Gastonia, NC-SC	Myers Park	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	North Charlotte	Yes	Yes

Area	Submarket	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Charlotte-Concord-Gastonia, NC-SC	South Charlotte	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Southwest Charlotte	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	UNC Charlotte	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Uptown/South End	Yes	Yes
Chicago-Naperville-Elgin, IL-IN-WI	The Loop	Yes	Yes
Colorado Springs, CO	North Colorado Springs	Yes	Yes
Dallas-Plano-Irving, TX	Addison/Bent Tree	Yes	Yes
Dallas-Plano-Irving, TX	Allen/McKinney	Yes	Yes
Dallas-Plano-Irving, TX	Carrollton/Farmers Branch	Yes	Yes
Dallas-Plano-Irving, TX	Central/East Plano	Yes	Yes
Dallas-Plano-Irving, TX	East Dallas	Yes	Yes
Dallas-Plano-Irving, TX	Frisco	Yes	Yes
Dallas-Plano-Irving, TX	Grand Prairie	Yes	Yes
Dallas-Plano-Irving, TX	Intown Dallas	Yes	Yes
Dallas-Plano-Irving, TX	Las Colinas/Coppell	Yes	Yes
Dallas-Plano-Irving, TX	Lewisville/Flower Mound	Yes	Yes
Dallas-Plano-Irving, TX	North Irving	Yes	Yes
Dallas-Plano-Irving, TX	North Oak Cliff/West Dallas	Yes	Yes
Dallas-Plano-Irving, TX	Oak Lawn/Park Cities	Yes	Yes
Dallas-Plano-Irving, TX	Richardson	Yes	Yes
Dallas-Plano-Irving, TX	Rockwall/Rowlett/Wylie	Yes	Yes
Dallas-Plano-Irving, TX	The Colony/Far North Carrollton	Yes	Yes
Dallas-Plano-Irving, TX	West Plano	Yes	Yes
Denver-Aurora-Lakewood, CO	Broomfield	Yes	Yes
Denver-Aurora-Lakewood, CO	Downtown/Highlands/ Lincoln Park	Yes	Yes
Denver-Aurora-Lakewood, CO	Highlands Ranch	Yes	Yes
Denver-Aurora-Lakewood, CO	Littleton	Yes	Yes
Denver-Aurora-Lakewood, CO	Northeast Denver	Yes	Yes
Denver-Aurora-Lakewood, CO	Parker/Castle Rock	Yes	Yes
Denver-Aurora-Lakewood, CO	South Lakewood	Yes	Yes
Denver-Aurora-Lakewood, CO	Southeast Aurora/East Arapahoe County	Yes	Yes

Area	Submarket	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Denver-Aurora-Lakewood, CO	Southeast Denver	Yes	Yes
Denver-Aurora-Lakewood, CO	Tech Center	Yes	Yes
Denver-Aurora-Lakewood, CO	Thornton/Northglenn	Yes	Yes
Denver-Aurora-Lakewood, CO	Westminster	Yes	Yes
Fort Lauderdale-Pompano Beach-Deerfield Beach, FL	Plantation/Davie/Weston	Yes	Yes
Fort Worth-Arlington, TX	Grapevine/Southlake	Yes	Yes
Fort Worth-Arlington, TX	Northeast Fort Worth/North Richland Hills		Yes
Hartford-West Hartford-East Hartford, CT	Southeast Hartford/Middlesex County		Yes
Houston-The Woodlands-Sugar Land, TX	Bear Creek	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Downtown/Montrose/River Oaks	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Far West Houston	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Friendswood/Pearland	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Galleria/Uptown	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Greater Heights/Washington Avenue	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Greenway/Upper Kirby	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Katy	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Memorial	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Sugar Land/Stafford	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	The Woodlands	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	West University/Medical Center/Third Ward	Yes	Yes
Jacksonville, FL	Baymeadows	Yes	Yes
Jacksonville, FL	Upper Southside	Yes	Yes
Kansas City, MO-KS	Lee's Summit/Blue Springs/Raytown	Yes	Yes
Las Vegas-Henderson-Paradise, NV	Henderson	Yes	Yes
Las Vegas-Henderson-Paradise, NV	Northwest Las Vegas	Yes	Yes

Area	Submarket	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Las Vegas-Henderson-Paradise, NV	Summerlin/The Lakes	Yes	Yes
Los Angeles-Long Beach-Glendale, CA	Downtown Los Angeles	Yes	Yes
Memphis, TN-MS-AR	Cordova/Bartlett	Yes	Yes
Memphis, TN-MS-AR	Germantown/Collierville	Yes	Yes
Mobile/Daphne, AL	North Mobile	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	Central Nashville	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	East Nashville	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	Franklin/Brentwood	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	South Nashville	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	Southeast Nashville	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	West Nashville		Yes
Orlando-Kissimmee-Sanford, FL	Altamonte Springs/Apopka	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Casselberry/Winter Springs/Oviedo	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Central Orlando	Yes	Yes
Orlando-Kissimmee-Sanford, FL	East Orange County	Yes	Yes
Orlando-Kissimmee-Sanford, FL	East Orlando	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Kissimmee/Osceola County	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Sanford/Lake Mary	Yes	Yes
Orlando-Kissimmee-Sanford, FL	South Orange County	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Southwest Orlando	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Winter Park/Maitland	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	Chandler	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	Deer Valley	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	North Glendale	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	South Phoenix	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Aloha/West Beaverton	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Central Portland	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Hillsboro	Yes	Yes

Area	Submarket	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Portland-Vancouver-Hillsboro, OR-WA	Lake Oswego/Tualatin/Wilsonville	Yes	Yes
Raleigh/Durham, NC	Central Raleigh	Yes	Yes
Raleigh/Durham, NC	Chapel Hill/Carrboro	Yes	Yes
Raleigh/Durham, NC	East Durham	Yes	Yes
Raleigh/Durham, NC	Far North Raleigh	Yes	Yes
Raleigh/Durham, NC	Near North Raleigh	Yes	Yes
Raleigh/Durham, NC	North Cary/Morrisville	Yes	Yes
Raleigh/Durham, NC	Northeast Raleigh	Yes	Yes
Raleigh/Durham, NC	Northwest Durham/Downtown		Yes
Raleigh/Durham, NC	Northwest Raleigh	Yes	Yes
Raleigh/Durham, NC	South Cary/Apex	Yes	Yes
Raleigh/Durham, NC	Southwest Durham	Yes	Yes
Reno, NV	South Reno	Yes	Yes
Richmond, VA	Northwest Richmond	Yes	Yes
Richmond, VA	Tuckahoe/Westhampton	Yes	Yes
Riverside-San Bernardino-Ontario, CA	Corona		Yes
Riverside-San Bernardino-Ontario, CA	Rancho Cucamonga/Upland	Yes	Yes
Riverside-San Bernardino-Ontario, CA	Temecula/Murrieta	Yes	Yes
Salt Lake City/Ogden/Clearfield, UT	Midvale/Sandy/Draper	Yes	Yes
Salt Lake City/Ogden/Clearfield, UT	Southwest Salt Lake City	Yes	Yes
San Antonio-New Braunfels, TX	Far North Central San Antonio	Yes	Yes
San Antonio-New Braunfels, TX	Far Northwest San Antonio	Yes	Yes
San Antonio-New Braunfels, TX	North Central San Antonio		Yes
San Antonio-New Braunfels, TX	Northwest San Antonio	Yes	Yes
San Diego-Carlsbad, CA	Downtown San Diego/Coronado		Yes
San Diego-Carlsbad, CA	Northeast San Diego	Yes	Yes
Seattle-Bellevue-Everett, WA	Downtown Seattle		Yes
Seattle-Bellevue-Everett, WA	Federal Way/Des Moines		Yes

Area	Submarket	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Seattle-Bellevue-Everett, WA	Redmond		Yes
Seattle-Bellevue-Everett, WA	Renton	Yes	Yes
Tampa-St. Petersburg-Clearwater, FL	Carrollwood/Citrus Park	Yes	Yes
Tampa-St. Petersburg-Clearwater, FL	Central Tampa	Yes	Yes
Tampa-St. Petersburg-Clearwater, FL	Town and Country/Westchase	Yes	Yes
Tucson, AZ	Casas Adobes/Oro Valley	Yes	Yes
Tucson, AZ	Catalina Foothills	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Germantown	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Loudoun County	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Manassas/Far Southwest Suburbs	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Navy Yard/Capitol South	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Northeast DC	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Reston/Herndon	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Tysons Corner/Falls Church/Merrifield	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	West Alexandria	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	West Fairfax County	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Woodbridge/Dale City	Yes	Yes

Appendix B: Submarkets By Bedroom Count

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Anaheim-Santa Ana-Irvine, CA	South Orange County	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Alpharetta/Cumming	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Briarcliff	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Buckhead	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Chamblee/Brookhaven	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Decatur	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Downtown Atlanta	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Duluth	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Dunwoody	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Kennesaw/Acworth	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Midtown Atlanta	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Norcross	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Northeast Atlanta	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Northeast Cobb/Woodstock	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Northeast Gwinnett County	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Roswell	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Sandy Springs	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Smyrna	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	South Cobb County/Douglasville	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Southeast Gwinnett County	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Southeast Marietta	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Southwest Atlanta	1	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Atlanta-Sandy Springs-Roswell, GA	Vinings	1	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	West Atlanta	1	Yes	Yes
Austin-Round Rock, TX	Arboretum	1	Yes	Yes
Austin-Round Rock, TX	Cedar Park	1	Yes	Yes
Austin-Round Rock, TX	Downtown/University	1	Yes	Yes
Austin-Round Rock, TX	East Austin	1	Yes	Yes
Austin-Round Rock, TX	Far South Austin	1	Yes	Yes
Austin-Round Rock, TX	Far West Austin	1	Yes	Yes
Austin-Round Rock, TX	Near North Austin	1	Yes	Yes
Austin-Round Rock, TX	North Central Austin	1	Yes	Yes
Austin-Round Rock, TX	Northwest Austin	1	Yes	Yes
Austin-Round Rock, TX	Pflugerville/Wells Branch	1	Yes	Yes
Austin-Round Rock, TX	Round Rock/Georgetown	1	Yes	Yes
Austin-Round Rock, TX	South Austin	1	Yes	Yes
Austin-Round Rock, TX	Southwest Austin	1	Yes	Yes
Baltimore-Columbia-Towson, MD	Columbia/North Laurel	1	Yes	Yes
Birmingham-Hoover, AL	Southeast Birmingham	1	Yes	Yes
Boston-Cambridge-Newton, MA-NH	Chelsea/Revere/Charlestown	1		Yes
Boston-Cambridge-Newton, MA-NH	East Middlesex County	1	Yes	Yes
Boston-Cambridge-Newton, MA-NH	Quincy	1	Yes	Yes
Boston-Cambridge-Newton, MA-NH	West Norfolk County	1		Yes
Charleston-North Charleston, SC	Downtown/Mount Pleasant/Islands	1	Yes	Yes
Charleston-North Charleston, SC	West Ashley	1	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Charlotte-Concord-Gastonia, NC-SC	Ballantyne	1	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Huntersville/Cornelius	1	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Matthews/Southeast Charlotte	1	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Myers Park	1	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	North Charlotte	1	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	South Charlotte	1	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Southwest Charlotte	1	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	UNC Charlotte	1	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Uptown/South End	1	Yes	Yes
Chicago-Naperville-Elgin, IL-IN-WI	The Loop	1	Yes	Yes
Colorado Springs, CO	North Colorado Springs	1	Yes	Yes
Dallas-Plano-Irving, TX	Addison/Bent Tree	1	Yes	Yes
Dallas-Plano-Irving, TX	Allen/McKinney	1	Yes	Yes
Dallas-Plano-Irving, TX	Carrollton/Farmers Branch	1	Yes	Yes
Dallas-Plano-Irving, TX	Central/East Plano	1	Yes	Yes
Dallas-Plano-Irving, TX	East Dallas	1	Yes	Yes
Dallas-Plano-Irving, TX	Frisco	1	Yes	Yes
Dallas-Plano-Irving, TX	Grand Prairie	1	Yes	Yes
Dallas-Plano-Irving, TX	Intown Dallas	1	Yes	Yes
Dallas-Plano-Irving, TX	Las Colinas/Coppell	1	Yes	Yes
Dallas-Plano-Irving, TX	Lewisville/Flower Mound	1	Yes	Yes
Dallas-Plano-Irving, TX	North Irving	1	Yes	Yes
Dallas-Plano-Irving, TX	North Oak Cliff/West Dallas	1	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Dallas-Plano-Irving, TX	Oak Lawn/Park Cities	1	Yes	Yes
Dallas-Plano-Irving, TX	Richardson	1	Yes	Yes
Dallas-Plano-Irving, TX	Rockwall/Rowlett/Wylie	1	Yes	Yes
Dallas-Plano-Irving, TX	The Colony/Far North Carrollton	1	Yes	Yes
Dallas-Plano-Irving, TX	West Plano	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Broomfield	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Downtown/Highlands/Lincoln Park	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Highlands Ranch	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Littleton	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Northeast Denver	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Parker/Castle Rock	1	Yes	Yes
Denver-Aurora-Lakewood, CO	South Lakewood	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Southeast Aurora/East Arapahoe County	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Southeast Denver	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Tech Center	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Thornton/Northglenn	1	Yes	Yes
Denver-Aurora-Lakewood, CO	Westminster	1	Yes	Yes
Fort Lauderdale-Pompano Beach-Deerfield Beach, FL	Plantation/Davie/Weston	1	Yes	Yes
Fort Worth-Arlington, TX	Grapevine/Southlake	1	Yes	Yes
Fort Worth-Arlington, TX	Northeast Fort Worth/North Richland Hills	1	Yes	Yes
Hartford-West Hartford-East Hartford, CT	Southeast Hartford/Middlesex County	1		Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Houston-The Woodlands-Sugar Land, TX	Bear Creek	1	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Downtown/Montrose/River Oaks	1	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Far West Houston	1	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Friendswood/Pearland	1		Yes
Houston-The Woodlands-Sugar Land, TX	Galleria/Uptown	1	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Greater Heights/Washington Avenue	1	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Greenway/Upper Kirby	1	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Katy	1	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Memorial	1	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Sugar Land/Stafford	1	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	The Woodlands	1	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	West University/Medical Center/Third Ward	1	Yes	Yes
Jacksonville, FL	Baymeadows	1	Yes	Yes
Jacksonville, FL	Upper Southside	1	Yes	Yes
Kansas City, MO-KS	Lee's Summit/Blue Springs/Raytown	1	Yes	Yes
Las Vegas-Henderson-Paradise, NV	Henderson	1	Yes	Yes
Las Vegas-Henderson-Paradise, NV	Northwest Las Vegas	1	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Las Vegas-Henderson-Paradise, NV	Summerlin/The Lakes	1	Yes	Yes
Los Angeles-Long Beach-Glendale, CA	Downtown Los Angeles	1	Yes	Yes
Memphis, TN-MS-AR	Cordova/Bartlett	1	Yes	Yes
Memphis, TN-MS-AR	Germantown/Collierville	1	Yes	Yes
Mobile/Daphne, AL	North Mobile	1	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	Central Nashville	1	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	East Nashville	1	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	Franklin/Brentwood	1	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	South Nashville	1	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	Southeast Nashville	1	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	West Nashville	1	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Altamonte Springs/Apopka	1	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Casselberry/Winter Springs/Oviedo	1	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Central Orlando	1	Yes	Yes
Orlando-Kissimmee-Sanford, FL	East Orange County	1	Yes	Yes
Orlando-Kissimmee-Sanford, FL	East Orlando	1	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Kissimmee/Osceola County	1	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Sanford/Lake Mary	1	Yes	Yes
Orlando-Kissimmee-Sanford, FL	South Orange County	1	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Southwest Orlando	1	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Orlando-Kissimmee-Sanford, FL	Winter Park/Maitland	1	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	Chandler	1	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	Deer Valley	1	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	North Glendale	1	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	South Phoenix	1	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Aloha/West Beaverton	1	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Central Portland	1	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Hillsboro	1	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Lake Oswego/Tualatin/Wilsonville	1	Yes	Yes
Raleigh/Durham, NC	Central Raleigh	1	Yes	Yes
Raleigh/Durham, NC	Chapel Hill/Carrboro	1		Yes
Raleigh/Durham, NC	East Durham	1	Yes	Yes
Raleigh/Durham, NC	Far North Raleigh	1		Yes
Raleigh/Durham, NC	Near North Raleigh	1	Yes	Yes
Ralcigh/Durham, NC	North Cary/Morrisvillc	1	Ycs	Ycs
Raleigh/Durham, NC	Northeast Raleigh	1	Yes	Yes
Raleigh/Durham, NC	Northwest Durham/Downtown	1	Yes	Yes
Raleigh/Durham, NC	Northwest Raleigh	1	Yes	Yes
Raleigh/Durham, NC	South Cary/Apex	1	Yes	Yes
Raleigh/Durham, NC	Southwest Durham	1	Yes	Yes
Reno, NV	South Reno	1	Yes	Yes
Richmond, VA	Northwest Richmond	1	Yes	Yes
Richmond, VA	Tuckahoe/Westhampton	1	Yes	Yes
Riverside-San Bernardino-Ontario, CA	Corona	1	Yes	Yes
Riverside-San Bernardino-Ontario, CA	Rancho Cucamonga/Upland	1	Yes	Yes
Riverside-San Bernardino-Ontario, CA	Temecula/Murrieta	1	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Salt Lake City/Ogden/Clearfield, UT	Midvale/Sandy/Draper	1	Yes	Yes
Salt Lake City/Ogden/Clearfield, UT	Southwest Salt Lake City	1	Yes	Yes
San Antonio-New Braunfels, TX	Far North Central San Antonio	1	Yes	Yes
San Antonio-New Braunfels, TX	Far Northwest San Antonio	1	Yes	Yes
San Antonio-New Braunfels, TX	North Central San Antonio	1	Yes	Yes
San Antonio-New Braunfels, TX	Northwest San Antonio	1	Yes	Yes
San Diego-Carlsbad, CA	Downtown San Diego/Coronado	1	Yes	Yes
San Diego-Carlsbad, CA	Northeast San Diego	1	Yes	Yes
Seattle-Bellevue-Everett, WA	Downtown Seattle	1	Yes	Yes
Seattle-Bellevue-Everett, WA	Federal Way/Des Moines	1		Yes
Seattle-Bellevue-Everett, WA	Redmond	1	Yes	Yes
Seattle-Bellevue-Everett, WA	Renton	1	Yes	Yes
Tampa-St. Petersburg-Clearwater, FL	Carrollwood/Citrus Park	1	Yes	Yes
Tampa-St. Petersburg-Clearwater, FL	Central Tampa	1	Yes	Yes
Tampa-St. Petersburg-Clearwater, FL	Town and Country/Westchase	1	Yes	Yes
Tucson, AZ	Casas Adobes/Oro Valley	1	Yes	Yes
Tucson, AZ	Catalina Foothills	1	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Germantown	1	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Loudoun County	1	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Manassas/Far Southwest Suburbs	1	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Washington-Arlington-Alexandria, DC-VA-MD-WV	Navy Yard/Capitol South	1	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Northeast DC	1	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Reston/Herndon	1	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Tysons Corner/Falls Church/Merrifield	1	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	West Alexandria	1	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	West Fairfax County	1	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Woodbridge/Dale City	1	Yes	Yes
Anaheim-Santa Ana-Irvine, CA	South Orange County	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Alpharetta/Cumming	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Briarcliff	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Buckhead	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Chamblee/Brookhaven	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Decatur	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Downtown Atlanta	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Duluth	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Dunwoody	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Kennesaw/Acworth	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Midtown Atlanta	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Norcross	2	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Atlanta-Sandy Springs-Roswell, GA	Northeast Atlanta	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Northeast Cobb/Woodstock	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Northeast Gwinnett County	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Roswell	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Sandy Springs	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Smyrna	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	South Cobb County/Douglasville	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Southeast Gwinnett County	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Southeast Marietta	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Southwest Atlanta	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	Vinings	2	Yes	Yes
Atlanta-Sandy Springs-Roswell, GA	West Atlanta	2	Yes	Yes
Austin-Round Rock, TX	Arboretum	2	Yes	Yes
Austin-Round Rock, TX	Cedar Park	2	Yes	Yes
Austin-Round Rock, TX	Downtown/University	2	Yes	Yes
Austin-Round Rock, TX	East Austin	2	Yes	Yes
Austin-Round Rock, TX	Far South Austin	2	Yes	Yes
Austin-Round Rock, TX	Far West Austin	2	Yes	Yes
Austin-Round Rock, TX	Near North Austin	2	Yes	Yes
Austin-Round Rock, TX	North Central Austin	2	Yes	Yes
Austin-Round Rock, TX	Northwest Austin	2	Yes	Yes
Austin-Round Rock, TX	Pflugerville/Wells Branch	2	Yes	Yes
Austin-Round Rock, TX	Round Rock/Georgetown	2	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Austin-Round Rock, TX	South Austin	2	Yes	Yes
Austin-Round Rock, TX	Southwest Austin	2	Yes	Yes
Baltimore-Columbia-Towson, MD	Columbia/North Laurel	2	Yes	Yes
Birmingham-Hoover, AL	Southeast Birmingham	2	Yes	Yes
Boston-Cambridge-Newton, MA-NH	East Middlesex County	2	Yes	Yes
Charleston-North Charleston, SC	Downtown/Mount Pleasant/Islands	2	Yes	Yes
Charleston-North Charleston, SC	West Ashley	2	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Ballantyne	2	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Huntersville/Cornelius	2	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Myers Park	2	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	North Charlotte	2	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	South Charlotte	2	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Southwest Charlotte	2	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	UNC Charlotte	2	Yes	Yes
Charlotte-Concord-Gastonia, NC-SC	Uptown/South End	2	Yes	Yes
Chicago-Naperville-Elgin, IL-IN-WI	The Loop	2		Yes
Colorado Springs, CO	North Colorado Springs	2	Yes	Yes
Dallas-Plano-Irving, TX	Addison/Bent Tree	2	Yes	Yes
Dallas-Plano-Irving, TX	Allen/McKinney	2	Yes	Yes
Dallas-Plano-Irving, TX	Carrollton/Farmers Branch	2		Yes
Dallas-Plano-Irving, TX	Central/East Plano	2	Yes	Yes
Dallas-Plano-Irving, TX	East Dallas	2	Yes	Yes
Dallas-Plano-Irving, TX	Frisco	2	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Dallas-Plano-Irving, TX	Grand Prairie	2	Yes	Yes
Dallas-Plano-Irving, TX	Intown Dallas	2	Yes	Yes
Dallas-Plano-Irving, TX	Las Colinas/Coppell	2	Yes	Yes
Dallas-Plano-Irving, TX	Lewisville/Flower Mound	2	Yes	Yes
Dallas-Plano-Irving, TX	North Irving	2		Yes
Dallas-Plano-Irving, TX	North Oak Cliff/West Dallas	2	Yes	Yes
Dallas-Plano-Irving, TX	Oak Lawn/Park Cities	2	Yes	Yes
Dallas-Plano-Irving, TX	Richardson	2	Yes	Yes
Dallas-Plano-Irving, TX	Rockwall/Rowlett/Wylie	2	Yes	Yes
Dallas-Plano-Irving, TX	The Colony/Far North Carrollton	2	Yes	Yes
Dallas-Plano-Irving, TX	West Plano	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Broomfield	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Downtown/Highlands/Lincoln Park	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Highlands Ranch	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Littleton	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Northeast Denver	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Parker/Castle Rock	2	Yes	Yes
Denver-Aurora-Lakewood, CO	South Lakewood	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Southeast Aurora/East Arapahoe County	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Southeast Denver	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Tech Center	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Thornton/Northglenn	2	Yes	Yes
Denver-Aurora-Lakewood, CO	Westminster	2	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Fort Lauderdale-Pompano Beach-Deerfield Beach, FL	Plantation/Davie/Weston	2	Yes	Yes
Fort Worth-Arlington, TX	Grapevine/Southlake	2	Yes	Yes
Fort Worth-Arlington, TX	Northeast Fort Worth/North Richland Hills	2		Yes
Hartford-West Hartford-East Hartford, CT	Southeast Hartford/Middlesex County	2	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Bear Creek	2		Yes
Houston-The Woodlands-Sugar Land, TX	Downtown/Montrose/River Oaks	2	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Far West Houston	2	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Friendswood/Pearland	2	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Galleria/Uptown	2	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Greater Heights/Washington Avenue	2	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Greenway/Upper Kirby	2	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Memorial	2	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	Sugar Land/Stafford	2	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	The Woodlands	2	Yes	Yes
Houston-The Woodlands-Sugar Land, TX	West University/Medical Center/Third Ward	2	Yes	Yes
Jacksonville, FL	Baymeadows	2	Yes	Yes
Jacksonville, FL	Upper Southside	2	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Kansas City, MO-KS	Lee's Summit/Blue Springs/Raytown	2	Yes	Yes
Las Vegas-Henderson-Paradise, NV	Henderson	2	Yes	Yes
Las Vegas-Henderson-Paradise, NV	Northwest Las Vegas	2	Yes	Yes
Las Vegas-Henderson-Paradise, NV	Summerlin/The Lakes	2	Yes	Yes
Los Angeles-Long Beach-Glendale, CA	Downtown Los Angeles	2	Yes	Yes
Memphis, TN-MS-AR	Cordova/Bartlett	2	Yes	Yes
Memphis, TN-MS-AR	Germantown/Collierville	2	Yes	Yes
Mobile/Daphne, AL	North Mobile	2	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	Central Nashville	2	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	East Nashville	2	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	Franklin/Brentwood	2	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	South Nashville	2	Yes	Yes
Nashville-Davidson--Murfreesboro--Franklin, TN	Southeast Nashville	2	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Altamonte Springs/Apopka	2	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Casselberry/Winter Springs/Oviedo	2	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Central Orlando	2	Yes	Yes
Orlando-Kissimmee-Sanford, FL	East Orange County	2	Yes	Yes
Orlando-Kissimmee-Sanford, FL	East Orlando	2	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Kissimmee/Osceola County	2	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Orlando-Kissimmee-Sanford, FL	Sanford/Lake Mary	2	Yes	Yes
Orlando-Kissimmee-Sanford, FL	South Orange County	2	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Southwest Orlando	2	Yes	Yes
Orlando-Kissimmee-Sanford, FL	Winter Park/Maitland	2	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	Chandler	2	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	Deer Valley	2	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	North Glendale	2	Yes	Yes
Phoenix-Mesa-Scottsdale, AZ	South Phoenix	2	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Aloha/West Beaverton	2	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Central Portland	2	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Hillsboro	2	Yes	Yes
Portland-Vancouver-Hillsboro, OR-WA	Lake Oswego/Tualatin/Wilsonville	2	Yes	Yes
Raleigh/Durham, NC	Central Raleigh	2	Yes	Yes
Raleigh/Durham, NC	Chapel Hill/Carrboro	2	Yes	Yes
Raleigh/Durham, NC	East Durham	2	Yes	Yes
Raleigh/Durham, NC	Far North Raleigh	2	Yes	Yes
Raleigh/Durham, NC	Near North Raleigh	2	Yes	Yes
Raleigh/Durham, NC	North Cary/Morrisville	2	Yes	Yes
Raleigh/Durham, NC	Northeast Raleigh	2	Yes	Yes
Raleigh/Durham, NC	Northwest Raleigh	2	Yes	Yes
Raleigh/Durham, NC	South Cary/Apex	2	Yes	Yes
Raleigh/Durham, NC	Southwest Durham	2	Yes	Yes
Reno, NV	South Reno	2	Yes	Yes
Richmond, VA	Northwest Richmond	2	Yes	Yes
Richmond, VA	Tuckahoe/Westhampton	2	Yes	Yes
Riverside-San Bernardino-Ontario, CA	Corona	2	Yes	Yes
Riverside-San Bernardino-Ontario, CA	Rancho Cucamonga/Upland	2	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Riverside-San Bernardino-Ontario, CA	Temecula/Murrieta	2	Yes	Yes
Salt Lake City/Ogden/Clearfield, UT	Midvale/Sandy/Draper	2	Yes	Yes
Salt Lake City/Ogden/Clearfield, UT	Southwest Salt Lake City	2	Yes	Yes
San Antonio-New Braunfels, TX	Far North Central San Antonio	2	Yes	Yes
San Antonio-New Braunfels, TX	Far Northwest San Antonio	2	Yes	Yes
San Antonio-New Braunfels, TX	North Central San Antonio	2		Yes
San Antonio-New Braunfels, TX	Northwest San Antonio	2		Yes
San Diego-Carlsbad, CA	Downtown San Diego/Coronado	2	Yes	Yes
San Diego-Carlsbad, CA	Northeast San Diego	2	Yes	Yes
Seattle-Bellevue-Everett, WA	Downtown Seattle	2	Yes	Yes
Seattle-Bellevue-Everett, WA	Federal Way/Des Moines	2		Yes
Seattle-Bellevue-Everett, WA	Renton	2	Yes	Yes
Tampa-St. Petersburg-Clearwater, FL	Carrollwood/Citrus Park	2	Yes	Yes
Tampa-St. Petersburg-Clearwater, FL	Central Tampa	2	Yes	Yes
Tampa-St. Petersburg-Clearwater, FL	Town and Country/Westchase	2	Yes	Yes
Tucson, AZ	Casas Adobes/Oro Valley	2	Yes	Yes
Tucson, AZ	Catalina Foothills	2	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Germantown	2	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Loudoun County	2	Yes	Yes

Area	Submarket	No. of Beds.	YS/AIRM 30% or More	YS/AIRM / OneSite 30% or More
Washington-Arlington-Alexandria, DC-VA-MD-WV	Manassas/Far Southwest Suburbs	2	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Navy Yard/Capitol South	2	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Northeast DC	2	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Reston/Herndon	2	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Tysons Corner/Falls Church/Merrifield	2	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	West Alexandria	2	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	West Fairfax County	2	Yes	Yes
Washington-Arlington-Alexandria, DC-VA-MD-WV	Woodbridge/Dale City	2	Yes	Yes

United States District Court for the Middle District of North Carolina

United States of America, Plaintiff, v. *Willow Bridge Property Company, LLC*, Defendant.

No. 1:24–cv–00710–WLO–JGM

Proposed Final Judgment

Whereas, Plaintiff, United States of America, filed its Complaint on January 7, 2025;

And Whereas, the United States and Defendant, Willow Bridge Property Company, LLC, have consented to entry of this Final Judgment without the taking of testimony, without trial or adjudication of any issue of fact or law, and without this Final Judgment constituting any evidence against or admission by any party relating to any issue of fact or law;

And Whereas, Defendant agrees to undertake certain actions and refrain from certain conduct to remedy the loss of competition alleged in the Complaint;

And Whereas, Defendant represents that the relief required by this Final Judgment can and will be made and that Defendant will not later raise a claim of hardship or difficulty as grounds for asking the Court to modify any provision of this Final Judgment;

Now Therefore, it is *Ordered, Adjudged, and Decreed*:

I. Jurisdiction

The Court has jurisdiction over the subject matter of, and each of the parties to, this action. The Complaint states a claim upon which relief may be granted against Defendant under Section 1 of the Sherman Act, 15 U.S.C. 1.

II. Definitions

As used in this Final Judgment:

A. ''Willow Bridge'' or ''Defendant'' means Defendant Willow Bridge Property Company, LLC, with its headquarters in Dallas Texas, its successors and assigns, and all of its subsidiaries, divisions, groups, affiliates, parents, partnerships, and joint ventures engaged in the management or ownership of multifamily rental properties in the United States and its territories, and their directors, officers, managers, agents, and employees.

B. ''Competitively Sensitive Information'' means, in this Final Judgment, property-specific data or information (whether past, present, or prospective) which, individually or when aggregated with such data or information from other properties, (1) could be reasonably used to determine current or future rental supply, demand, or pricing at a property or of any property's units, including but not limited to executed rents, rental price concessions or discounts, guest traffic, guest applications, occupancy or vacancy, lease terms, or lease expirations; (2) relates to the Property Owner's or Property Manager's use of settings or user-specified parameters within Revenue Management Products with respect to such property or properties; or (3) relates to the Property Owner's or Property Manager's rental pricing amount, formula, or strategy,

including rental price concessions or discounts with respect to such property or properties.

C. ''Cooperation Subject Matter'' means the claims alleged in *United States et al.* v. *RealPage et al.* (currently docketed as No. 1:24–cv–00710 in the Middle District of North Carolina), and includes conduct as well as the effects of conduct.

D. ''External Nonpublic Data'' means all Nonpublic Data from any Third-Party. It does not include data for a Defendant Property.

E. ''Including'' means including, but not limited to.

F. ''Model Training'' means the process of analyzing data, including by machine learning or regression analysis, to create or adjust the parameters of a model or algorithm to improve the accuracy of the model's or algorithm's predictions.

G. ''Nonpublic Data'' means any Competitively Sensitive Information that is not Public Data.

H. ''Person'' means any natural person, corporate entity, partnership, association, joint venture, limited liability company, fund, investment vehicle, or any other legal entity or trust.

I. ''Property Manager(s)'' means any Person, or the Person's agent, who manages a multifamily rental property.

J. ''Property Owner(s)'' means any Person who (directly or indirectly) owns or controls a multifamily rental property or that Person's agent; multifamily rental properties have the same Property Owner if they are (directly or indirectly) owned or controlled by the same Person.

K. ''Pseudocode'' means any description of the steps in an algorithm or other software program in plain or natural language.

L. ''Public Data'' means information on a rental property or unit's asking rental price (including publicly offered concessions), amenities, availability, and other information that is readily accessible to the general public, including but not limited to, on the property's website, at a physical building, in brochures, or on an internet listing service. Public Data also includes information on a rental property or unit's asking price, concessions, amenities, and availability provided by a Property Manager or a Property Owner to any natural person who reasonably presents himself as a prospective renter. Public Data does not include any Competitively Sensitive Information obtained through communications between competitors, unless such information is also readily accessible to the general public. For the avoidance of doubt, the fact that information is available by paid subscription from a third party does not, on its own, render the information either Non-Public or Competitively Sensitive Information.

M. ''RealPage'' means RealPage, Inc., a Delaware corporation with its headquarters in Richardson, Texas.

N. ''RealPage Final Judgment'' means the Final Judgment between the United States and RealPage entered in *United States et al.* v. *RealPage et al.* (currently docketed as No. 1:24–cv–00710 in the Middle District of North Carolina).

O. ''RealPage Meeting(s)'' means RealPage steering committees, RealPage subcommittees, RealPage user groups, RealPage Idea Exchange, or any variation of these meetings. For avoidance of doubt, a RealPage Meeting does not include any communications between Willow Bridge and the Property Owner of a Willow Bridge Property or any other Person providing services to that Willow Bridge Property, or any software feedback provided solely to RealPage that is not otherwise shared by Willow Bridge with other Property Managers or Property Owners.

P. ''Revenue Management Product(s)'' means any software or service, including software as a service, that generates rental prices or rental pricing recommendations for multifamily housing rentals. For avoidance of doubt, a Revenue Management Product does not include general purpose spreadsheet software like Microsoft Excel.

Q. ''Runtime Operation'' means any action taken by a Revenue Management Product while it runs, including generating rental prices or pricing recommendations for any unit or set of units at a property. Runtime Operation does not mean Model Training.

R. ''Settled Civil Claims'' means any civil federal antitrust claim by the United States arising from Defendant's conduct accruing before the filing of the complaint in this action relating to (1) Revenue Management Products, including RealPage Revenue Management Products that use competitors' Competitively Sensitive Information, as well as (2) communications described by Paragraph VI.A.

S. ''Third-Party'' means any Person other than Defendant or a Defendant affiliate.

T. ''Willow Bridge Property'' means a multifamily rental property, located within the United States or its territories, for which Defendant provides revenue management or related reporting or consulting services (collectively referred to as ''Willow Bridge Properties''). Willow Bridge Property does not include student housing, affordable housing, age-restricted or senior housing, or military housing.

U. ''Willow Bridge Revenue Management Product'' means Defendant's proprietary Revenue Management Products, including RaMi.

III. Applicability

This Final Judgment applies to Defendant, as defined above, and all other Persons in active concert or participation with Defendant who receive actual notice of this Final Judgment.

IV. Use of Proprietary Revenue Management Product(s)

A. The Willow Bridge Revenue Management Product must not generate rental prices or rental pricing recommendations for a Willow Bridge Property during its Runtime Operation using (1) External Nonpublic Data in any way, or (2) Nonpublic Data from one Willow Bridge Property for another Willow Bridge Property with a different Property Owner by pooling or combining Nonpublic Data from Defendant Properties that have different Property Owners.

B. In any Model Training of the Willow Bridge Revenue Management Product, Defendant must not (1) use External Nonpublic Data in any way, or (2) pool or combine rental pricing, concessions, discounts, occupancy rates or capacity, or other rental pricing terms from Willow Bridge Properties with different Property Owners.

C. The Willow Bridge Revenue Management Product must not disclose in any way Nonpublic Data from a Willow Bridge Property to any Third-Party Property Manager or Third-Party Property Owner (other than a Third-Party Property Owner of the Willow Bridge Property from which the data arises or to which it relates, or to a Third-Party Property Manager that provides services to Willow Bridge Properties).

D. Willow Bridge may license its proprietary revenue management software to Third Parties, so long as the product complies with this Final Judgment, including the terms set forth in Paragraphs V.A.1–2, and such license otherwise complies with all applicable laws.

E. Except as provided in Paragraph V.A, if, during the term of this Final Judgment, revenue management responsibilities or ownership of a property within the United States or its territories is transferred from a Third-Party Property Manager or a Third-Party Property Owner to Defendant, Defendant will have 90 days from the

date of transfer to transition the transferred property to a Revenue Management Product that complies with the terms of this Final Judgment.

V. Restrictions Concerning Use of Third-Party Revenue Management Product(s)

A. Beginning 180 days after entry of the Stipulation and Order, Willow Bridge must not, within the United States and its territories:

1. license or use, for any Defendant Property, any Third-Party Revenue Management Product that: (1) uses External Nonpublic Data (other than Nonpublic Data of the Property Owner of the subject Willow Bridge Property) in its Runtime Operation to generate rental prices or rental pricing recommendations for a Willow Bridge Property; (2) uses Nonpublic Data from a Willow Bridge Property in its Runtime Operation to generate rental prices or rental pricing recommendations for any other Property Manager or Property Owner (unless the Property Owner of the non-Willow Bridge Property is the same as the Property Owner of the Willow Bridge Property from which the data arises or to which it relates); (3) discloses in any way Nonpublic Data from a Willow Bridge Property to any Third-Party Property Manager or Third-Party Property Owner (other than a Third-Party Property Owner of the Willow Bridge Property from which the data arises or to which it relates, or to a Third-Party Property Manager that provides services to Defendant Properties); (4) pools or combines Nonpublic Data from Willow Bridge Properties that have different Property Owners; or (5) contains or uses a pricing model or algorithm that has been trained using Nonpublic Data (other than Nonpublic Data of the Property Owner of the subject Defendant Property); or

2. license or use any Third-Party Revenue Management Product that: (1) incorporates a rental price floor or a limit on rental price recommendation decreases (excluding a rental price floor, or limit on rental price decreases, that Willow Bridge or the Property Owner manually selects and is not based on Nonpublic Data other than Nonpublic Data of the Property Owner of the subject Willow Bridge Property); or (2) requires Willow Bridge to accept, or provides any financial rewards for Defendant to accept, any recommended rental prices.

3. agree (expressly or tacitly) with any other Property Owner or Non-Willow Bridge Property Manager to use a particular Revenue Management Product (or the utilities or functionalities thereof) or require any other Person to use a particular Revenue Management Product (or the utilities or functionalities thereof). Willow Bridge is not prohibited by the preceding sentence from using a particular Revenue Management Product at a particular property pursuant to an agreement with another Person who is the Property Owner or who, along with Willow Bridge, provides services to that particular property on behalf of the Property Owner, provided that the Revenue Management Product complies with Paragraphs V.A.1–2.

B. If management responsibilities or ownership of a property within the United States or its territories is transferred from another Property Manager or Property Owner to Willow Bridge, then Willow Bridge will have 90 days from the date of transfer to comply with the requirements of Paragraph V.A. for the transferred property.

C. Within 180 days after entry of the Stipulation and Order, Willow Bridge must first notify the United States, in writing, of its intention to license or use a Third-Party Revenue Management Product 30 calendar days prior to using a Third-Party Revenue Management Product. Thereafter, if Defendant intends to license or use any other commercially available Revenue Management Product at any Willow Bridge Property, Defendant must first notify the United States, in writing, of its intention to license or use such a commercially available Revenue Management Product 30 calendar days prior to licensing or using the commercially available Revenue Management Product.

D. Notwithstanding Paragraphs IV.A–C and V.A, Willow Bridge may license or use a Revenue Management Product that complies with the terms of the RealPage Final Judgment.

E. Beginning 180 days after entry of the Stipulation and Order, if Defendant elects to license or use a Third-Party Revenue Management Product:

1. After entry by the Court of the RealPage Final Judgment, Defendant may license or use a RealPage Revenue Management Product at any Defendant Property without the need to obtain certification as required in this Paragraph V.E.

2. If Defendant licenses or uses a Third-Party Revenue Management Product from a Person other than RealPage or a reseller of a RealPage Revenue Management Product at any Defendant Property, Defendant must secure and submit to the United States a certification from the vendor of the Revenue Management Product that the Revenue Management Product complies with the requirements in Paragraph V.A or complies with the requirements for Revenue Management Products established in the RealPage Final Judgment.

VI. Other Prohibited Conduct

A. Willow Bridge must not, directly or indirectly, as part of setting rental prices or generating rental pricing recommendations for any Willow Bridge Property (1) disclose Nonpublic Data to any Third-Party Property Manager or Third-Party Property Owner (except to a Third-Party Property Owner of the particular Willow Bridge Property from which the data arises or to which it relates, or a Third-Party Property Manager that provides services to Defendant Properties); (2) solicit External Nonpublic Data from any Third-Party Property Manager or Third-Party Property Owner (except from a Third-Party Property Owner of the particular Willow Bridge Property from which the data arises or to which it relates, or from a Third-Party Property Manager that provides services to Defendant Properties); or (3) use External Nonpublic Data obtained from any Third-Party Property Manager or Third-Party Property Owner (except from a Third-Party Property Owner of the particular Willow Bridge Property from which the data arises or to which it relates, or from a Third-Party Property Manager that provides services to Defendant Properties). For the avoidance of doubt, the restrictions set forth in this Paragraph include Nonpublic Data obtained through any means, whether directly or through an intermediary, including call arounds or market surveys, in-person meetings, calls, text messages, chat communications, emails, surveys, spreadsheets, shared documents (*e.g.,* Google documents and SharePoint documents), industry meetings (*e.g.,* user groups), online fora, private meetings, Revenue Management Products, or information-exchange services.

B. Notwithstanding Paragraph VI.A, a Defendant employee may (1) disclose or solicit Nonpublic Data about a particular property for the purpose of evaluating or effectuating a bona fide sale or purchase of the property, as long as any Nonpublic Data received is not used to set rental prices or generate rental pricing recommendations, or (2) disclose Nonpublic Data about a particular Defendant Property between a departing Property Manager and replacement Property Manager as part of a bona fide transfer of management responsibilities for that property.

C. Defendant must not, within the United States or its territories, use or access, as part of setting rental prices or generating rental pricing recommendations for any Willow Bridge Property, any External Nonpublic Data (other than Nonpublic Data of the Property Owner of the subject Willow Bridge Property), including such data derived from any RealPage Revenue Management Product, in Defendant's possession, custody, or control as of the Court's entry of the Stipulation and Order in this matter, acquired through any means. Within 180 days of entry of the Stipulation and Order, Defendant must identify to the United States in writing the existence and location of any structured data set containing such External Nonpublic Data. For the avoidance of doubt, the proscriptions in this Paragraph do not apply to data for Willow Bridge Properties maintained in OneSite, Yardi Voyager, or other property management software.

D. Defendant will not attend or participate in any RealPage Meetings. If Willow Bridge attends or participates in a RealPage Meeting it will report such meeting within 30 days to the United States. Defendant must identify the date, time, and location of the meeting, identify all participants in that meeting, provide a description of the content of the meeting, provide a description of any document shown during the meeting, produce all documents received or provided by Defendant during the meeting, and produce any chats, recordings, or documents associated with the meeting.

VII. Antitrust Compliance

A. Within 30 days of entry of the Stipulation and Order, Defendant must adopt a written antitrust compliance policy, to be approved by the United States in its sole discretion, that complies with the obligations set forth in this Final Judgment. Defendant must annually train all employees on this written policy. As part of that policy, Defendant must designate a chief antitrust compliance officer, who will be responsible for implementing and enforcing Defendant's antitrust compliance policy and annual training. Defendant must identify to the United States the chief antitrust compliance officer's name, business address, telephone number, and email address. Within 45 days of a vacancy in Defendant's chief antitrust compliance officer position, Defendant must appoint a replacement and must identify to the United States the replacement's name, business address, telephone number, and email address. Defendant's initial and replacement appointment of a chief antitrust compliance officer is subject to the approval of the United States in its sole discretion. Defendant is responsible for all costs and expenses related to the chief antitrust compliance officer. The chief antitrust compliance officer will conduct an annual antitrust compliance audit. The annual audits must, at a minimum, cover: (1) employees (including supervisors) engaged in or overseeing Willow Bridge's revenue management of multifamily rental properties in the United States and its territories; and (2) randomly selected, local, regional, or supervisory employees who manage property operations (at least 12 each year). The chief antitrust compliance officer will provide the United States with an annual report identifying all individuals audited.

B. On an annual basis beginning 180 calendar days after entry of the Stipulation and Order, during the term of this Final Judgment, Defendant must:

1. submit to the Antitrust Division a certification from the General Counsel of Willow Bridge attesting under penalty of perjury that (1) Defendant has established and maintained the annual antitrust compliance policy and training required by Paragraph VII.A; (2) Defendant has complied with the attestation requirements in Paragraph VII.B.2.; (3) Defendant has provided the Antitrust Division with an annual report identifying the individuals audited pursuant to Paragraph VII.A; (4) Willow Bridge Revenue Management Product continues to satisfy the requirements in Section IV or if applicable, the requirements of the RealPage Final Judgment; (5) if required under this Final Judgment, the vendors of any Third-Party Revenue Management Products licensed or used by Willow Bridge have provided the certification(s) required by Paragraph VII.C; and (6) Defendant has complied with Paragraph VI.D.

2. require all of Defendant's employees (1) engaged in or overseeing Defendant's revenue management of multifamily rental properties in the United States and its territories, and (2) overseeing property management for multiple of Defendant's multifamily rental properties in the United States and its territories to attest under penalty of perjury that they have complied with Paragraphs V.A.3, VI.A, and VI.D;

C. if required under this Final Judgment, including Paragraph V.E, obtain and submit to the Antitrust Division a certification, as described in Paragraph V.E, that each Third-Party Revenue Management Product that Willow Bridge licenses or uses complies with Paragraph V.A or complies with the requirements for Revenue Management Products established in the RealPage Final Judgment; and

D. If applicable, provide the Antitrust Division a report that identifies for each Willow Bridge Property for which Willow Bridge uses a Third-Party Revenue Management Product: (1) the name of the Property Owner(s) and (2) any Third-Party Revenue Management Product used within the preceding twelve months for that Willow Bridge Property.

VIII. Cooperation

A. Defendant must cooperate fully and truthfully with the United States relating to the Cooperation Subject Matter in any civil investigation or civil litigation the United States brings or has brought. Defendant must use its best efforts to ensure that all current and former officers, directors, agents, and employees also fully and promptly cooperate with the United States relating to the Cooperation Subject Matter in any civil investigation or civil litigation the United States brings or has brought. Defendant's cooperation must include:

1. as requested on reasonable notice by the Antitrust Division, making up to 15 employees available for voluntary interviews for up to 60 hours total regarding the Cooperation Subject Matter;

2. providing full and truthful written or oral testimony in any deposition, trial, or other proceeding relating to the Cooperation Subject Matter and making witnesses available to the United States upon reasonable notice before any such testimony;

3. providing proffers, which may be made by counsel for Defendant, describing Defendant's knowledge of and evidence relating to the Cooperation Subject Matter;

4. within 30 days of receiving a written request (whether formal process or informal request) from the United States for documents, information, or other material relating to the Cooperation Subject Matter (or whatever additional time the Antitrust Division grants in its sole discretion), producing to the United States all responsive documents, information, and other materials, wherever located, not protected under the attorney-client privilege or the work-product doctrine, in the possession, custody, or control of Defendant, as well as a log of any responsive documents, information, or other materials that were not provided, including an explanation of the basis for withholding such materials;

5. authenticating or otherwise assisting with establishing the

evidentiary foundation of any documents Defendant produced or produces to the United States; and

6. taking all necessary steps to preserve all documents, information, and other materials relating to the Cooperation Subject Matter until the United States provides written notice to Defendant that its obligation to do so has expired.

B. Subject to Defendant's full, truthful, and continuing cooperation, as required under Paragraph VIII.A, Defendant is fully and finally discharged and released from Settled Civil Claims.

C. Nothing in this Section VIII affects Defendant's obligation to respond to any formal discovery requests in litigation or a civil investigative demand issued by the United States.

IX. Appointment of Monitor

A. Defendant will not be subject to a Monitor if all Third-Party Revenue Management Products that Defendant licenses or uses at Defendant Properties have been certified pursuant to, or are otherwise compliant with, Paragraph V.E.

B. However, if Defendant elects to license or use a Third-Party Revenue Management Product that has not been certified pursuant to, or is not otherwise compliant with, Paragraph V.E, at any Defendant Property, or if a Court finds that Defendant has violated any other term of the Final Judgment, upon application of the United States, which Defendant may not oppose, the Court will appoint an independent Third-Party antitrust monitor (the ''Monitor'') selected by the United States and approved by the Court.

C. Defendant may propose to the United States a pool of three candidates to serve as the Monitor, and the United States may consider Defendant's perspectives on the proposed candidates or any other candidates identified and considered by the United States. The United States will retain the ultimate right, in its sole discretion, either to select the Monitor from among the three candidates proposed by Defendant or to select a different candidate. Once approved, the Monitor should be considered by the United States and Defendant to be an arm and representative of the Court.

D. The Monitor will have the power and authority to monitor Defendant's compliance with Section IV and Paragraphs V.A, VI.A, VI.D, VII.A, and VII.B of this Final Judgment, including by determining whether employees (including supervisors) in Defendant's residential-property revenue management group have complied with their obligations set forth in those Sections. As part of its monitoring duties, the Monitor may also choose, in consultation with the United States, a yearly selection of other local, regional, or supervisory employees of Defendant who manage property operations (not to exceed 15 annually) and investigate whether those individuals have complied with the obligations set forth in Paragraphs V.A.3, V.B, and VI.A. The Monitor will have other powers as the Court deems appropriate. The Monitor will have no responsibility for the operation of the Defendant's business. No attorney-client relationship will be formed between Defendant and the Monitor.

E. The Monitor will have the authority to take such steps as, in the Monitor's discretion and the United States' view, may be necessary to accomplish the Monitor's responsibilities. The Monitor may seek information from Defendant's personnel, including in-house counsel, compliance personnel, and internal auditors. Defendant will annually communicate to all employees that employees may disclose any information to the Monitor without reprisal for such disclosure. Defendant must not retaliate against any employee or Third-Party for disclosing information to the Monitor.

F. Defendant may not object to actions taken by the Monitor in fulfillment of the Monitor's responsibilities under any Order of the Court on any ground other than malfeasance by the Monitor. Disagreements between the Monitor and Defendant related to the scope of the Monitor's responsibilities do not constitute malfeasance. Objections by Defendant must be conveyed in writing to the United States and the Monitor within 10 calendar days of the Monitor's action that gives rise to Defendant's objection, or else Defendant will have waived any such objections.

G. The Monitor will serve at the cost and expense of Defendant pursuant to a written agreement, on terms and conditions, including confidentiality requirements and conflict of interest certifications, approved by the United States in its sole discretion. If the Monitor and Defendant are unable to reach such a written agreement within 14 calendar days of the Court's appointment of the monitor, or if the United States, in its sole discretion, declines to approve the proposed written agreement, the United States, in its sole discretion, may take appropriate action, including making a recommendation as to the Monitor's costs and expenses to the Court, which may set the terms and conditions for the Monitor's costs and expenses.

H. The Monitor may hire, at the cost and expense of Defendant, any agents and consultants, including investment bankers, attorneys, and accountants, that are reasonably necessary in the Monitor's judgment to assist with the Monitor's duties. These agents or consultants will be directed by and solely accountable to the Monitor and will serve on terms and conditions, including confidentiality requirements and conflict-of-interest certifications, approved by the United States in its sole discretion. Within three business days of hiring any agents or consultants, the Monitor must provide written notice of the hiring and the rate of compensation to Defendant and the United States.

I. The Monitor must provide yearly reports to the United States, with the first report due six months after the Monitor is appointed and subsequent reports due yearly thereafter, setting forth Defendant's efforts to comply with its obligations under this Final Judgment. If the Monitor learns of any potential violation of the Final Judgment by Defendant's officers, agents, or employees, the Monitor must promptly disclose to the Antitrust Division the nature and extent of any such potential violation and the Antitrust Division may require, in its sole discretion and without prejudice to any other remedy available for any violation of the Final Judgment, that the Monitor conduct additional investigation of compliance with this Final Judgment beyond any limits set forth in Paragraph IX.D.

J. The Monitor must account for all costs and expenses incurred.

K. The compensation of the Monitor and agents or consultants retained by the Monitor must be on reasonable and customary terms commensurate with the individuals' experience and responsibilities.

L. Defendant's failure to promptly pay the Monitor's accounted-for costs and expenses, including for agents and consultants, will constitute a violation of this Final Judgment and may result in sanctions imposed by the Court. If Defendant disputes any part of the Monitor's accounted-for costs and expenses, Defendant must establish an escrow account into which Defendant must pay the disputed costs and expenses until the dispute is resolved.

M. Defendants must use best efforts to cooperate fully with the Monitor and to assist the Monitor to monitor Defendant's compliance with its obligations under this Final Judgment. Subject to reasonable protection for trade secrets, other confidential

research, development, or commercial information, or any applicable privileges, Defendant must provide the Monitor and agents or consultants retained by the Monitor with full and complete access to all personnel (current and former), agents, consultants, books, records, and facilities. Defendant may not take any action to interfere with or to impede accomplishment of the Monitor's responsibilities.

N. If the United States determines that the Monitor is not acting diligently or in a reasonably cost-effective manner, or if the Monitor becomes unable to continue in its role for any reason, the United States may recommend that the Court appoint a substitute.

O. Once appointed by the Court, the Monitor will serve until (1) the expiration of the Final Judgment; or (2) if a Monitor has been appointed pursuant to Paragraph IX.B, the United States will move the Court to terminate the monitorship upon the United States' determination that Defendant complies with the requirements in Paragraph V.E.

X. Compliance Inspection

A. For the purposes of determining or securing compliance with this Final Judgment or of related orders such as the Stipulation and Order entered in this matter or of determining whether this Final Judgment should be modified or vacated, upon written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, and reasonable notice to Defendant, Defendant must permit, from time to time and subject to legally recognized privileges, authorized representatives, including agents retained by the United States:

1. to have access during Defendant's office hours to inspect and copy, or at the option of the United States, to require Defendant to provide, no later than 30 days after receiving a written request (whether formal or informal) from the United States, electronic copies of all books, ledgers, accounts, records, data, and documents in the possession, custody, or control of Defendant relating to any matters contained in this Final Judgment; and

2. to interview, either informally or on the record, Defendant's officers, agents, or employees, who may have their individual counsel present, relating to any matters contained in this Final Judgment. The interviews must be subject to the reasonable convenience of the interviewee and without restraint or interference by Defendant.

B. For the purposes of determining or securing compliance with this Final Judgment or related orders or determining whether this Final Judgment should be modified or vacated, upon the written request of an authorized representative of the Assistant Attorney General for the Antitrust Division, Defendant must submit written reports or respond to written interrogatories, under oath if requested, relating to any matters contained in this Final Judgment.

C. Upon request of the United States, Defendant must provide documents sufficient to show how Defendant's Revenue Management Product is trained and how it determines prices for Defendant Properties during its Runtime Operation, and changes to these processes.

D. The United States will have the right to obtain and inspect at an Antitrust Division office, or at another location at the Antitrust Division's discretion, the code and Pseudocode of the Defendant Revenue Management Product to ensure compliance with Section IV. Defendant will be responsible for the costs and expenses associated with said inspection once annually.

XI. Public Disclosure

A. No information or documents obtained pursuant to any provision or this Final Judgment, including reports the Monitor provides to the United States pursuant to Paragraph IX.I, may be divulged by the United States or the Monitor to any person other than an authorized representative of the executive branch of the United States, except in the course of legal proceedings to which the United States is a party, including grand-jury proceedings, or as otherwise required by law.

B. In the event that the Monitor should receive a subpoena, court order, or other court process seeking production of information or documents obtained pursuant to any provision in this Final Judgment, including reports the Monitor provides to the United States pursuant to Paragraph IX.I, the Monitor must notify Defendant immediately and prior to any disclosure, so that Defendant may address such potential disclosure and, if necessary, pursue alternative legal remedies, including intervention in the relevant proceedings.

C. In the event of a request by a Third-Party, pursuant to the Freedom of Information Act, 5 U.S.C. 552, for disclosure of information obtained pursuant to any provision of this Final Judgment, the Antitrust Division will act in accordance with that statute, and the Department of Justice regulations at 28 CFR part 16, including the provision on confidential commercial information, at 28 CFR 16.7. Defendant, when submitting information to the Antitrust Division, should designate the confidential commercial information portions of all applicable documents and information under 28 CFR 16.7. Designations of confidentiality expire 10 years after submission, ''unless the submitter requests and provides justification for a longer designation period.'' See 28 CFR 16.7(b).

D. If at the time that Defendant furnishes information or documents to the United States pursuant to any provision of this Final Judgment, Defendant represents and identifies in writing information or documents for which a claim of protection may be asserted under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure, and the Defendant marks each pertinent page of such material, ''Subject to claim of protection under Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure,'' the United States must give Defendant 10 calendar days' notice before divulging the material in any legal proceeding (other than a grand-jury proceeding).

XII. Retention of Jurisdiction

The Court retains jurisdiction to enable any party to this Final Judgment to apply to the Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions.

XIII. Enforcement of Final Judgment

A. The United States retains and reserves all rights to enforce the provisions of this Final Judgment, including the right to seek an order of contempt from the Court. Defendant agrees that in a civil contempt action, a motion to show cause, or a similar action brought by the United States relating to an alleged violation of this Final Judgment, the United States may establish a violation of this Final Judgment and the appropriateness of a remedy therefor by a preponderance of the evidence, and Defendant waives any argument that a different standard of proof should apply.

B. This Final Judgment should be interpreted to give full effect to the procompetitive purposes of the antitrust laws and to restore the competition the United States alleges was harmed by the challenged conduct. Defendant agrees that it may be held in contempt of, and that the Court may enforce, any provision of this Final Judgment that, as interpreted by the Court in light of these procompetitive principles and applying

ordinary tools of interpretation, is stated specifically and in reasonable detail, whether or not it is clear and unambiguous on its face. In any such interpretation, the terms of this Final Judgment should not be construed against either party as the drafter.

C. In an enforcement proceeding in which the Court finds that Defendant has violated this Final Judgment, the United States may apply to the Court for an extension of this Final Judgment, together with other relief that may be appropriate. In connection with a successful effort by the United States to enforce this Final Judgment against Defendant, whether litigated or resolved before litigation, Defendant agrees to reimburse the United States for the fees and expenses of its attorneys, as well as all other costs including experts' fees, incurred in connection with that effort to enforce this Final Judgment, including in the investigation of the potential violation.

D. For a period of four years following the expiration of this Final Judgment, if the United States has evidence that Defendant violated this Final Judgment before it expired, the United States may file an action against Defendant in this Court requesting that the Court order: (1) Defendant to comply with the terms of this Final Judgment for an additional term of at least four years following the filing of the enforcement action; (2) all appropriate contempt remedies; (3) additional relief needed to ensure Defendant complies with the terms of this Final Judgment; and (4) fees or expenses as called for by this Section.

XIV. Expiration of Final Judgment

Unless the Court grants an extension, this Final Judgment will expire five years from the date of its entry, except that after three years from the date of its entry, this Final Judgment may be terminated upon notice by the United States to the Court and Defendant that the continuation of this Final Judgment is no longer necessary or in the public interest.

XV. Reservation of Rights

The Final Judgment relates only to the resolution of the Settled Civil Claims. The United States reserves all rights for any other claims against Defendant that may be brought in the future. The entry of the Final Judgment does not limit the ability of any non-settling attorney general of any State to bring or maintain any action under federal or state law against Defendant.

XVI. Public Interest Determination

Entry of this Final Judgment is in the public interest. The parties have complied with the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16, including by making available to the public copies of this Final Judgment and the Competitive Impact Statement, public comments thereon, and any response to comments by the United States. Based upon the record before the Court, which includes the Competitive Impact Statement and, if applicable, any comments and response to comments filed with the Court, entry of this Final Judgment is in the public interest.

Date: _____

[Court approval subject to procedures of Antitrust Procedures and Penalties Act, 15 U.S.C. 16]

_____

United States District Judge

United States District Court for The Middle District of North Carolina

UNITED STATES OF AMERICA, Plaintiff, v. *WILLOW BRIDGE PROPERTY COMPANY, LLC,* Defendent.

No. 1:24–cv–00710–WLO–JGM

Competitive Impact Statement

In accordance with the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h) (the ''APPA'' or ''Tunney Act''), the United States of America files this Competitive Impact Statement related to the proposed Final Judgment against Defendant Willow Bridge Property Company, LLC, which has been filed in this civil antitrust proceeding (Doc. 200–1).

I. Nature and Purpose Of The Proceeding

On August 23, 2024, the United States, along with co-plaintiff States, filed a civil antitrust Complaint (the ''Complaint'') against RealPage, Inc. (''RealPage''). On January 7, 2025, the United States and its co-plaintiff States amended the Complaint to add Willow Bridge Property Company, LLC (''Willow Bridge'') and five other property management companies (''property managers'') as Defendants. Willow Bridge licenses revenue management products called AI Revenue Management (''AIRM'') and YieldStar from RealPage. RealPage also licenses AIRM and YieldStar to Willow Bridge's competitors, including the other property managers or property owners (collectively, ''landlords'') named as Defendants in the Complaint. Willow Bridge and other landlords use RealPage's revenue management products to determine how to price floor plans and units for the conventional multifamily rental housing that they each manage and lease, in competition with each other in numerous local rental housing markets around the country.

The Complaint alleges that Willow Bridge violated Section 1 of the Sherman Act, 15 U.S.C. 1, by unlawfully sharing its confidential and competitively sensitive information with RealPage for use in its and competing landlords' pricing. Under their licensing agreements with RealPage, Willow Bridge and competing landlords have provided RealPage with daily, competitively sensitive, nonpublic information relating to their leasing businesses, including details like how many leases have been renewed, on what terms, and at what price. The transactional data that Willow Bridge and other landlords have agreed to provide to RealPage includes current, forward-looking, granular, and highly competitively sensitive information. As reflected in the design, development, and operation of its revenue management products, RealPage has used Willow Bridge's competitively sensitive, nonpublic information to influence rental prices and other leasing recommendations across conventional multifamily rental housing managed by competing landlords. Through RealPage's revenue management products, Willow Bridge's rental prices and related recommendations for conventional multifamily housing rentals were likewise influenced by its competitors' competitively sensitive, nonpublic information. In each relevant market, RealPage and participating landlords, including Willow Bridge, collectively have sufficient market power, as indicated by market and data penetration, to harm renters and the competitive process through their unlawful sharing of confidential and competitively sensitive information with each other.

The Complaint also alleges that Willow Bridge and other landlords, by adopting and using RealPage's revenue management products, have agreed with RealPage to align their pricing, thereby violating Section 1 of the Sherman Act, 15 U.S.C. 1. RealPage has entered into agreements with Willow Bridge and its competing landlords relating to how to price floor plans and rental units by licensing its revenue management products, AIRM and YieldStar, to landlords, and by training and running its revenue management products using competitively sensitive, nonpublic transactional data shared by landlords. Adoption and use of RealPage's revenue management products by Willow Bridge and other landlords has the likely effect of aligning their pricing processes, strategies, and pricing responses, and

Willow Bridge and other landlord users understand this likely effect.

On July 6, 2026, the United States filed a proposed Final Judgment and a Stipulation and Order (''Stipulation and Order''), which are designed to remedy the loss of competition alleged in the Complaint due to Willow Bridge's conduct.

The proposed Final Judgment, which is explained more fully below, imposes several requirements and restrictions on Willow Bridge that address the United States' concerns regarding Willow Bridge's anticompetitive conduct alleged in the Complaint. Specifically:

i. Any Willow Bridge proprietary revenue management product cannot use any third-party nonpublic data, including in training its models or in the runtime operation;

ii. Any Willow Bridge proprietary revenue management product cannot pool pricing information across its different owners;

iii. Willow Bridge cannot license or use any third-party revenue management product that uses third-party nonpublic data to recommend or set prices;

iv. Willow Bridge cannot license or use any third-party revenue management product that pools information across Willow Bridge properties with different owners;

v. Willow Bridge cannot disclose, solicit, or use competitively sensitive information from competitors that can be used to set rental prices or generate pricing;

vi. Willow Bridge must cooperate in this civil antitrust proceeding (*United States et al.* v. *RealPage et al.*) with respect to the claims against other defendants;

vii. Willow Bridge must adopt a written antitrust compliance policy and designate a chief antitrust compliance officer who will train Willow Bridge employees on the policy, enforce the policy, and perform annual audits for compliance with the policy;

viii. Willow Bridge must allow the United States to inspect its documents and to interview its employees to ensure compliance with the Final Judgment;

ix. Willow Bridge must allow the United States to inspect documents regarding its proprietary revenue management product and review the relevant code and pseudocode;

x. If Willow Bridge uses a third-party revenue management product, Willow Bridge will be subject to the appointment of a monitor unless Willow Bridge obtains a certification that meets certain requirements, including affirming, among other things, that the product complies with all required limitations regarding use of competitors' competitively sensitive data in its runtime operation or model training; and

xi. Willow Bridge will also be subject to the appointment of a monitor if the Court finds that Willow Bridge has violated the terms of the proposed Final Judgment.

Under the terms of the Stipulation and Order, Willow Bridge must abide by and comply with the provisions of the proposed Final Judgment until it is entered by the Court or until the time for all appeals of any Court ruling declining entry of the proposed Final Judgment has expired.

The United States and Willow Bridge have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the APPA. Entry of the proposed Final Judgment will terminate this action with respect to the United States and Willow Bridge, except that the Court will retain jurisdiction to construe, modify, or enforce the provisions of the proposed Final Judgment and to punish violations thereof by Willow Bridge.

II. Description of Events Giving Rise to The Alleged Sherman Act Violations

Willow Bridge has been a user of commercial revenue management and property management products that RealPage licenses to landlords, and it has used RealPage's revenue management product to help set rental prices for the properties it manages and/or owns. RealPage currently licenses three revenue management products, including AIRM, to landlords. AIRM, which Willow Bridge has been using, leverages confidential, competitively sensitive data collected from competing landlords as a critical input to generate pricing recommendations for competing landlords. This data includes rental applications, executed new leases, renewal offers and acceptances, and occupancy estimates and projections. The data is pulled from property management software, such as RealPage's OneSite product or Yardi's Voyager, that Willow Bridge and other landlords use to collect and track rental payments, manage leases, property maintenance, accounting, and other property management functions.

When deciding where to live, renters often visit numerous properties that are owned or managed by competing landlords so that they can compare rental offerings and select their best housing option considering price and other terms. When competing landlords do not have access to each other's nonpublic data, or when their recommendations are not informed by competitors' nonpublic data, they are more likely to act independently and compete more vigorously on price and better leasing terms to secure new leases and renewals from renters. RealPage, however, provides landlords who use its revenue management products with pricing recommendations and pricing based on competitors' competitively sensitive data. Widespread adoption and use of RealPage's revenue management products leads to pricing decisions by competing landlords such as Willow Bridge that are based on recommendations coming from a common pricing model and powered by competitively sensitive, nonpublic data, harming the ability of renters to obtain a competitive price for their housing. The use of competitors' competitively sensitive data in this manner thus harms renters as well as the competitive process itself.

Willow Bridge, headquartered in Dallas, Texas, is one of the largest apartment managers in the United States. Willow Bridge manages over 240,000 units in the United States. As an apartment manager, Willow Bridge makes strategic and competitive decisions for the apartments it manages, including determination of new lease and renewal terms, such as rental price. As of the date of the Complaint, Willow Bridge licensed AIRM and YieldStar from RealPage. Per the licensing agreement, Willow Bridge relied on AIRM and YieldStar to recommend rental prices for its units, which is informed by competitively sensitive data provided by Willow Bridge's competitors. Willow Bridge also provided its competitively sensitive data to RealPage, to be used to inform the rental prices that RealPage's software recommends to Willow Bridge's competitors. Further, Willow Bridge has agreed with RealPage to use AIRM and YieldStar as RealPage designed them. It reviews AIRM and YieldStar floor plan price recommendations daily and uses these revenue management products to set scheduled floor plan rents and even unit-level prices.

In summary, the Complaint alleges that Willow Bridge unlawfully shared its competitively sensitive information for use in pricing by competing landlords that also license RealPage's revenue management products, that Willow Bridge benefited from using competitors' sensitive information for its own pricing, and that Willow Bridge agreed to align its pricing with that of its competitors by using RealPage's revenue management products in the way the products were designed and with the data it uses. Willow Bridge

uses RealPage's revenue management products to inform its setting of rental prices and discounts—such as concessions of a free month of rent—and to make other competitive and strategic decisions relating to rental prices and terms.

III. Explanation of the Proposed Final Judgment

The relief required by the proposed Final Judgment will remedy the loss of competition in the conventional multifamily rental housing market [13] alleged in the Complaint by precluding Willow Bridge from sharing competitively sensitive, nonpublic information, directly or indirectly, with competing landlords and from forming agreements, directly or indirectly, to align prices with its competitors. The terms described below are designed to ensure that Willow Bridge ends its anticompetitive conduct and to prevent Willow Bridge from engaging in the same or similar conduct in the future.

A. Willow Bridge's Use of Proprietary Revenue Management Product(s)

The proposed Final Judgment requires Willow Bridge to limit the type of data it uses in its proprietary software, RaMI. Paragraph IV.A of the proposed Final Judgment precludes Willow Bridge's proprietary revenue management product from using other landlords' competitively sensitive data to set rental prices. Paragraph IV.A also prevents Willow Bridge from pooling different property owners' competitively sensitive data even if they are Willow Bridge clients. This prohibition ensures that property owners who compete in the multifamily rental housing industry are not using their relationship with Willow Bridge to gain access to each other's data.

Paragraph IV.B prohibits Willow Bridge from training its revenue management product's models using certain competitively sensitive data from other landlords. A model is a set of rules or instructions that software relies on to calculate a defined output which, in this case, is a recommended rental price for a floorplan or unit. Models are trained using data to define and refine the rules or instructions by which it operates. Paragraph IV.B restricts Willow Bridge from pooling or combining data on rental pricing, concessions, discounts, occupancy rates or capacity, or other rental pricing terms from Willow Bridge properties for different property owners. The restriction on pooling competitors' data thus also prohibits Willow Bridge from training its software models using pricing and occupancy data from competing property owners, therefore reducing concerns about competitors benefiting from each other's competitively sensitive data to plan their pricing.

Paragraph IV.C prohibits Willow Bridge's proprietary revenue management product from disclosing any of Willow Bridge's property data to any other property management company or property owner.

Paragraph IV.D allows Willow Bridge to license its proprietary product to third parties, as long as the product complies with the restrictions described in Paragraphs V.A.1–2 regarding use of competitively sensitive data and product features. This term could increase competition in revenue management software for multifamily housing.

B. Restrictions Concerning Use of Third-Party Revenue Management Products

The decree prohibits Willow Bridge from using third-party revenue management products unless certain conditions are met. If Willow Bridge decides to use a third-party revenue management product, Paragraph V.A requires Willow Bridge to select a product that does not (1) use competitively sensitive data from other landlords to set rental prices or generate rental pricing recommendations, (2) use data from different Willow Bridge owners to set rental prices or generate rental pricing recommendations, (3) disclose data from a Willow Bridge property to a rival property management company or property owner, (4) pool or combine data from different owners, or (5) contain or use a pricing algorithm that has been trained using non-Willow Bridge data. Paragraph V.A also prohibits Willow Bridge from selecting and using a third-party revenue management product that has rental floors or limits rental pricing recommendation decreases based on competing properties' rental prices.

The proposed Final Judgment includes an additional restriction on Willow Bridge's ability to make agreements with non-clients regarding revenue management products. Specifically, Paragraph V.A.3 prohibits Willow Bridge from agreeing with a non-client property owner or a competing property management company to use a particular revenue management product. This provision reduces the risk of competitors agreeing with each other to use the same revenue management product across their clients.

If Willow Bridge chooses to use a third-party revenue management product in the future, Paragraph V.C requires Willow Bridge to notify the United States 30 days prior to switching to that product. Paragraph V.E requires Willow Bridge to submit to the United States a certification from the third-party revenue management product vendor that the product complies with the requirements in Paragraph V.A of the proposed Final Judgment.

C. Other Prohibited Conduct

In addition to restrictions and conditions on Willow Bridge's use of revenue management products, the proposed Final Judgment also limits Willow Bridge's ability to communicate with competitors regarding certain competitively sensitive information for the purpose of setting prices. Paragraph VI.A prohibits Willow Bridge from disclosing, soliciting, or using any competitively sensitive data from competitors as part of setting rental prices or generating rental price recommendations, except for the property owner of that particular property. Paragraph VI.A clarifies that the restrictions include any data obtained through any form of communication, including call arounds or market surveys, meetings, calls, text messages, emails, or shared documents.

Paragraph VI.C prevents Willow Bridge from using any competitively sensitive data belonging to other landlords, whether Willow Bridge derived that non-Willow Bridge data from a revenue management product or obtained it from direct communications with other landlords. Willow Bridge must also identify to the United States the existence and location of any such data. This does not apply to any data for Willow Bridge properties maintained in OneSite.

In addition, the proposed Final Judgment prohibits Willow Bridge from attending or participating in RealPage Meetings, which include steering committees, RealPage subcommittees, RealPage user groups, and RealPage Idea Exchange. Paragraph VI.D. provides that if Willow Bridge attends a RealPage Meeting, it must notify the United States within 30 days and provide a description of the content and any documents shown during the meeting. Additionally, Willow Bridge must produce to the United States any chats or documents associated with the meeting.

[13] As stated in the Complaint, the conventional multifamily rental housing market includes apartments available to the general public in properties that have five or more living units. It does not include student housing, affordable housing, age-restricted or senior housing, or military housing. (Am. Compl. ¶ 183).

D. Cooperation

Under the terms of the proposed Final Judgment, and subject to reaching settlement with certain States, Willow Bridge must cooperate with the United States relating to the United States' claims against the remaining defendants included in the Complaint. This required cooperation includes voluntary interviews with up to 15 Willow Bridge employees for up to 60 hours. In addition, Willow Bridge must provide cooperation to the United States by making witnesses available before trial, providing testimony, proffering evidence, and producing documents and other information.

E. Compliance Terms

Pursuant to Paragraph X.A, Willow Bridge must provide the United States with access to Willow Bridge's books, records, data, and documents, including communications with other property managers, to enable the United States to assess Willow Bridge's compliance with the terms of the Final Judgment. Willow Bridge must also permit the United States to interview Willow Bridge's officers, employees, or agents relating to any matters contained in this Final Judgment. Willow Bridge must also provide the United States with documents describing how Willow Bridge's proprietary revenue management product is trained and how it determines prices for properties it manages, as well as changes to these processes. Willow Bridge must also allow the United States to inspect Willow Bridge's software code and pseudocode of that software for independent verification.

Additionally, Paragraph VII.A requires Willow Bridge's chief antitrust compliance officer to audit Willow Bridge's operations. The annual audits must, at a minimum, include employees in Willow Bridge's revenue management group and a randomly selected group of employees who manage property operations. Paragraph VII.B requires Willow Bridge to submit an annual certification from its General Counsel that Willow Bridge has established and maintained the annual antitrust compliance policy and training, that Willow Bridge identified the audited individuals to the United States, and that any revenue management product used by Willow Bridge continues to satisfy the requirements in the proposed Final Judgment.

Finally, VII.B.2 requires Willow Bridge employees engaged in or overseeing Defendant's revenue management of multifamily rental properties or overseeing multiple multifamily rental properties to attest, under penalty of perjury, that they have not (i) agreed with any non-Willow Bridge landlord to use a particular revenue management product; (ii) disclosed, solicited or used non-Willow Bridge competitively sensitive data as part of setting or generating pricing information; or (iii) attended RealPage meetings.

F. Compliance Monitor

The proposal Final Judgment requires that Willow Bridge be subject to an appointed compliance monitor in certain circumstances.

First, Paragraph IX.B requires that a monitor be appointed if the Court determines that Willow Bridge has violated the proposed Final Judgment.

Second, Paragraph IX.B requires that Willow Bridge be subject to a monitor unless Willow Bridge obtains a certification, as required by Paragraph V.E, for a non-RealPage revenue management product. The product's vendor must certify that the product does not use competitors' competitively sensitive data to determine rental prices and satisfies other software requirements.

In the event a monitor is appointed, which selection shall be in the United States' sole discretion, the monitor will assess Willow Bridge's compliance with the Final Judgment, in particular, its use of a revenue management product and its communications with other landlords. Paragraph IX.D provides the monitor with authority to investigate Willow Bridge's compliance with the Final Judgment, including by selecting up to 15 Willow Bridge employees to interview and giving the monitor access to review those employees' files. Further, per Paragraph IX.E, the monitor will have the authority to take steps necessary to ensure compliance with the Final Judgment. These steps may include interviewing Willow Bridge employees and collecting Willow Bridge documents. The monitor will also provide an annual report to the United States setting forth Willow Bridge's efforts to comply with its obligations under the Final Judgment.

If appointed, the monitor will serve at Willow Bridge's expense, on such terms and conditions as the United States approves in its sole discretion. Willow Bridge will be required to assist the monitor in fulfilling his or her obligations. The monitor will serve for the remainder of the term of the Final Judgment or until Willow Bridge obtains the certification required by the proposed Final Judgment, as described above.

G. Other Provisions

The proposed Final Judgment also contains provisions designed to promote compliance with and make enforcement of the Final Judgment as effective as possible. Paragraph XIII.A provides that the United States retains and reserves all rights to enforce the Final Judgment, including the right to seek an order of contempt from the Court. Under the terms of this paragraph, Willow Bridge has agreed that in any civil contempt action, any motion to show cause, or any similar action brought by the United States regarding an alleged violation of the Final Judgment, the United States may establish the violation and the appropriateness of any remedy by a preponderance of the evidence and that Willow Bridge has waived any argument that a different standard of proof should apply. This provision aligns the standard for compliance with the Final Judgment with the standard of proof that applies to the underlying offense addressed by the Final Judgment.

Paragraph XIII.B provides additional clarification regarding the interpretation of the provisions of the proposed Final Judgment. Pursuant to Paragraph XIII.B of the proposed Final Judgment, Willow Bridge agrees that it will abide by the proposed Final Judgment and that it may be held in contempt of the Court for failing to comply with any provision of the proposed Final Judgment that is stated specifically and in reasonable detail, as interpreted in light of its procompetitive purpose.

Paragraph XIII.C provides that if the Court finds in an enforcement proceeding that Willow Bridge has violated the Final Judgment, the United States may apply to the Court for an extension of the Final Judgment, together with such other relief as may be appropriate. In addition, to compensate American taxpayers for any costs associated with investigating and enforcing violations of the Final Judgment, Paragraph XIII.C provides that in any successful effort by the United States to enforce the Final Judgment against Willow Bridge, whether litigated or resolved before litigation, Willow Bridge must reimburse the United States for attorneys' fees, experts' fees, and other costs incurred in connection with that effort to enforce this Final Judgment, including the investigation of the potential violation.

Paragraph XIII.D of the proposed Final Judgment states that the United States may file an action against Willow Bridge for violating the Final Judgment for up to four years after the Final Judgment has expired or been

terminated. This provision is meant to address circumstances such as when evidence that a violation of the Final Judgment occurred during the term of the Final Judgment is not discovered until after the Final Judgment has expired or been terminated, or when there is not sufficient time for the United States to complete an investigation of an alleged violation until after the Final Judgment has expired or been terminated. This provision therefore makes clear that, for four years after the Final Judgment has expired or been terminated, the United States may still challenge a violation that occurred during the term of the Final Judgment.

Finally, Section XIV of the proposed Final Judgment provides that the Final Judgment will expire five years from the date of its entry, except that after three years from that date, the Final Judgment may be terminated upon notice by the United States to the Court and to Willow Bridge that continuation of the Final Judgment is no longer necessary or in the public interest.

IV. Remedies Available to Potential Private Plaintiffs

Section 4 of the Clayton Act, 15 U.S.C. 15, provides that any person who has been injured as a result of conduct prohibited by the antitrust laws may bring suit in federal court to recover three times the damages the person has suffered, as well as costs and reasonable attorneys' fees. Entry of the proposed Final Judgment neither impairs nor assists the bringing of any private antitrust damage action. Under the provisions of Section 5(a) of the Clayton Act, 15 U.S.C. 16(a), the proposed Final Judgment has no prima facie effect in any subsequent private lawsuit that may be brought against Willow Bridge.

V. Procedures Available for Modification of the Proposed Final Judgment

The United States and Willow Bridge have stipulated that the proposed Final Judgment may be entered by the Court after compliance with the provisions of the APPA, provided that the United States has not withdrawn its consent. The APPA conditions entry upon the Court's determination that the proposed Final Judgment is in the public interest.

The APPA provides a period of at least 60 days preceding the effective date of the proposed Final Judgment within which any person may submit to the United States written comments regarding the proposed Final Judgment. Any person who wishes to comment should do so within 60 days of the date of publication of this Competitive Impact Statement in the **Federal Register**, or within 60 days of the first date of publication in a newspaper of the summary of this Competitive Impact Statement, whichever is later. All comments received during this period will be considered by the U.S. Department of Justice, which remains free to withdraw its consent to the proposed Final Judgment at any time before the Court's entry of the Final Judgment. The comments and the responses of the United States will be filed with the Court. In addition, the comments and the United States' responses will be published in the **Federal Register** unless the Court agrees that the United States instead may publish them on the U.S. Department of Justice, Antitrust Division's internet website.

Written comments should be submitted in English to: Danielle Hauck, Acting Chief, Technology and Digital Platforms Section, Antitrust Division, United States Department of Justice, 450 Fifth St. NW, Suite 7100, Washington, DC 20530.

The proposed Final Judgment provides that the Court retains jurisdiction over this action, and the parties may apply to the Court for any order necessary or appropriate for the modification, interpretation, or enforcement of the Final Judgment.

VI. Alternatives to the Proposed Final Judgment

As an alternative to the proposed Final Judgment, the United States considered a full trial on the merits against Willow Bridge. The United States could have continued its litigation against Willow Bridge and brought the case to trial, seeking relief including an injunction against Willow Bridge's sharing of its competitively sensitive, nonpublic data with RealPage and other landlords, an injunction against Willow Bridge using AIRM, YieldStar, or similar revenue management products that use competing properties' nonpublic data to recommend prices, and an injunction preventing any communication with competitors that leads to alignment of prices. Under the circumstances present here, however, the United States concludes that entry of the proposed Final Judgment is in the public interest insofar as it avoids the time, expense, and uncertainty of a full trial on the merits.

VII. Standard of Review Under the Appa for the Proposed Final Judgment

Under the Clayton Act and APPA, proposed Final Judgments, or ''consent decrees,'' in antitrust cases brought by the United States are subject to a 60-day comment period, after which the Court shall determine whether entry of the proposed Final Judgment ''is in the public interest.'' 15 U.S.C. 16(e)(1). In making that determination, the Court, in accordance with the statute as amended in 2004, is required to consider:

> (A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and
>
> (B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1)(A) & (B). In considering these statutory factors, the Court's inquiry is necessarily a limited one as the government is entitled to ''broad discretion to settle with the defendant within the reaches of the public interest.'' *United States* v. *Microsoft Corp.,* 56 F.3d 1448, 1461 (D.C. Cir. 1995); *United States* v. *US Airways Grp., Inc.,* 38 F. Supp. 3d 69, 75 (D.D.C. 2014) (explaining that the ''court's inquiry is limited'' in Tunney Act settlements); *United States* v. *InBev N.V./S.A.,* No. 08–1965 (JR), 2009 U.S. Dist. LEXIS 84787, at *3 (D.D.C. Aug. 11, 2009) (noting that a court's review of a proposed Final Judgment is limited and only inquires ''into whether the government's determination that the proposed remedies will cure the antitrust violations alleged in the complaint was reasonable, and whether the mechanisms to enforce the final judgment are clear and manageable''); *United States* v. *Charleston Area Med. Ctr., Inc.,* No. CV 2:16–3664, 2016 WL 6156172, at *2 (S.D.W. Va. Oct. 21, 2016) (explaining that in evaluating whether the proposed final judgment is in the public interest, the inquiry is ''a narrow one''); *United States* v. *Mountain Health Care,* 1:02–CV–288–T, 2003 WL 22359598, at *7 (W.D.N.C. 2003) (''[W]ith respect to the adequacy of the relief secured by the decree, a court may not 'engage in an unrestricted evaluation of what relief would best serve the public.'''') *citing United States* v. *BNS Inc.,* 858 F.2d 456, 462–63 (9th Cir. 1988)).

As the U.S. Court of Appeals for the D.C. Circuit has held, under the APPA

a court considers, among other things, the relationship between the remedy secured and the specific allegations in the government's Complaint, whether the proposed Final Judgment is sufficiently clear, whether its enforcement mechanisms are sufficient, and whether it may positively harm third parties. *See Microsoft,* 56 F.3d at 1458–62; *United States* v. *Math Works,* No. 02–888–A, 2003 WL 1922140, *17 (E.D. Va. 2003). With respect to the adequacy of the relief secured by the proposed Final Judgment, a court may not ''make de novo determination of facts and issues.'' *United States* v. *W. Elec. Co.,* 993 F.2d 1572, 1577 (D.C. Cir. 1993) (quotation marks omitted); *see also Microsoft,* 56 F.3d at 1460–62; *United States* v. *Alcoa, Inc.,* 152 F. Supp. 2d 37, 40 (D.D.C. 2001); *United States* v. *Enova Corp.,* 107 F. Supp. 2d 10, 16 (D.D.C. 2000); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *3. Instead, ''[t]he balancing of competing social and political interests affected by a proposed antitrust decree must be left, in the first instance, to the discretion of the Attorney General.'' *W. Elec. Co.,* 993 F.2d at 1577 (quotation marks omitted). ''The court should also bear in mind the *flexibility* of the public interest inquiry: the court's function is not to determine whether the resulting array of rights and liabilities is the one that will *best* serve society, but only to confirm that the resulting settlement is within the *reaches* of the public interest.'' *Microsoft,* 56 F.3d at 1460 (quotation marks omitted); *see also United States* v. *Deutsche Telekom AG,* No. 19–2232 (TJK), 2020 WL 1873555, at *7 (D.D.C. Apr. 14, 2020); *Math Works,* 2003 WL 1922140 at *18; *Mountain Health Care,* 2003 WL 22359598, at *7. More demanding requirements would ''have enormous practical consequences for the government's ability to negotiate future settlements,'' contrary to congressional intent. *Microsoft,* 56 F.3d at 1456. ''The Tunney Act was not intended to create a disincentive to the use of the consent decree.'' *Id.*

The United States' predictions about the efficacy of the remedy are to be afforded deference by the Court. *See, e.g., Microsoft,* 56 F.3d at 1461 (recognizing courts should give ''due respect to the Justice Department's . . . view of the nature of its case''); *United States* v. *Iron Mountain, Inc.,* 217 F. Supp. 3d 146, 152–53 (D.D.C. 2016) (''In evaluating objections to settlement agreements under the Tunney Act, a court must be mindful that [t]he government need not prove that the settlements will perfectly remedy the alleged antitrust harms[;] it need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.'' (internal citations omitted)); *United States* v. *Republic Servs., Inc.,* 723 F. Supp. 2d 157, 160 (D.D.C. 2010) (noting ''the deferential review to which the government's proposed remedy is accorded''); *United States* v. *Archer-Daniels-Midland Co.,* 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (''A district court must accord due respect to the government's prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case.''). The ultimate question is whether ''the remedies [obtained by the Final Judgment are] so inconsonant with the allegations charged as to fall outside of the 'reaches of the public interest.' '' *Microsoft,* 56 F.3d at 1461 (*quoting W. Elec. Co.,* 900 F.2d at 309).

Moreover, the Court's role under the APPA is limited to reviewing the remedy in relationship to the violations that the United States has alleged in its Complaint, and does not authorize the Court to ''construct [its] own hypothetical case and then evaluate the decree against that case.'' *Microsoft,* 56 F.3d at 1459; *see also US Airways,* 38 F. Supp. 3d at 75 (noting that the court must simply determine whether there is a factual foundation for the government's decisions such that its conclusions regarding the proposed settlements are reasonable); *InBev,* 2009 U.S. Dist. LEXIS 84787, at *20 (''[T]he 'public interest' is not to be measured by comparing the violations alleged in the complaint against those the court believes could have, or even should have, been alleged''); *Math Works,* 2003 WL 1922140 at *18; *Mountain Health Care,* 2003 WL 22359598, at *8. Because the ''court's authority to review the decree depends entirely on the government's exercising its prosecutorial discretion by bringing a case in the first place,'' it follows that ''the court is only authorized to review the decree itself,'' and not to ''effectively redraft the complaint'' to inquire into other matters that the United States did not pursue. *Microsoft,* 56 F.3d at 1459–60.

In its 2004 amendments to the APPA, Congress made clear its intent to preserve the practical benefits of using judgments proposed by the United States in antitrust enforcement, Pub. L. 108–237 § 221, and added the unambiguous instruction that ''[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.'' 15 U.S.C. 16(e)(2); *see also US Airways,* 38 F. Supp. 3d at 76 (indicating that a court is not required to hold an evidentiary hearing or to permit intervenors as part of its review under the Tunney Act). This language explicitly wrote into the statute what Congress intended when it first enacted the Tunney Act in 1974. As Senator Tunney explained: ''[t]he court is nowhere compelled to go to trial or to engage in extended proceedings which might have the effect of vitiating the benefits of prompt and less costly settlement through the consent decree process.'' 119 Cong. Rec. 24,598 (1973) (statement of Sen. Tunney). ''A court can make its public interest determination based on the competitive impact statement and response to public comments alone.'' *US Airways,* 38 F. Supp. 3d at 76 (citing *Enova Corp.,* 107 F. Supp. 2d at 17).

VIII. Determinative Documents

There are no determinative materials or documents within the meaning of the APPA that were considered by the United States in formulating the proposed Final Judgment.

Dated: July 6, 2026
Respectfully submitted,
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Part IV

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 405, 406, et al.

Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 400, 405, 406, 407, 410, 414, 415, 417, 422, 423, 424, 425, 427, 428, 512

[CMS–1848–P]

RIN 0938–AV82

Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule addresses: changes to the physician fee schedule (PFS); other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, relative value of services, and changes in the statute; codification of establishment of new policies for: the Medicare Prescription Drug Inflation Rebate Program under the Inflation Reduction Act of 2022; the Ambulatory Specialty Model; updates to drugs and biological products paid under Part B; Medicare Shared Savings Program requirements; updates to the Quality Payment Program; updates to policies for Rural Health Clinics and Federally Qualified Health Centers; update to the Ambulance Fee Schedule regulations; codification of the Inflation Reduction Act and Consolidated Appropriations Act, 2026 provisions; updates to Clinical Laboratory Fee Schedule regulations; updates to the Medicare Promoting Interoperability Program.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by September 14, 2026.

ADDRESSES: In commenting, please refer to file code CMS–1848–P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to *https://www.regulations.gov/docket/CMS-2026-2377*. Follow the ''Submit a comment'' instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1848–P, P.O. Box 8016, Baltimore, MD 21244–8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1848–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for any issues not identified below. Please indicate the specific issue in the subject line of the email. For all questions related to reporting a service on a claim, please contact your Medicare Administrative Contractor.

Michael Soracoe, Morgan Kitzmiller, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to practice expense, work RVUs, conversion factor, and PFS specialty-specific impacts.

Hannah Ahn, Allison Bramlett, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to potentially misvalued services under the PFS.

Mikayla Murphy, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to direct supervision using two-way audio/video communication technology, telehealth, and other services involving communications technology.

Maya Peterson or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to E/M overlap between stand-alone visits and global periods, and E/M visit complexity add-on code (MOD1 and MOD2).

Terry Simananda, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to smoking and tobacco use cessation, screening, brief intervention, and referral to treatment, psychiatric collaborative care model, and shared medical appointments.

Sarah Leipnik, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to global surgery payment accuracy.

Pamela West, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to comprehensive outpatient rehabilitation facility (CORF) services and KX modifier thresholds.

Zehra Hussain, or *MedicarePhysicianFeeSchedule@cms.hhs.gov*, for issues related to payment of skin substitutes.

Laura Kennedy, (410) 786–3377, Rebecca Ray, (667) 414–0879, and Jae Ryu, (667) 414–0765 for issues related to Drugs and Biological Products Paid Under Medicare Part B.

Lisa Parker, (410) 786–4949, or *FQHC-PPS@cms.hhs.gov*, Michele Franklin, (410) 786–9226, or *RHC@cms.hhs.gov*, and Patrick Sartini, (410) 786–9252 for issues related to FQHC and RHC payments.

Patrick Sartini, (410) 786–9252, or *CLFS_Inquiries@cms.hhs.gov* for issues related to Clinical Laboratory Fee Schedule.

Sabrina Ahmed, (410) 786–7499, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Medicare Shared Savings Program (Shared Savings Program) quality performance standard and other quality reporting requirements.

Kimberly Spalding Bush, (410) 786–3232, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to the Shared Savings Program certified electronic health record technology (CEHRT) use requirements.

Janae James, (410) 786–0801, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to Shared Savings Program beneficiary assignment and financial methodology.

Lucy Bertocci, (443) 681–0762, or *SharedSavingsProgram@cms.hhs.gov*, for issues related to reducing or eliminating Part B cost sharing, prepaid shared savings, beneficiary notifications, advance investment payments or identifying ACOs experienced with performance-based risk.

Elisabeth Daniel, (667) 290–8793, for issues related to the Medicare Prescription Drug Inflation Rebate Program.

Benjamin Picillo or Genevieve Kehoe, *AmbulatorySpecialtyModel@cms.hhs.gov*, or 1–844–711–2664 (Option 4) for issues related to the Ambulatory Specialty Model.

Amy Gruber, (410) 786–1542, for issues related to Ambulance Fee Schedule.

Kati Moore, (410) 786–5471, for inquiries related to the Merit-based Incentive Payment System (MIPS) track of the Quality Payment Program (QPP).

Trevey Davis, (410) 786–6600, for inquiries related to the Advanced

Alternative Payment Models (APMs) track of QPP.

Jessica Warren, (410) 786–7519, and Lisa Marie Gomez, (410) 786–1175, for inquiries related to the Medicare Promoting Interoperability Program.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/*.

Addenda Available Only Through the internet on the CMS website: The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2027 PFS final rule, refer to item CMS–1848–P. Readers with questions related to accessing any of the Addenda or other supporting documents referenced in this proposed rule and posted on the CMS website identified above should contact *MedicarePhysicianFeeSchedule@cms.hhs.gov*.

CPT (Current Procedural Terminology) Copyright Notice: Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2020 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary

A. Purpose

This major annual rule proposes to revise payment policies under the Medicare PFS and makes other policy changes, including proposals to implement certain provisions of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4, March 15, 2025), Further Continuing Appropriations and Other Extensions Act of 2024 (Pub. L. 118–22, November 17, 2023), Consolidated Appropriations Act, 2023 (Pub. L. 117–328, December 29, 2022), Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, August 16, 2022), Consolidated Appropriations Act, 2022 (Pub. L. 117–103, March 15, 2022), Consolidated Appropriations Act, 2021 (CAA, 2021) (Pub. L. 116–260, December 27, 2020), Bipartisan Budget Act of 2018 (BBA of 2018) (Pub. L. 115–123, February 9, 2018), the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act) (Pub. L. 115–271, October 24, 2018) and Consolidated Appropriations Act, 2026 (Pub. L. 119–75, February 3, 2026), related to Medicare Part B payment. In addition, this proposed rule includes provisions regarding other Medicare payment provisions described in sections III. and IV. of this proposed rule.

This proposed rule updates policies for the Medicare Prescription Drug Inflation Rebate Program codified at 42 CFR parts 427 and 428 consistent with sections 1847A(i) and 1860D–14B of the Social Security Act (the Act). For the Medicare Part B Drug Inflation Rebate Program, this rule describes the identification of the Consumer Price Index for all Urban Consumers (CPI–U) for the payment amount benchmark quarter and the rebate period in certain instances when CPI–U survey data are unavailable and the calculation of the Part B rebate amount in such instances; proposes to clarify the definition of ''first marketed date''; and proposes to clarify that certain skin substitutes would not be excluded from the definition of a Part B rebatable drug. For the Medicare Part D Drug Inflation Rebate Program, this rule describes the identification of the CPI–U for the payment amount benchmark period and applicable period in certain instances when CPI–U survey data are unavailable and the calculation of the Part D rebate amount in such instances; proposes a modification to the methodology finalized in the CY 2026 PFS final rule to account for 340B-eligible units for AIDS Drug Assistance Program (ADAP) enrollees for the applicable period beginning October 1, 2025; and proposes to require Medicare providers and suppliers that are 340B covered entities to submit Part D 340B claims data to the Medicare Part D Claims Data 340B Repository beginning in 2027.

This proposed rule proposes to modify policies for the Shared Savings Program, which is a voluntary program that started in 2012. The program allows groups of providers and suppliers to form or participate in Accountable Care Organizations (ACOs), and to be held accountable for the quality and total cost of care for an assigned population of Medicare fee-for-service (FFS) beneficiaries.

B. Summary of the Key Provisions

Section 1848 of the Act requires us to establish payments under the PFS, based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The statute requires that RVUs be established for three categories of resources: work, practice expense (PE), and malpractice (MP) expense. In addition, the statute requires that each year we establish, by regulation, the payment amounts for physicians' services paid under the PFS, including geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas.

In this major proposed rule, we are proposing RVUs for CY 2027 for the PFS to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. This proposed rule also includes discussions and provisions regarding several other Medicare Part B payment policies, and other policies regarding programs administered by CMS.

Specifically, this proposed rule addresses:

- Background (section II.A.)
- Determination of PE RVUs (section II.B.)
- Payment for Medicare Telehealth Services (section II.C.)
- Valuation of Specific Codes, Including Potentially Misvalued Codes (PMVC) (section II.D.)
- Redesigning Primary Care to Make America Healthy Again (section II.E.)
- Comprehensive Outpatient Rehabilitation Facility (CORF) Services and KX Modifier Thresholds (section II.F.)
- Supporting Beneficiaries Planning for Future Medical Decisions (section II.G.)

- Current Procedural Terminology (CPT) Request for Information (RFI) (section II.H.)
- Drugs and Biological Products Paid Under Medicare Part B: Discarded Drugs (section III.A.)
- Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) (section III.B.)
- Clinical Laboratory Fee Schedule (CLFS): CAA, 2026 (section III.C.)
- Proposed Changes to the Ambulatory Specialty Model (ASM) (section III.D.)
- Limiting Medicare Coverage of Certain Individuals (section III.E.)
- Medicare Prescription Drug Inflation Rebate Program (section III.F.)
- Medicare Shared Savings Program (section III.G.)
- Changes to the Regulations Associated with the Ambulance Fee Schedule (section III.H.)
- Request for Information (RFI) on Duplicate Laboratory Testing, Imaging, and Result Sharing and Interoperability (section III.I.)
- CY2027 Modifications to the Quality Payment Program Reporting and Data Submission (section IV.)
- Collection of Information Requirements (section V.)
- Response to Comments (section VI.)
- Regulatory Impact Analysis (section VII.)

C. Summary of Costs and Benefits

Based on our estimates, the Office of Information and Regulatory Affairs in the Office of Management and Budget has determined that this proposed rule is economically significant under section 3(f)(1) of Executive Order 12866. As required by section 1848(d)(1)(A) of the Act, beginning in 2026, there are two separate conversion factors (CFs): one for items and services furnished by a qualifying APM participant (QP) as defined in section 1833(z)(2) of the Act and 42 CFR 414.1305 (referred to as the qualifying APM conversion factor) and another for items and services furnished by clinicians who are not QPs (referred to as the nonqualifying APM conversion factor), equal to the respective conversion factor for the previous year multiplied by the update established under section 1848(d)(20) of the Act for such respective conversion factor for such year. Under these provisions, the 2027 qualifying APM conversion factor represents a projected decrease of $0.40 (-1.19 percent) from the current conversion factor of $33.4009. Similarly, the 2027 nonqualifying APM conversion factor represents a projected decrease of $0.56 (−1.68 percent) from the current conversion factor of $33.5875.

For a detailed discussion of the economic impacts, see section VII., Regulatory Impact Analysis, of this proposed rule.

II. Provisions of the Rule for the PFS

A. Background

In accordance with section 1848 of the Social Security Act (the Act), CMS has paid for physicians' services under the Medicare physician fee schedule (PFS) since January 1, 1992. The PFS relies on national relative values that are established for work, practice expense (PE), and malpractice (MP), which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the relative value units (RVUs) into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101–239, December 19, 1989), and the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) (Pub. L. 101–508, November 5, 1990). The final rule published in the November 25, 1991 **Federal Register** (56 FR 59502) set forth the first fee schedule used for Medicare payment for physicians' services.

We note that throughout this proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for the services they furnish to Medicare beneficiaries.

B. Determination of PE RVUs

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice (MP) expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical equipment. Indirect expenses include administrative labor, office expenses, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service specific PE RVUs. We refer readers to the CY 2010 Physician Fee Schedule (PFS) final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC) and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the 5-year review of work RVUs under the PFS and proposed changes to the PE methodology in the CY 2007 PFS proposed rule (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour (PE/HR) worked to develop the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the PE/HR by specialty obtained from the AMA's Socioeconomic Monitoring System (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of physicians and NPPs paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We have stated that we believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology or how the PE/HR data are used. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for

some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs nor independent labs participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the Medicare Economic Index (MEI) to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS based PE/HR. We use crosswalks for specialties that did not participate in the PPIS. These crosswalks have been generally established through notice and comment rulemaking and are available in the file titled ''CY 2027 PFS proposed rule PE/HR'' on the CMS website under downloads for the CY 2027 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Under current policy, we allocate the indirect costs at the code level based on the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporate the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. That is, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represent 25 percent of total costs for the specialties that furnish the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVU of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, under current policy, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had a work RVU of 4.00 and the clinical labor portion of the direct PE RVU was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Then, we incorporate the specialty specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

In the CY 2007 PFS final rule with comment period, we implemented the ''bottom up'' methodology for the development of PE RVUs (71 FR 69630–69643). We finalized the use of the work RVU or the clinical labor portion of the direct PE RVU, whichever is greater, to allocate indirect costs. We also finalized a modified formula for a global service (that is, a service with a professional component (PC) and a technical component (TC)) to utilize both the work RVU and the clinical labor PE RVU to allocate indirect costs. As noted in the CY 2007 PFS final rule with comment period, we do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVU and the clinical labor PE RVU. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.

In recent years, as we have conducted analyses aimed at improving the accuracy of payment under the PFS, we have re-examined this longstanding policy that effectively allocates a larger share of indirect PE RVUs to services that can be reported using technical, professional, and global components than to those that cannot. We refer the reader to a report by RAND Corporation, under contract with CMS, which addresses several approaches to improving the accuracy of other PFS

services relative to services that have a professional and technical component. This report is available at *https://www.rand.org/pubs/research_reports/RRA4720-2.html*.

This longstanding policy inadvertently advantages services that can be reported using technical, professional, and global components, referred to as ''triplet services'' in the report by RAND Corporation, because indirect PE RVUs are allocated on the sum, whereas services that can only be reported as a global service, referred to as ''non-triplet services'' in the report, depend on the maximum (rather than sum) of clinical labor PE RVUs and physician work RVUs. This is an unintended advantage of the arithmetic required for the global component RVUs to equal the sum of the PC and TC RVUs. We believe it would be more accurate than the current PE methodology to use the same allocation methodology for all PFS services. Therefore, we are proposing to allocate indirect PE using both the work RVU and the clinical labor RVU for all services, with the exception of codes with 010- and 090-day global periods, instead of just applying that methodology to those services that can be reported using technical, professional, and global components (typically diagnostic and imaging services). In the description of the calculation of the PE methodology below, we indicate the portion of the methodology that would be calculated differently under this proposal.

(3) Facility and Non-Facility Costs

For procedures that can be furnished in a physician's office, as well as in a facility setting, where Medicare makes a separate payment to the facility for its costs in furnishing a service, we establish two PE RVUs: facility and non-facility. The methodology for calculating PE RVUs is generally the same for both the facility and non-facility RVUs but is applied independently to yield two separate PE RVUs. In calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service. For this reason, the facility PE RVUs are generally lower than the non-facility PE RVUs. In the CY 2026 PFS final rule (90 FR 49292–49296), we finalized a modification in the allocation of indirect PE to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs beginning in CY 2026.

(4) Services With Technical Components and Professional Components

Diagnostic services are generally comprised of two components: a professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different healthcare providers, or they may be furnished together as a global service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this, we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global direct PE RVUs.)

(5) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we direct readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746). We also direct readers to the file titled ''Calculation of PE RVUs under Methodology for Selected Codes'' which is available on our website under downloads for the CY 2027 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. This file contains a table that illustrates the calculation of PE RVUs as described in this proposed rule for individual codes.

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/non-facility place of service level, and the specialty specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. We set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the projected aggregate work RVUs.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, use the CF to calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling adjustment to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs as long as the same CF is used in Step 4 and Step 5. Different CFs would result in different direct PE scaling adjustments, but this has no effect on the final direct cost PE RVUs since changes in the CFs and the associated direct scaling adjustments offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

We generally use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. Codes with low Medicare service volume require special attention since billing or enrollment irregularities for a given year can result in significant changes in specialty mix assignment. We finalized a policy in the CY 2018 PFS final rule (82 FR 52982 through 52983) to use the most recent year of claims data to determine which codes are low volume for the coming year (those that have fewer than 100 allowed services in the Medicare claims data). For codes that fall into this category, instead of assigning a specialty mix based on the specialties of the practitioners reporting the services in the claims data, we use the expected specialty that we identify on a list developed based on medical review and input from expert interested parties. We display this list of expected specialty assignments as part of the annual set of data files we make available as part of notice and comment rulemaking and consider recommendations from the RUC and other interested parties on changes to this list annually. Services for which the

specialty is automatically assigned based on previously finalized policies under our established methodology (for example, ''always therapy'' services) are unaffected by the list of expected specialty assignments. We also finalized in the CY 2018 PFS final rule (82 FR 52982 through 52983) a policy to apply these service-level overrides for both PE and MP, rather than one or the other category.

In prior years, we reviewed information submitted during the proposed rule comment period regarding potential additions to the list of expected specialty assignments, to determine whether the specialty assignments commenters recommended were appropriate for the services in question. Our review process has been based on determining if the recommended specialty matched the dominant specialty in the claims data. However, we have long held reservations on whether this was the most accurate method for implementing updates to the expected specialty assignments list. Since these updates to the list were never formally proposed in the proposed rule of each calendar year, there was never an opportunity for interested parties to comment and provide feedback before the assignments were finalized in the final rule. We believe that it would provide greater transparency and more opportunities for public comment if additions to the expected specialty assignments list were instead proposed in each year's proposed rule.

Therefore, we did not finalize any additions to the expected specialty assignments list in the CY 2026 PFS final rule (90 FR 49270). We stated that we would instead review the list of approximately 75 low volume HCPCS codes submitted by commenters and propose additions to the list in this year's CY 2027 PFS proposed rule. We will also review any submissions for inclusion to the expected specialty assignments list by the same February 10th deadline that we have finalized in the past for consideration of RUC recommendations and invoice-based updates to supply and equipment pricing. We believe that synchronizing submissions to the expected specialty assignments list for low volume services with the same annual date used for RUC recommendations and invoice submissions will help standardize the process, while also providing more opportunities for feedback from interested parties by going through the annual comment process.

During the comment period for the CY 2026 PFS rule, several commenters stated that they had performed an analysis to identify all codes that meet the criteria to receive a specialty override under this CMS policy and drafted updated recommendations for codes that meet these criteria. Commenters stated that the purpose of assigning a specialty to these codes was to avoid the significant adverse impact on MP RVUs that results from errors in specialty utilization data magnified in representation (percentage) by small sample size. These commenters submitted a list of approximately 75 low volume HCPCS codes with recommended expected specialty assignments.

After reviewing the information provided by the commenters to determine whether the specialty assignments they recommended were appropriate for the services in question, based on determining if the recommended specialty matches the dominant specialty in the claims data, we are proposing the additions to the list of expected specialty assignments for low volume services identified in Table A–B1. We agree with the commenters that, based on claims data, CPT codes 33277 through 33281 and 33287 through 33288 should be crosswalked to the Cardiac Electrophysiology specialty and that CPT codes 93584 through 93588 should be crosswalked to the Interventional Cardiology specialty. We also agree with commenters that CPT code 23077 should be crosswalked to the Surgical Oncology specialty. However, we do not have PE/HR data for these specialties as they were not part of the PPIS when it was conducted in 2007; therefore, we are crosswalking these CPT codes to the closest available specialties (Cardiology for the first two groups of codes and All Physicians for CPT code 23077), as listed on Table A–B1.

We disagree with the commenters on a series of additional suggested assigned specialties. In each case, there was another specialty which was reported more than twice as often in the claims data as the specialty suggested by commenters and in some cases reported as much as five times as often. Therefore, we are crosswalking CPT codes 15135 and 41000 to the Otolaryngology specialty, CPT codes 26118 and 26650 to the Orthopedic Surgery specialty, CPT codes 93025 and 93150 to the Cardiology specialty, and CPT codes 93152 and 93153 to the Pulmonary Disease specialty as these were the dominant specialties in the claims data. These crosswalks are included in Table A–B1.

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TABLE A-B1: PROPOSED NEW ADDITIONS TO THE EXPECTED SPECIALTY ASSIGNMENT LIST

HCPCS	Short Descriptor	Expected Specialty Assignment
0596T	Temp fml iu vlv-pmp 1st insj	UROLOGY
0597T	Temp fml iu valve-pmp rplcmt	UROLOGY
11463	Exc skn hdrdnt ing complex	PLASTIC AND RECONSTRUCTIVE SURGERY
15135*	Drm agrft f/s/n/h/f/g/m 1st	OTOLARYNGOLOGY
20979	Us bone stimulation	PODIATRY
21407	Opn tx orbit fx w/implant	PLASTIC AND RECONSTRUCTIVE SURGERY
22836	Ant thrc vrt body tethrg <7	ORTHOPEDIC SURGERY
22837	Ant thrc vrt body tethrg 8+	ORTHOPEDIC SURGERY
22838	Rev rplc/rmv thrc vrt tethrg	ORTHOPEDIC SURGERY
22860	Tot disc arthrp 2ntrspc lmbr	NEUROSURGERY
23077*	Resect shoulder tumor < 5 cm	ALL PHYSICIANS
23675	Cltx sho dislc neck fx mnpj	ORTHOPEDIC SURGERY
25440	Repair nonu scphd carpl b1	HAND SURGERY
26118*	Rad resect hand tumor 3 cm/>	ORTHOPEDIC SURGERY
26650*	Treat thumb fracture	ORTHOPEDIC SURGERY
27087	Remove hip foreign body	ORTHOPEDIC SURGERY
27393	Lengthening of thigh tendon	ORTHOPEDIC SURGERY
28055	Neurectomy foot	PODIATRY
31032	Explore sinus remove polyps	OTOLARYNGOLOGY
31292	Nsl/sins ndsc med/inf dcmprn	OTOLARYNGOLOGY
32096	Open wedge/bx lung infiltr	THORACIC SURGERY
32141	Remove/treat lung lesions	THORACIC SURGERY
33277*	Insj phrnc nrv stim transvns	CARDIOLOGY
33278*	Rmvl phrnc nrv stim sys	CARDIOLOGY
33279*	Rmvl phrnc nrv stim transvns	CARDIOLOGY
33280*	Rmvl phrnc nrv stim pg only	CARDIOLOGY
33281*	Reposg phrnc nrv stim trnsvn	CARDIOLOGY
33287*	Rmv&rplcmt phrnc nrv stim pg	CARDIOLOGY
33288*	Rmv&rplcmt phrnc nrv stim ld	CARDIOLOGY
33875	Thoracic aortic graft	THORACIC SURGERY
34813	Femoral endovas graft add-on	VASCULAR SURGERY
35682	Composite byp grft 2 veins	VASCULAR SURGERY
35881	Revise graft w/vein	VASCULAR SURGERY
36474	Endovenous mchnchem add-on	VASCULAR SURGERY
41000*	Drainage of mouth lesion	OTOLARYNGOLOGY
41530	Tongue base vol reduction	OTOLARYNGOLOGY
42815	Excision of neck cyst	OTOLARYNGOLOGY
43501	Surgical repair of stomach	GENERAL SURGERY
44850	Repair of mesentery	GENERAL SURGERY
45550	Repair rectum/remove sigmoid	COLORECTAL SURGERY
50542	Laparo ablate renal mass	UROLOGY
50951	Endoscopy of ureter	UROLOGY
51570	Removal of bladder	UROLOGY
51880	Repair of bladder opening	UROLOGY
53260	Treatment of urethra lesion	UROLOGY
58580	Transcrv abltj utrn fibrd rf	OBSTETRICS/GYNECOLOGY
61055	Injection into brain canal	DIAGNOSTIC RADIOLOGY

HCPCS	Short Descriptor	Expected Specialty Assignment
61516	Crnec treph exc cyst sttl	NEUROSURGERY
61889	Ins sk-mnt crnl nstm pg/rcvr	NEUROSURGERY
61891	Rev/rplcmt sk-mnt crnl nstm	NEUROSURGERY
61892	Rmv sk-mnt crnl nstm pg/rcvr	NEUROSURGERY
62281	Treat spinal cord lesion	PHYSICAL MEDICINE AND REHABILITATION
63200	Release spinal cord lumbar	NEUROSURGERY
67550	Insert eye socket implant	OPHTHALMOLOGY
74415	Urography nfs drip&/bls w/nf	DIAGNOSTIC RADIOLOGY
76145	Med physic dos eval rad exps	INTERVENTIONAL RADIOLOGY
76812	Ob us detailed addl fetus	OBSTETRICS/GYNECOLOGY
92583	Select picture audiometry	AUDIOLOGIST
93025*	Microvolt t-wave assess	CARDIOLOGY
93150*	Therapy activation ipnss	CARDIOLOGY
93152*	Interrog&prgrmg ipnss polysm	PULMONARY DISEASE
93153*	Interrog w/o prgrmg ipnss	PULMONARY DISEASE
93584*	Vngrph chd anom/persist svc	CARDIOLOGY
93585*	Vngrph chd azygs/hemiazygs	CARDIOLOGY
93586*	Vngrph chd coronary sinus	CARDIOLOGY
93587*	Vngrph chd vnvn cltrl at/abv	CARDIOLOGY
93588*	Vngrph chd vnvn cltrl below	CARDIOLOGY
95866	Needle emg hemidiaphragm	NEUROLOGY
96203	Mlt fam grp bhv train ea add	PSYCHIATRY
96933	Rcm celulr subcelulr img skn	DERMATOLOGY
G0017	Crisis psychotherapy 60m	PSYCHIATRY
G0018	Crisis psychotherapy add 30m	PSYCHIATRY

* Recommended specialty assignment crosswalked.

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The full list of expected specialty assignments is included in the CY 2027 public use files, which are available on the CMS website under downloads for the CY 2027 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

Under current policy, for most services the indirect allocator is: indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* Under current policy, for global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs would be allocated using the work RVUs, and for the TC service, indirect PEs would be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes'', the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- Under current policy, the second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

We note that for CY 2026, we finalized a change to the methodology so that when work RVUs are used to allocate indirect PE to the facility RVUs, they are assigned at one-half the amount allocated to the non-facility PE RVUs for that same service. These PE methodology changes are discussed in greater detail in the CY 2026 PFS final rule (90 FR 49292 through 49296).

Proposed Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: the direct PE RVUs; the clinical labor PE RVUs; and the work RVUs.

The proposed indirect allocator is: indirect PE percentage *(direct PE RVUs/direct percentage) + work RVUs + clinical labor RVUs. The proposed change is to include both the work RVUs and clinical labor RVUs in the indirect allocator for all services, except for codes with 010- and 090-day global periods, as opposed to including the

work RVUs and clinical labor RVUs only for global services as detailed above.

If this proposed policy were to be finalized, this Proposed Step 8 would replace the Step 8 listed earlier. For presentation purposes, in the examples in the download file titled ''Calculation of PE RVUs under Methodology for Selected Codes,'' the formulas were divided into two parts for each service.

- The first part is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is the sum of the work RVU and the clinical labor PE RVU, including the methodology change finalized in CY 2026 for services performed in the facility setting (when work RVUs are used to allocate indirect PE to the facility RVUs, they are assigned at one-half the amount allocated to the non-facility PE RVUs for that same service).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 8 by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Under current policy, calculate the indirect practice cost index (IPCI). We refer readers to the CY 2007 PFS final rule with comment period (71 FR 69633) for more information about the establishment of the IPCI.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty specific indirect PE/HR data, calculate specialty specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 as the denominator and Step 13 as the numerator, calculate the specialty specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

Proposal regarding Steps 12 through 17: We develop the indirect practice expense (PE) RVUs under the PFS to reflect the relative resources involved in furnishing the services. Since the implementation of the resource-based PE RVUs, we have assumed that aggregate specialty level practice costs derived primarily from the 2007 PE/HR survey data are a reasonable way to help establish the resource-based indirect PE RVUs. We have historically used that data both to allocate indirect costs to each code and to re-scale the resulting PE RVUs for each code at the end of the established methodology to ensure that the overall allocation of PE RVUs for each specialty across the PFS approximates those expected based on the index derived from the PE/HR survey data. Over time, however, we have identified various limitations of the survey data, especially as the data we use has become increasingly dated and are intrinsically limited to small, selective samples based on pre-determined assumptions about where costs are likely to differ, and, as we addressed in CY 2026 PFS rulemaking, have not been adequately updated. (We refer readers to an extended discussion of our concerns with and decision not to update this data in the CY 2026 PFS final rule at 90 FR 49286 through 49292.) This has resulted in a PE methodology that privileges the historic survey data over incorporation of more recent data about specific services and produces unpredictable and counterintuitive results that are not transparent to the public.

Because we have taken various steps to improve the data used in the pricing inputs and the indirect allocation methodologies, we are proposing to remove the steps of the current methodology that rely on the indirect practice cost index (IPCI) from the calculation of the PE RVUs. We propose this change, because the steps of the current methodology that rely on the IPCI calculation effectively favor the aggregate specialty-level survey data over the code level inputs and allocators and consequently limit the influence of improvements to inputs and allocation methodologies. We are proposing to implement this change over a 2-year transition period. Specifically, in the first year, only half of the measured variation in the IPCI will be applied to the indirect allocator. In the second year, the IPCI will no longer be applied.

The steps of the current methodology that rely on the IPCI calculation are steps 12 through 17. Thus, under this proposal, steps 12 through 17 would no longer be a part of the calculation, and the total PE RVU, prior to the calculation of final PE RVUs described below at Step 18, would be the sum of step 5 (Direct Cost PE RVUs) and step 11 (Indirect Cost PE RVUs).

(d) Calculate the Final PE RVUs

Step 18: Under current policy, add the direct PE RVUs from Step 5 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the sum of steps 5 and 17 to the aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs. This adjustment ensures that all PE RVUs in the PFS account for the fact that certain specialties are excluded from the calculation of PE RVUs but included in maintaining overall PFS BN. (See ''Specialties excluded from ratesetting calculation'' later in this proposed rule). Under the proposed policy, add the direct cost PE RVUs from Step 5 to the indirect cost PE RVUs from Step 11 and apply the final PE BN adjustment.

Proposed Step 19: Calculate and apply the PE stabilization factor for each PE RVU by comparing the result of step 18 with the results of the prior year's PE RVUs from step 18. As described previously in this section, we are proposing to remove the IPCI from the PE methodology, which we believe will improve the transparency and stability of PE RVUs over time. However, we recognize that the IPCI, because it is rooted in static PE/HR data, effectively resulted in stabilizing year-to-year changes in PE RVUs, especially due to changes in input valuations and changes to allocation methodologies. We have long noted that extreme volatility in PE RVUs can have

unintended consequences and distortions. To mitigate volatility that could otherwise occur, we are proposing a PE stabilization adjustment to further improve predictability and reduce volatility within the PE RVUs. Specifically, we are proposing that the PE RVU calculated after the application of the cognitive services floor and any adjustments that occur outside of the PE methodology will be subject to a cap and will not increase or decrease by more than 5 percent each year. In the proposed Step 19 we would compare the PE RVU after the application of the cognitive services floor and any code-level adjustments in the current ratesetting year to the allocation methodology from the prior year and then apply the 5 percent cap. We note that the proposed stabilization adjustment in Proposed Step 19 will be applied prior to the statutory phase-in of significant RVU reductions required by Section 1848(c)(7) of the Act, discussed in more detail later in this section, which limits all codes that are not new or revised to a 19 percent decrease in total RVU in an individual calendar year. Therefore, a code may be impacted by both the PE stabilization adjustment and the statutory phase-in, meaning a code's PE RVU may ultimately differ by greater than the PE stabilization adjustment detailed in proposed Step 19.

This proposed adjustment would not apply to new and revised codes or codes formerly contractor priced that are newly nationally priced, because it is not clear what the comparison PE RVU would be for those codes. Because we believe the benefits of the PE stabilization adjustment would ideally apply to new and revised codes and newly nationally priced codes, we are seeking comment on an approach that would allow us to expand the PE stabilization adjustment to these categories of codes. Additionally, the proposed PE stabilization adjustment would not apply to revalued codes because we believe the statutory phase-in sufficiently limits large reductions to individual codes undergoing review and/or revaluation, and limits the amount of time a revalued code would remain overvalued by being significantly constrained from reductions found to be appropriate through revaluation.

Step 19 (*under our proposal, step 19 would be renumbered as step 20*): Apply the phase-in of significant RVU reductions and its associated adjustment. Section 1848(c)(7) of the Act specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs must be phased in over a 2-year period. In implementing the phase-in, we consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach limits the year 1 reduction for the service to the maximum allowed amount (that is, 19 percent), and then phases in the remainder of the reduction. To comply with section 1848(c)(7) of the Act, we adjust the PE RVUs to ensure that the total RVUs for all services that are not new or revised codes decrease by no more than 19 percent, and then apply a relativity adjustment to ensure that the total pool of aggregate PE RVUs remains relative to the pool of work and MP RVUs. For a more detailed description of the methodology for the phase-in of significant RVU changes, we refer readers to the CY 2016 PFS final rule with comment period (80 FR 70927 through 70931).

In summary, for CY 2027, we are proposing to:

- Modify step 8 to calculate indirect PE based on both work RVUs and clinical labor RVUs for all services except 010- and 090-day global period codes;
- Remove steps 12 through 17 that rely on the IPCI from the calculation of the PE RVUs over a 2-year transition period, and;
- Add a new step to apply a stabilization adjustment to the PE RVUs (proposed step 19).

(e) Setup File Information

- Specialties excluded from ratesetting calculation: To calculate the PE and MP RVUs, we exclude certain specialties, such as NPPs paid at a percentage of the PFS and low volume specialties, from the calculation. These specialties are included to calculate the BN adjustment. They are displayed in Table A–B2.

TABLE A-B2: SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty Code	Specialty Description
49	Ambulatory surgical center
50	Nurse practitioner
51	Medical supply company with certified orthotist
52	Medical supply company with certified prosthetist
53	Medical supply company with certified prosthetist-orthotist
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist
56	Individual certified prosthetist
57	Individual certified prosthetist-orthotist
58	Medical supply company with registered pharmacist
59	Ambulance service supplier, for example, private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies
61	Voluntary health or charitable agencies
73	Mass immunization roster biller
74	Radiation therapy centers
87	All other suppliers (for example, drug and department stores)
88	Unknown supplier/provider specialty
89	Certified clinical nurse specialist
96	Optician
97	Physician assistant
A0	Hospital
A1	Skilled nursing facility
A2	Intermediate care nursing facility
A3	Nursing facility, other
A4	HHA
A5	Pharmacy
A6	Medical supply company with respiratory therapist
A7	Department store
A8	Grocery store
B1	Supplier of oxygen and/or oxygen related equipment (eff. 10/2/2007)
B2	Pedorthic personnel
B3	Medical supply company with pedorthic personnel
B4	Rehabilitation Agency
B5	Ocularist
C1	Centralized Flu
C2	Indirect Payment Procedure
C5	Dentistry

- *Crosswalk certain low volume physician specialties:* Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.
- *Physical therapy utilization:* Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.
- *Identify professional and technical services not identified under the usual technical component (TC) and professional component (PC or 26) modifiers:* Flag the services that are PC and TC services but do not use TC and PC/26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).
- *Payment modifiers:* In the CY 2013 PFS proposed rule (77 FR 68901), we introduced a more detailed methodology for adjusting volume and time to account for payment modifiers and other special payment rules, such as multiple procedure payment reductions, in the utilization data. We are proposing that, beginning in CY 2027, we would utilize a new approach to account for payment modifiers and other special payment rules. For each paid claim line, we would calculate the ratio of allowed charges to the national PFS payment amount. This would account for differences resulting from payment modifiers and other special payment rules, as well as differences in geography. We are proposing to use the same ratio to adjust time, rather than a separate calculation under our current methodology, with the exception of anesthesia, for which we calculate time using only procedures with modifiers indicating they are personally performed. These proposed changes will

allow us to more accurately capture any combination of modifiers and special payment rules and automatically account for updates in modifiers and/or special payment rules in future years. These proposed changes have a very minimal impact on the resulting PE RVUs but will produce a more accurate result. As under our current methodology, the adjusted volume will be displayed in the utilization file that is posted in conjunction with each PFS rule.

- *Work RVUs:* The setup file contains the work RVUs from this proposed rule.

(6) Equipment Cost per Minute

The equipment cost per minute is calculated as:

(1/(minutes per year * usage)) * price * ((interest rate/(1 (1/((1 + interest rate) − life of equipment)))) + maintenance)

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally, 150,000 minutes.
usage = variable, see discussion later in this proposed rule.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion later in this proposed rule.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act.

Useful Life: In the CY 2005 PFS final rule we stated that we updated the useful life for equipment items primarily based on the AHA's ''Estimated Useful Lives of Depreciable Hospital Assets'' guidelines (69 FR 66246). The most recent edition of these guidelines was published in 2018. This reference material provides an estimated useful life for hundreds of different types of equipment, the vast majority of which fall in the range of 5 to 10 years, and none of which are lower than 2 years in duration. We believe that the updated editions of this reference material remain the most accurate source for estimating the useful life of depreciable medical equipment.

In the CY 2021 PFS final rule, (85 FR 84482 through 84483) we finalized a proposal to treat equipment life durations of less than 1 year as having a duration of 1 year for the purpose of our equipment price per minute formula. In the rare cases where items are replaced every few months, we noted that we believe it is more accurate to treat these items as disposable supplies with a fractional supply quantity as opposed to equipment items with very short equipment life durations. For a more detailed discussion of the methodology associated with very short equipment life durations, we refer readers to the CY 2021 PFS final rule (85 FR 84482 through 84483).

- *Maintenance:* We finalized the 5 percent factor for annual maintenance in the CY 1998 PFS final rule with comment period (62 FR 33164). As we previously stated in the CY 2016 PFS final rule with comment period (80 FR 70897), we do not believe the annual maintenance factor for all equipment is precisely 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also noted that we believe it likely overstates the maintenance costs for other equipment. When we solicited comments regarding data sources containing equipment maintenance rates, commenters could not identify an auditable, robust data source that CMS could use on a wide scale. We noted that we did not believe voluntary submissions regarding the maintenance costs of individual equipment items would be an appropriate methodology for determining costs. As a result, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining a different maintenance factor, in the proposed rule, we did not propose a variable maintenance factor for equipment cost per minute pricing as we did not believe that we have sufficient information at present. We noted in the CY 2026 PFS proposed rule (90 FR 32593) that we would continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

- *Interest Rate:* In the CY 2013 PFS final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation (see 77 FR 68902 for a thorough discussion of this issue). The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table A–B3.

TABLE A-B3: SBA MAXIMUM INTEREST RATES

Price	Useful Life	Interest Rate
<$25K	<7 Years	7.50%
$25K to $50K	<7 Years	6.50%
>$50K	<7 Years	5.50%
<$25K	7+ Years	8.00%
$25K to $50K	7+ Years	7.00%
>$50K	7+ Years	6.00%

We are not proposing any changes to the equipment interest rates for CY 2027.

3. Adjusting RVUs To Match the PE Share of the Medicare Economic Index (MEI)

We have long stated that we believe that the MEI is the best measure available to determine the relative weights of the three components in payments under the PFS—work, practice expense (PE), and malpractice (MP). Accordingly, we believe that to ensure that the PFS payments reflect the relative resources in each of these PFS components as required by section 1848(c)(3) of the Act, the RVUs used in developing rates should reflect the same weights in each component as the cost share weights in the Medicare Economic Index (MEI). Accordingly, we have finalized to accomplish this (78 FR 74241 through 74242) by holding the work RVUs constant and adjusting the PE RVUs, MP RVUs, and conversion factor (CF) to produce the appropriate balance in RVUs among the three PFS

components and payment rates for individual services, that is, that the total RVUs on the PFS are proportioned to approximately 51 percent work RVUs, 45 percent PE RVUs, and 4 percent MP RVUs. Historically, as the MEI cost shares are updated, we have proposed to modify steps 3 and 10 to adjust the aggregate pools of PE costs (direct PE in step 3 and indirect PE in step 10) in proportion to the change in the PE share in the MEI cost share weights, and to recalibrate the relativity adjustment that we apply in step 18 as described in the CY 2023 PFS final rule (87 FR 69414 and 69415) and CY 2014 PFS final rule (78 FR 74236 and 74237). The most recent recalibration was done for the CY 2014 RVUs.

However, due to overarching concerns with the data as described in the CY 2026 PFS final rule (90 FR 49287 through 49293) and our previously described policy goal to balance PFS payment stability and predictability with incorporating new data through routine updates to the MEI, we finalized our proposal to maintain the current PE/HR and 2006-based MEI cost shares (rather than transitioning to the 2017-based MEI cost shares), for CY 2026 PFS ratesetting due to the concerns about data quality and payment stability. Additionally, for CY 2027, we are proposing to continue to use the current PE/HR and 2006-based MEI cost shares for CY 2027 PFS ratesetting.

4. Changes to Direct PE Inputs for Specific Services

This section focuses on specific PE inputs. The direct PE inputs are included in the CY 2027 direct PE input public use files, which are available on the CMS website under downloads for the CY 2027 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-fafor-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

a. Standardization of Clinical Labor Tasks

As we noted in the CY 2015 PFS final rule with comment period (79 FR 67640 through 67641), we continue to make improvements to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the preservice, service, and post service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this level of detail would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information would facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It would also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the detailed information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to physician preservice time packages. We believe that setting and maintaining such standards would provide greater consistency among codes that share the same clinical labor tasks and could improve the relativity of values among codes. For example, as medical practice and technologies change over time, standards could be updated simultaneously for all codes with the applicable clinical labor tasks instead of waiting for individual codes to be reviewed.

In the CY 2016 PFS final rule with comment period (80 FR 70901), we solicited comments on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology. After consideration of comments received, we finalized standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS'' and ''Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' In the CY 2017 PFS final rule (81 FR 80184 through 80186), we finalized a policy to establish a range of appropriate standard minutes for the clinical labor activity, ''Technologist QCs images in PACS, checking for all images, reformats, and dose page.'' These standard minutes will be applied to new and revised codes that make use of this clinical labor activity when they are reviewed by us for valuation. We finalized a policy to establish 2 minutes as the standard for the simple case, 3 minutes as the standard for the intermediate case, 4 minutes as the standard for the complex case, and 5 minutes as the standard for the highly complex case. These values were based upon a review of the existing minutes assigned for this clinical labor activity; we determined that 2 minutes is the duration for most services and a small number of codes with more complex forms of digital imaging have higher values. We also finalized standard times for a series of clinical labor tasks associated with pathology services in the CY 2016 PFS final rule with comment period (80 FR 70902). We do not believe these activities would be dependent on the number of blocks or batch size, and we believe that the finalized standard values accurately reflect the typical time it takes to perform these clinical labor tasks.

In reviewing the RUC-recommended direct PE inputs for CY 2019, we noticed that the 3 minutes of clinical labor time traditionally assigned to the ''Prepare room, equipment and supplies'' (CA013) clinical labor activity were split into 2 minutes for the ''Prepare room, equipment and supplies'' activity and 1 minute for the ''Confirm order, protocol exam'' (CA014) activity. We proposed to maintain the 3 minutes of clinical labor time for the ''Prepare room, equipment and supplies'' activity and remove the clinical labor time for the ''Confirm order, protocol exam'' activity wherever we observed this pattern in the RUC-recommended direct PE inputs. Commenters explained in response that when the new version of the PE worksheet introduced the activity codes for clinical labor, there was a need to translate old clinical labor tasks into the new activity codes, and that a prior clinical labor task was split into two of the new clinical labor activity codes: CA007 (*Review patient clinical extant information and questionnaire*) in the preservice period, and CA014 (*Confirm order, protocol exam*) in the service period. Commenters stated that the same clinical labor from the old PE worksheet was now divided into the CA007 and CA014 activity codes, with a standard of 1 minute for each activity. We agreed with commenters that we would finalize the RUC-recommended 2 minutes of clinical labor time for the CA007 activity code and 1 minute for the CA014 activity code in situations where this was the case. However, when reviewing the clinical labor for the reviewed codes affected by this issue, we found that several of the codes did not include this old clinical labor task, and we also noted that several of the reviewed codes that contained the CA014 clinical labor activity code did not contain any clinical labor for the CA007 activity. In these situations, we believe that the three total minutes of

clinical staff time would be more accurately described by the CA013 ''Prepare room, equipment and supplies'' activity code, and we finalized these clinical labor refinements. We direct readers to the discussion in the CY 2019 PFS final rule (83 FR 59463 through 59464) for additional details.

Following the publication of the CY 2020 PFS proposed rule, a commenter expressed concern with the published list of common refinements to equipment time. The commenter stated that these refinements were the formulaic result of applying refinements to the clinical labor time and did not constitute separate refinements; the commenter requested that CMS no longer include these refinements in the table published each year. In the CY 2020 PFS final rule, we agreed with the commenter that these equipment time refinements did not reflect errors in the equipment recommendations or policy discrepancies with the RUC's equipment time recommendations. However, we believed it was important to publish the specific equipment times that we were proposing (or finalizing in the case of the final rule) when they differed from the recommended values due to the effect these changes can have on the direct costs associated with equipment time. Therefore, we finalized the separation of the equipment time refinements associated with changes in clinical labor into a separate table of refinements. We direct readers to the discussion in the CY 2020 PFS final rule (84 FR 62584) for additional details.

Historically, the RUC has submitted a ''PE worksheet'' that details the recommended direct PE inputs for our use in developing PE RVUs. The format of the PE worksheet has varied over time, and among the medical specialties developing the recommendations. These variations have made it difficult for the RUC's development and our review of code values for individual codes. Beginning with its recommendations for CY 2019, the RUC mandated the use of a new PE worksheet for its recommendation development process that standardizes the clinical labor tasks and assigns them a clinical labor activity code. We believe the RUC's use of the new PE worksheet in developing and submitting recommendations helps us simplify and standardize the hundreds of clinical labor tasks currently listed in our direct PE database. To facilitate rulemaking for CY 2027, we are displaying the Labor Task Detail public use file that contains the current listing of clinical labor activity codes. This file is available on the CMS website under downloads for the CY 2027 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

b. Updates to Prices for Existing Direct PE Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking, beginning with the CY 2012 PFS proposed rule. Beginning in CY 2019 and continuing through CY 2022, we conducted a market-based supply and equipment pricing update using information developed by our contractor which updated pricing recommendations for approximately 1300 supplies and 750 equipment items currently used as direct PE inputs. Given the potentially significant changes in payment that would occur, in the CY 2019 PFS final rule, we finalized a policy to phase in our use of the new direct PE input pricing over a 4-year period using a 25/75 percent (CY PFS 2019), 50/50 percent (CY PFS 2020), 75/25 percent (CY PFS 2021), and 100/0 percent (CY PFS 2022) split between new and old pricing. We believe that implementing the proposed updated prices with a 4-year phase-in would improve payment accuracy while maintaining stability and allowing interested parties to address potential concerns about changes in payment for particular items. This 4-year transition period to update supply and equipment pricing concluded in CY 2022; for a more detailed discussion, we refer readers to the CY 2019 PFS final rule with comment period (83 FR 59473 through 59480).

For CY 2027, we are proposing to update the price of nine supplies and two equipment items in response to the public submission of invoices following the publication of the CY 2026 PFS final rule. These supply and equipment items with updated prices are listed in the valuation of specific codes section of the rule under Table A–D9, CY 2027 Invoices Received for Existing Direct PE Inputs.

These proposed pricing updates include a request from the RUC to update the pricing of the moderate sedation pack (SA044) to more accurately reflect its components. The RUC determined that a sterile gown is not needed as part of the moderate sedation pack, however, a regular staff gown should be included to protect the sedation provider from all body fluids, substance, and excretions. The RUC also requested that a mask would be an appropriate addition in the sedation pack, resulting in a price change from the current $19.20, minus the $5.13 sterile gown, plus the $1.19 staff gown and $0.43 mask, for a new total price of $15.69. We are proposing this $15.69 price for the SA044 moderate sedation pack which is reflected in Table A–E, CY 2027 Invoices Received for Existing Direct PE Inputs.

Additionally, we received a potentially misvalued code (PMVC) nomination for SA119 kit, low frequency ultrasound wound therapy (MIST) and are proposing an updated supply cost from $320.18 to $100 for SA119. We refer readers to section II.D. of this proposed rule for more information about this proposal.

(1) Invoice Submission

We remind readers that we routinely accept public submissions of invoices as part of our process for developing payment rates for new, revised, and potentially misvalued codes. Often, these invoices are submitted in conjunction with the RUC-recommended values for the codes. To be included in a given year's proposed rule, we generally need to receive invoices by the same February 10th deadline we noted for consideration of RUC recommendations. However, we will consider invoices submitted as public comments during the comment period following the publication of the CY 2027 PFS proposed rule and will consider any invoices received after February 10th or outside of the public comment process as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov.*

(2) Supply Pack Pricing Update

Interested parties previously notified CMS that they identified numerous discrepancies between the aggregated cost of some supply packs and the individual item components contained within. The interested parties indicated that CMS should rectify these mathematical errors as soon as possible to ensure that the sum correctly matches the totals from the individual items, and they recommended that we resolve these pricing discrepancies in the supply packs during CY 2024 rule. The AMA RUC convened a workgroup on this subject and submitted recommendations to update pricing for a series of supply packs along with the

RUC's comment letter for the CY 2024 rule cycle.

We appreciated the additional information and RUC workgroup recommendations regarding discrepancies in the aggregated cost of some supply packs. However, due to the projected significant cost revisions in the pricing of supply packs and because we did not propose to address supply pack pricing in the CY 2024 proposed rule, we stated in the CY 2024 final rule that this issue would be better addressed in future rulemaking. For example, the cleaning and disinfecting endoscope pack (SA042) is included as a supply input in more than 300 HCPCS codes, which could have a sizable impact on the overall valuation of these services, and which was not incorporated into the proposed RVUs published for the CY 2024 proposed rule. We stated that interested parties would be better served if we comprehensively addressed this topic during future rulemaking in which commenters could provide feedback in response to proposed pricing updates (88 FR 78833 through 78834).

For CY 2025, we proposed implementing the supply pack pricing update and associated revisions as recommended by the RUC's workgroup (89 FR 97726 through 97727). We proposed to update the pricing of the ''pack, cleaning and disinfecting, endoscope'' (SA042) supply from $19.43 to $31.29, to update the pricing of the ''pack, drapes, cystoscopy'' (SA045) supply from $17.33 to $14.99, to update the pricing of the ''pack, ocular photodynamic therapy'' (SA049) supply from $16.35 to $26.35, to update the pricing of the ''pack, urology cystoscopy visit'' (SA058) supply from $113.70 to $37.63, and to update the pricing of the ''pack, ophthalmology visit (w-dilation)'' (SA082) supply from $3.91 to $2.33. As recommended by the RUC workgroup, we also proposed to delete the ''pack, drapes, laparotomy (chest-abdomen)'' (SA046) supply entirely. The updated prices for these supply packs were listed in the valuation of specific codes section of this rule under Table A–B5, CY 2025 Invoices Received for Existing Direct PE Inputs (89 FR 97852).

In accordance with the RUC workgroup's recommendations, we also proposed to create eight new supply codes, including components contained within previously existing supply packs. Aside from the SB056 supply, which is a replacement in several HCPCS codes for the deleted SA046 supply pack, all of these new supplies are not included as standalone direct PE inputs in any current HCPCS codes, as they are, again, components contained within previously existing supply packs. We proposed to add:

- The kit, ocular photodynamic therapy (PDT) (SA137) supply at a price of $26.00 as a component of the SA049 supply pack;
- The Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply at a price of $8.049 as a replacement for the SA046 supply pack;
- The drape, surgical, legging (SB057) supply at a price of $3.284 as a component of the SA045 supply pack;
- The drape, surgical, split, impervious, absorbent (SB058) supply at a price of $8.424 as a component of the SA045 supply pack;
- The post-mydriatic spectacles (SB059) supply at a price of $0.328 as a component of the SA082 supply pack;
- The y-adapter cap (SD367) supply at a price of $0.352 as a component of the SA049 supply pack;
- The ortho-phthalaldehyde 0.55 percent (for example, Cidex OPA) (SM030) supply at a price of $0.554 as a component of the SA042 supply pack; and
- The ortho-phthalaldehyde test strips (SM031) supply at a price of $1.556 as a component of the SA042 supply pack.

The new supply pack component items were listed in the valuation of specific codes section of the rule under Table A–B8, CY 2025 PFS (89 FR 97722) New Invoices (89 FR 97853).

We also proposed the following additional supply substitutions based on the recommendations of the RUC workgroup. We proposed to remove the deleted SA046 supply pack and replace it with the drape, sterile, fenestrated 16in x 29in (SB011) supply for CPT codes 19020, 19101, 19110, 19112, 20101, and 20102. We proposed to remove the deleted SA046 supply pack and replace it with two supplies—the drape, sterile, three-quarter sheet (SB014) and the drape, towel, sterile 18in x 26in (SB019)—for CPT codes 19000 and 60300. We proposed to remove the deleted SA046 supply pack and replace it with 2 supplies—the drape, towel, sterile 18in x 26in (SB019) and the newly created Abdominal Drape Laparotomy Drape Sterile (100 in x 72 in x 124 in) (SB056) supply—for CPT codes 22510, 22511, 22513, and 22514. We proposed to remove the deleted SA046 supply pack without replacing it with anything for CPT code 22526; the RUC workgroup did not make a recommendation on what to do with CPT code 27278, which also previously contained the SA046 supply pack. Therefore, we also proposed not to replace the SA046 supply pack with any supplies for this code. The RUC workgroup also recommended removing the SA046 supply pack from CPT code 64595 with no replacement; however, this code was recently reviewed at the April 2022 RUC meeting and it no longer includes the SA046 supply.

In the comments on the CY 2025 PFS proposed rule (89 FR 97727), several commenters supported the proposed supply pack pricing update as recommended by the RUC workgroup, however they indicated concern over the proposed decrease in the price of the urology cystoscopy visit pack (SA058) from $113.70 to $37.63. The commenters stated that the proposed pricing reduction in the SA058 supply could result in drastic payment rate cuts for physicians performing cystoscopy services in the office setting. The commenters requested that CMS either delay the pricing update or phase-in the supply pack changes over a 4-year period like it has done for other PE changes with significant redistributive effects, allowing independent urology practices to better prepare for the negative financial impact this change will have.

After considering these comments, we agreed that the use of a phased-in transition period would be appropriate to allow practitioners to adjust to the updated pricing of these supplies. During our previous supply and equipment pricing update in the CY 2019 PFS final rule (83 FR 59475), we finalized a policy to phase in any updated pricing that we established during the 4-year transition period for very commonly used supplies and equipment, such as sterile gloves (SB024) or exam tables (EF023), even if invoices were provided as part of the formal review of a code family. Based on this previously established policy, we finalized the use of a pricing transition for three supply packs in Table A–B4.

TABLE A-B4: CY 2025 SUPPLY PACK PRICING TRANSITION

CMS_ CODE	HCPCS Codes	CMS_2024 Price	Recommended Price	Year 1 (CY 2025) Price	Year 2 (CY 2026) Price	Year 3 (CY 2027) Price	Final (CY 2028) Price
SA042	306	$19.43	$31.29	$22.40	$25.36	$28.33	$31.29
SA058	38	$113.70	$37.63	$94.68	$75.67	$56.65	$37.63
SA082	145	$3.91	$2.33	$3.52	$3.12	$2.73	$2.33

Following the same pattern as our previous supply/equipment and clinical labor pricing updates, we finalized the implementation of this pricing transition over 4 years such that one-quarter of the difference between the current price and the fully phased-in price is implemented for CY 2025 PFS (89 FR 97722), one-third of the difference between the CY 2025 PFS (89 FR 97722) price and the final price is implemented for CY 2026 PFS, and one-half of the difference between the CY 2026 price and the final price is implemented for CY 2027, with the new direct PE prices fully implemented for CY 2028. For the other proposed supply packs, the cystoscopy drapes pack (SA045) is only included in seven HCPCS codes and the ocular photodynamic therapy pack (SA049) is only included in a single HCPCS code which do not meet these criteria established in previous rulemaking and described previously in this section. Therefore, we finalized each of them at their updated pricing for CY 2025 PFS (89 FR 97722) as proposed in the proposed rule. We believe that the use of this pricing transition will minimize any potential disruptive effects during the 4-year transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply packs.

Several commenters also stated that although five incomplete packs would have their pricing updated in the proposed rule, mathematical errors still remained for a number of additional supply packs. Commenters stated that only 3 of the 18 affirmed packs were priced correctly to match their components and provided tables showing the pricing of an additional 15 packs that needed mathematical correction by deconstructing the packs to determine the correct price through summing their individual components. Commenters requested that CMS initiate a correction of the packs pricing such that the sum of the individual components match the price of the corresponding pack as detailed in Table A–B5.

TABLE A-B5: SUPPLY PACK PRICING REQUESTED BY CY 2025 COMMENTERS

HCPCS Codes	Item Name	CMS Code	Current Price	New Price	% Change
111 codes	pack, basic injection	SA041	$10.45	$17.28	65%
560 codes	pack, cleaning, surgical instruments	SA043	$12.61	$11.09	-12%
3 codes	pack, moderate sedation	SA044	$18.55	$19.20	4%
4568 codes	pack, minimum multi-specialty visit	SA048	$5.02	$1.98	-61%
168 codes	pack, ophthalmology visit (no dilation)	SA050	$2.72	$1.35	-50%
239 codes	pack, pelvic exam	SA051	$20.16	$2.81	-86%
1079 codes	pack, post-op incision care (staple)	SA052	$4.80	$9.90	106%
469 codes	pack, post-op incision care (suture & staple)	SA053	$5.47	$11.54	111%
1708 codes	pack, post-op incision care (suture)	SA054	$4.62	$10.34	124%
12 codes	pack, post-op incision care, craniotomy	SA055	$7.30	$18.18	149%
24 codes	pack, post-op incision care, neurosurgical	SA056	$6.20	$16.05	159%
120 codes	pack, drapes, ortho, large	SA080	$37.30	$25.38	-32%
29 codes	pack, drapes, ortho, small	SA081	$2.25	$1.88	-16%
119 codes	pack, protective, ortho, large	SA083	$10.86	$14.75	36%
27 codes	pack, protective, ortho, small	SA084	$5.99	$8.15	36%

While we shared the concerns of the commenters regarding the need for accuracy in the pricing of these supply packs, we had reservations about their potential for pricing disruptions. Ten of these supply packs are included in the direct PE inputs for at least 100 HCPCS codes, and three of the packs are included in more than 1000 HCPCS codes. Many of these pricing updates would lead to drastic changes in pricing for these supply packs which are included in hundreds of HCPCS codes, such as the SA051 pelvic exam pack decreasing in price from $20.16 to $2.81 (−86 percent) and the SA048 minimum multi-specialty visit pack decreasing in price from $5.02 to $1.98 (−61 percent). We were particularly concerned that these changes in supply pack pricing could lead to significant shifts in the overall PE RVU for affected HCPCS codes, without these proposed rates appearing in the proposed rule or allowing any opportunity for public comment.

Therefore, we did not finalize pricing updates for these additional 15 supply packs as requested by commenters. We anticipated returning to this subject in future rulemaking to allow any changes in associated pricing for HCPCS codes to appear in the proposed rule and provide an opportunity for the public to comment. Should these supply pack pricing updates be proposed in future

rulemaking, we anticipated that we might propose the same pricing transition described above due to the number of potentially affected HCPCS codes. We finalized all of the other supply pack pricing changes as proposed, with the exception of the 4-year pricing transition for three supply packs as described previously in this section.

For CY 2026, we proposed to continue implementing the supply pack pricing update and associated revisions as previously recommended by the RUC's workgroup. We proposed to update the price of the 15 supply packs detailed in Table A–B5 which were received too late in CY 2025 PFS (89 FR 97722) to allow for proposed pricing or public comment. In the case of the surgical instruments cleaning pack (SA043), the moderate sedation pack (SA044) and the small ortho drapes pack (SA081), the proposed pricing update is modest enough that we proposed these supplies move immediately to their final prices for CY 2026.

For the 12 other supply packs, we proposed that they be incorporated into the muti-year supply pack pricing transition finalized in CY 2025 rulemaking. Rather than having two separate 4-year pricing transitions associated with supply packs, we proposed that these 12 additional supply packs fold into the previous pricing transition using the same methodology, such that one-third of the difference between the CY 2025 PFS (89 FR 97722) price and the final price is implemented for CY 2026, and one-half of the difference between the CY 2026 price and the final price is implemented for CY 2027, with the new direct PE prices fully implemented for CY 2028 (89 FR 97728). With the inclusion of the SA042, SA058, and SA082 supply packs which began their pricing transition for CY 2025, we proposed the total supply pack pricing update detailed in Table A–B6.

TABLE A-B6: SUPPLY PACK PRICING TRANSITION

CMS_ CODE	HCPCS Codes	CMS_2024 Price	Recommended Price	Year 1 (CY 2025) Price	Year 2 (CY 2026) Price	Year 3 (CY 2027) Price	Final (CY 2028) Price
SA042	306	$19.43	$31.29	$22.40	$25.36	$28.33	$31.29
SA058	38	$113.70	$37.63	$94.68	$75.67	$56.65	$37.63
SA082	145	$3.91	$2.33	$3.52	$3.12	$2.73	$2.33
SA041	111	$10.45	$17.28	-	$12.73	$15.00	$17.28
SA048	4568	$5.02	$1.98	-	$4.01	$2.99	$1.98
SA050	168	$2.72	$1.35	-	$2.26	$1.81	$1.35
SA051	239	$20.16	$2.81	-	$14.38	$8.59	$2.81
SA052	1079	$4.80	$9.90	-	$6.50	$8.20	$9.90
SA053	469	$5.47	$11.54	-	$7.49	$9.52	$11.54
SA054	1708	$4.62	$10.34	-	$6.53	$8.43	$10.34
SA055	12	$7.30	$18.18	-	$10.93	$14.55	$18.18
SA056	24	$6.20	$16.05	-	$9.48	$12.77	$16.05
SA080	120	$37.30	$25.38	-	$33.33	$29.35	$25.38
SA083	119	$10.86	$14.75	-	$12.16	$13.45	$14.75
SA084	27	$5.99	$8.15	-	$6.71	$7.43	$8.15
SD089	100	$20.56	$41.15	-	$27.42	$34.29	$41.15

Table A–B6 also includes the hydrophilic guidewire (SD089) supply which we proposed to transition in pricing over 3 years given its inclusion in approximately 100 HCPCS codes. We continue to believe that the use of this pricing transition will minimize any potential disruptive effects during the transition period that could be caused by other sudden shifts in RVUs due to the high number of services that make use of these very common supply items. After consideration of the public comments, we finalized our supply pack pricing policies as proposed in the CY 2026 PFS final rule (90 FR 49284).

For CY 2027, these supply packs will continue with the third year of the previously finalized 4-year transition process as detailed in Table A–B6. As is the case with other supply and equipment pricing, we will consider invoices associated with these supply packs which are submitted as public comments during the comment period following the publication of the CY 2027 PFS proposed rule as part of our established annual process for requests to update supply and equipment prices. Interested parties are encouraged to submit invoices with their public comments or, if outside the notice and comment rulemaking process, via email at *PE_Price_Input_Update@cms.hhs.gov*.

c. Technical Corrections to Direct PE Input Database and Supporting Files

Following the publication of the CY 2026 PFS final rule, the RUC submitted a potential technical correction issue related to global period assignment for approximately three dozen codes. The RUC stated that these codes had long descriptors which indicated that they were add-on codes ''(List separately in addition to code for primary procedure)''; however, these codes were assigned the XXX global period instead of the ZZZ global period. The RUC requested that CMS consider assigning the ZZZ global period for these codes as a technical correction.

We reviewed the list of codes submitted by the RUC and we agree that there appears to be a technical error in the global period assignment for these codes. Most of the affected codes have non-payable status codes and no RVUs, while the handful of affected HCPCS codes that do have RVUs specifically state in their descriptors that they were intended to be add-on codes, such as CPT code 88332 (Pathology consultation during surgery; each additional tissue block with frozen section(s)). We are therefore proposing to change the

following codes to the ZZZ global period:

BILLING CODE 4169–69–P

TABLE A-B7: PROPOSED ZZZ GLOBAL PERIOD CODES

HCPCS	Short Descriptor
20930	Sp bone algrft morsel add-on
20936	Sp bone agrft local add-on
22841	Insert spine fixation device
81266	Str markers spec anal addl
81416	Exome sequence analysis
81426	Genome sequence analysis
81536	Oncology gynecologic
82952	Gtt-added samples
87187	Sc std microdil/agar mlc
87503	Influenza dna amp prob addl
87904	Phenotype dna hiv w/clt add
88314	Histochemical stains add-on
88332	Path consltj surg ea add blk
94645	Cont inhlj tx each addl hour
95940	Ionm in operatng room 15 min
95941	Ionm remote/>1 pt or per hr
99486	Suprv interfac trnsport addl
99602	Home nfs visit each addl hr
0054T	Bone srgry cmptr fluor image
0055T	Bone srgry cmptr ct/mri imag
0076T	S&i stent/chest vert art
0095T	Rmvl artific disc addl crvcl
0098T	Rev artific disc addl
0174T	Cad cxr with interp
0397T	Ercp w/optical endomicroscpy
G1028	Take home supply 8mg per 0.1
G2078	Take-home meth
G2079	Take-hom buprenorphine
G2080	Add 30 mins counsel
G2215	Home supply nasal naloxone
G2216	Home supply inject naloxon
S2351	Diskectomy, anterior, with d
S2900	Robotic surgical system

BILLING CODE 4169–69–C

The RUC also requested assigning the ZZZ global period to three anesthesia codes: CPT codes 01953, 01968, and 01969. However, currently all anesthesia codes use the XXX global period, and it is unclear whether the concept of an add-on global period would apply to anesthesia coding given that they are valued using base units and time units, unlike all other PFS services. For this reason, we are not proposing the ZZZ global period for these three codes at this time. We are soliciting comments from interested parties regarding the global period assignment for these three anesthesia codes, as well as the other codes listed in Table A–B7.

d. Updates to Practice Expense (PE) Methodology—Site of Service Payment Differential

We proposed a significant refinement to our PE methodology to better reflect trends in physician practice settings in the CY 2026 PFS final rule (90 FR 49292 through 49297). Under the finalized policy, we allocate half the amount of indirect PE RVUs per work RVU for services furnished in the facility setting compared to those allocated to services furnished in the non-facility setting. We noted in the CY 2026 PFS proposed rule (90 FR 32374) that this change to the indirect cost allocation methodology was intended to better recognize the relative resources involved in furnishing services paid under the PFS in facility and non-facility settings. We compared this change to our current methodology prior to CY 2026, which functionally presumed approximately equal indirect costs incurred by physicians across sites of service. This presumption was initially made in the context of most practitioners maintaining office practices independent of the facilities in which they provided care, and as we discussed in the CY 2026 PFS proposed and final rules, appears to be inconsistent with contemporary trends in physician practice where some significant portion of services furnished in facility settings are performed by medical practitioners who do not maintain fully independent practices

and are less likely to incur a comparable amount of indirect costs.

Since finalizing the proposal in the CY 2026 PFS final rule, we have heard from interested parties that the implementation of this policy resulted in an unintended, but significant, site of service differential for physician visits in nursing facility settings based solely on whether the beneficiary's stay is covered under Part A. For purposes of PFS payment, a service furnished to a patient in a skilled nursing facility during a Part A hospital stay (place of service 31) is considered to be in the ''facility'' setting, while a service furnished to a patient in a Part B stay (place of service 32) is considered to be in the ''non-facility'' setting, per the Medicare Claims Processing Manual (MCPM), Chapter 12, Section 20.4.2 at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c12.pdf.* Prior to CY 2026, the payment rate for these E/M services furnished in a skilled nursing facility (''facility'') and a nursing facility (''non-facility'') were equal. As intended, the 50 percent reduction to the allocation of indirect PE based on work RVUs that we finalized for CY 2026 shifted PE RVUs from the facility setting to the non-facility setting. However, for nursing facility and skilled nursing facility visits, the current site of service differential is determined based on the status of the beneficiary (that is, a Part A versus Part B stay) in that setting, rather than in the setting of care itself. Given that the resource costs for the professional involved in furnishing an E/M service would not be expected to differ based on whether the patient is in a Part A stay or not, we believe it is more accurate for these E/M services to be paid the same amount without regard to the beneficiary's Part A status. Therefore, we are proposing to address this anomaly for CY 2027 by equalizing the rate for nursing facility visits without regard to the beneficiary's status by setting the facility PE RVU equal to the non-facility PE RVU for CPT codes 99304 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward or low level of medical decision making. When using total time on the date of the encounter for code selection, 25 minutes must be met or exceeded.*), 99305 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 35 minutes must be met or exceeded.*), 99306 (*Initial nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 50 minutes must be met or exceeded.*), 99307 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*), 99308 (*Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.*), 99309 *(Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and moderate level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*), 99310 *(Subsequent nursing facility care, per day, for the evaluation and management of a patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 45 minutes must be met or exceeded.*), 99315 *(Nursing facility discharge management; 30 minutes or less total time on the date of the encounter*), and 99316 *(Nursing facility discharge management; more than 30 minutes total time on the date of the encounter*).

This particular situation illuminates ongoing concerns regarding the current site of service differential. For example, interested parties have suggested that the current binary of facility and non-facility does not account for the range of employment models associated with physician services that drive significant differences in actual practice expenses. Interested parties have encouraged us to refine our previously finalized policy to ensure it is more empirically grounded and narrowly tailored to independent physicians, consistent with the policy's original intent. Interested parties have also stated that the facility PE reductions have had a disparate effect on hospital medicine groups and hospitalists, particularly those that operate independently from their hospital or health systems. Interested parties have stated that independent hospital medicine groups account for approximately one-third to one-half of the hospital medicine groups nationwide, and they are unable to cut administrative and overhead costs enough to absorb our CY 2026 facility PE reductions. As a result, some interested parties have stated that the reductions are accelerating the insolvency of independent physician practices and leading to an increase in hospital consolidation. We note that we have heard no general consensus among interested parties to this effect, and we have received feedback that this policy supports independent practices.

In the CY 2026 PFS proposed rule, we sought comments on whether our proposal to reduce the portion of the facility PE RVUs allocated based on work RVUs to half the amount allocated to non-facility PE RVUs was an appropriate reduction or whether we should consider a different percentage reduction for CY 2026 or in future years. In finalizing the proposal, we noted that, while our change to the methodology for CY 2026 represented a starting point to correcting historic distortions in the allocation of indirect PE costs across settings of care, we intended to further examine our methodology and consider additional refinements based upon feedback received and any studies or data sources identified.

For CY 2027, we remain open to more specific data that addresses the variability, as well as feedback on how to update the valuation and payment methodologies to better reflect the relative resources involved in furnishing the services, both across settings of care, and within the context of an evolving ecosystem of care models and business arrangements. Historically, we have relied extensively on specialty-specific PE/HR survey data and the binary site of service differential to best reflect variable PE costs.

To better inform our consideration of how to account for practice expenses under the PFS methodologies, including the current differentials that are effectuated based on the binary facility/non-facility settings of care, we are seeking comment on how PE costs vary for physicians and other professionals, not only based on whether they practice in part or exclusively in a facility setting but also based on how their costs vary when they are employed by health systems, hospitals, or other entities. We noted in the CY 2026 PFS final rule that (90 FR 49292) that the AMA has stated

that physician practices maintain some indirect PE costs for physicians who are solely facility-based such as coding, billing, and scheduling. That being said, we generally agree with the concerns presented by MedPAC on the growth of exclusively facility-based physicians and agree that potential overpayments for indirect practice expense costs could be a driver of clinician movement to higher cost settings without creating commensurate clinical value. This is why we lowered indirect PE for facility-based physician to 50 percent in the CY 2026 PFS final rule.

Moving forward, we remain interested in ensuring indirect PE RVUs are appropriately accounting for indirect PE costs. As such, we are seeking information that will help illuminate to what extent these costs are truly incurred when the professionals are employed by the hospital and/or practice primarily in the hospital and are not already accounted for in the existing OPPS payments. For example, when a physician is employed by and practicing in a hospital, what portion of the indirect PE is associated with the PFS service, versus costs that are associated with the payment to the hospital, such as those paid under the OPPS?

We are seeking comment on the amount of indirect PE hospital-employed physicians incur when they furnish care within a facility. For these physicians, is the 50 percent indirect PE allocation accurate or could it possibly be less than 50 percent, such as 0 percent? In the case that there are little to no indirect costs incurred by the physician or other professionals, and these costs are borne by the hospital, we believe that these costs are not appropriately accounted for under the PFS and we may well be overestimating the relative resource costs compared to other PFS services. In consideration of the accuracy of the current 50 percent indirect PE allocation for services furnished in the facility setting, we are also seeking comment on whether and how we might, alternatively or additionally, define and identify physicians and professionals who are employed by hospitals, health systems, or other entities to ensure the services they furnish are not inappropriately consuming PE RVUs that would be more appropriately assigned to services furnished by professionals incurring comparatively greater practice expenses. Specifically, we are seeking comment on whether a new HCPCS modifier for employed physicians would be a reasonable way to identify and reduce facility PE from the services they perform in the facility setting, or whether there are other methods we could consider.

We are seeking comment on what are the primary variables we should consider to continue to improve our data sources, allocation methodologies, and payment rates across settings of care, to best reflect the resources involved in furnishing PFS services by professionals and suppliers operating in a complex marketplace, across settings of care. We remain interested in objective data regarding payment arrangements between hospitals, health systems, other employers and physicians, including which costs are incurred and whether the full range of costs are truly incurred by physicians and other professionals in these kinds of employment relationships. This would help us understand and improve how PE is allocated across settings of care, both in general and for specific kinds of services.

6. Strategies To Improve Payment Transparency, Accuracy, and Congruency Across Payment Systems

a. Professional and Technical Components

Because PFS services are paid across settings of care, and are the primary way that Medicare pays medical professionals, understanding the structure of PFS payment is a critical part of price transparency for Medicare, other payers, and consumers. Likewise, misunderstanding or confusion about what relative resources are incorporated in specific PFS payment rates can be a significant obstacle for payers and consumers navigating the health care market. For example, approximately 4,100 services paid as ''global surgical packages,'' (herein 'globals') are valued as bundled payments that aggregate multiple components of care into a single payment amount, including post-operative visits that are presumed to occur in particular settings (for example, inpatient hospital, outpatient hospital, office) regardless of where the services actually take place. Most PFS services are valued with a site of service binary, where the non-facility setting is the aggregation of all relative resources involved in furnishing the professional and technical aspects of the service, and the facility setting, where the rate generally excludes the facility costs involved in the service since those costs are addressed through separately reported facility fees. In contrast to these two constructs, there are other codes (mainly describing diagnostic and imaging services) that may be billed with professional component (PC, or modifier 26) and technical component (TC) modifiers, or without modifiers (global codes) that are paid for the complete global service. These differences in how payments are constructed and displayed can make it difficult for interested parties and CMS to evaluate relative payment rates, underlying resource costs, and value across settings of care.

These challenges are further compounded by differences across Medicare payment systems in how similar services are defined, bundled, and paid. For example, some payment systems incorporate technical inputs and facility resources into a single payment. This variation can obscure meaningful comparisons across sites of care and may complicate efforts to advance site-neutral payment policies aimed at reducing incentives for hospitals to acquire physician practices and limit site-of-care decisions based on financial considerations. As CMS continues to consider approaches that remove obstacles from market competition across settings of care, especially by improving transparency, comparability of PFS payments is an important foundational step.

To facilitate more consistent comparisons across services and settings, we have developed a public use file that displays, for services that are not currently billable with TC/26 modifiers, RVUs amounts that reflect the relative resources involved in furnishing professional and technical aspects of the services, which is available on the CMS website under downloads for the CY 2027 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* This file is intended to improve transparency regarding how PFS payments may be conceptually divided between physician professional and technical components of the services, especially to illuminate the differences in fees between technical aspects of PFS services compared to facility fees across settings of care. We believe that making these components more visible, where feasible, may help interested parties better understand the structure of PFS payments and support more informed comparisons across settings of care. We note that we have excluded 010- and 090-day global surgery services from display in this public use file since there are numerous ways to consider how the structure of payment for those codes may be best understood. The use of bundled payments for the 010- and 090-day global surgery services results in aggregated valuation for all pre-operative, intra-operative, and post-

operative services furnished over a defined period (0-, 10-, or 90-day global periods), including services by both physician and clinical staff and practice expense without clear visibility into how each component contributes to the total bundled valuation. While we note that the current structure of global surgery services has effectively obscured how the components of care are individually valued and limited our ability to disaggregate them for purposes of this public use file, we seek comment on how to address this problem, either in possible improvements to the global surgery packages or, at least, in the best way to make their component pieces transparent. Additionally, we note that there is a subset of additional exclusions from this public use file, such as codes subject to the cognitive services floor and the statutory phase-in of significant RVU reductions, due to technical challenges with how these policies are implemented that hinder the disaggregation of their component parts.

We emphasize that we are not proposing any changes to existing payment or billing policies, including the use of the 010- and 090-day globals. Rather, this effort is intended to improve transparency and provide a foundation for future rulemaking. We believe that greater visibility into how the professional and technical aspects of PFS services are valued and paid, where feasible, may enhance the ability of consumers, and payers (including CMS) to assess relativity across services, may enhance CMS's efforts to improve valuation over time, and support broader efforts to align payments across settings of care. We are seeking comment on several aspects of this approach. First, we seek comment on the utility of displaying RVUs associated with professional and technical aspects of services that are not currently billable with TC/26 modifiers, including how we may use this information to assess payment differences across settings. Again, we also seek comment on potential approaches CMS could consider in future rulemaking to improve transparency for services currently paid as globals. Specifically, we are interested in feedback on how CMS could develop methodologies to more clearly identify and, where appropriate, disaggregate the underlying components of these services. We are also interested in comments on how CMS could ''right-size'' payments for the globals over time to ensure they remain aligned with current clinical practice and resource costs, are more readily updated based on empirical data, and do not obscure differences in cost and value across settings of care.

b. Global Surgical Packages

We finalized a policy in the CY 2015 PFS final rule (79 FR 67582 through 67591) to transition all 10-day and 90-day globals to 0-day globals, allowing any post-operative visits furnished after the day of the procedure to be billed as a standalone visit. CMS was prohibited from implementing this policy through section 523(a) of the Medicare Access and CHIP Reauthorization Act (MACRA) and was required to collect data on how to best value globals. CMS did so through a research contract with RAND and a data-collection process over several years to develop data to improve the payment rates for these services. Data collection has been based on reporting of CPT code 99024 (*Postoperative follow-up visit, normally included in the surgical package, to indicate that an evaluation and management service was performed during a postoperative period for a reason(s) related to the original procedure*), which is limited to practices with 10 practitioners or more, limited to nine States, and is used solely for data collection so it has no associated payment with reporting the code. In the CY 2019 PFS final rule (83 FR 59503), we released findings that only 4 percent of reviewed 10-day globals and 67 percent of reviewed 90-day globals had one or more post-operative visit which occurred during the global period and sought comment on potential approaches for revaluing the globals based on these findings (83 FR 59504). In the CY 2023 PFS proposed rule (87 FR 45877 through 45880), CMS reviewed the prior work and conversations around global valuations, solicited feedback from the public, and has continued to explore ways over the years to address valuation of the globals that would be minimally disruptive to the PFS.

Over the past several years, CMS has taken several iterative steps to improve payment accuracy for the globals. In the CY 2025 PFS final rule (89 FR 97964 through 97968), CMS expanded the applicability of the transfer of care modifiers to address instances where separate practitioners are billing for standalone E/M visits during the global period more directly with mandatory reporting of payment modifiers in clinical cases when there is both a formal or informal transfer of care between practitioners furnishing distinct portions of a global service. CMS also created a post-operative care services add-on code to more appropriately reflect the time and resources involved for practitioners who were not involved in furnishing the surgical procedure. CMS is continuing to explore further steps to improve accountability and more accurate payment and what additional next steps CMS could take to improve the payment rates for global services.

In keeping with the administration priorities and aligning spending and value, we are proposing to pause the data collection required by MACRA based on RAND's findings over the past several years. We remain interested in how best to use and collect this data going forward and ways we might consider improving this data collection. We currently have several years of data that have continued to illustrate what we believe is the issue with the post-operative visits during the global period and how these visits are not occurring, yet providers are still being paid for these visits under the current global payment policy. Additionally, we believe that the current data collection may be causing undo burden to providers and we believe that pausing the data collection will aid in burden reduction for practitioners. We do however question whether a more robust data collection would be appropriate and if we should have all providers report CPT code 99024.

We are also seeking comment on the question we mentioned earlier in this section, as to whether CMS should have all providers report CPT code 99024, and also other data sources we might consider to more accurately value the globals.

We are posting a public use file with this proposed rule to display the imputed RVUs associated with both the 10- and 90-day post-operative visits based on a purely arithmetic approach to understand the valuation of the services based on the data that was analyzed. This public use file shows the current work RVUs, the number of post-operative visits that are reported to CMS using no-pay HCPCS code 99024, and the work RVUs remaining if all post-operative visits are removed. This public use file is available on the CMS website under downloads for the CY 2027 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-ServicePayment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* We welcome comments on potential revaluation strategies that we may consider through future rulemaking.

C. Payment for Medicare Telehealth Services

As discussed in prior rulemaking, several conditions must be met for Medicare to make payment for

telehealth services under the PFS. See further details and full discussion of the scope of Medicare telehealth services in the CY 2018 PFS final rule (82 FR 53006), the CY 2021 PFS final rule (85 FR 84502), the CY 2024 PFS final rule (88 FR 78861 through 78866), the CY 2026 PFS final rule (90 FR 49316 through 49320), and in 42 CFR 410.78 and 414.65. Our current 3-step review process reflects the stepwise method by which we consider requests to add services to or remove services from the Medicare Telehealth Services List, beginning with the CY 2026 Medicare Telehealth Services List:

Step 1. Determine whether the service is separately payable under the PFS.

Step 2. Determine whether the service is subject to the provisions of section 1834(m) of the Act.

Step 3. Review the elements of the service as described by the HCPCS code and determine whether each of them is capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3).

1. Changes to the Medicare Telehealth Services List

a. Requests To Add Services to the Medicare Telehealth Services List for CY 2027

We did not receive any requests to add or remove services from the Medicare Telehealth Services List for CY 2027.

Consistent with the deadline for our receipt of code valuation recommendations from the American Medical Association's Relative Value Scale Update Committee (AMA RUC) and other interested parties established in the CY 2019 PFS final rule (83 FR 59491) and with the process set forth in prior calendar years, for CY 2027, requests to add services to the Medicare Telehealth Services List must have been submitted to and received by CMS by February 10, 2026. Consistent with the deadline for our receipt of code valuation recommendations from the AMA RUC and other interested parties established in the CY 2019 PFS final rule (83 FR 59491) and with the process set forth in prior calendar years, for CY 2028, requests to add services to the Medicare Telehealth Services List must be submitted to and received by CMS by February 10, 2027. Each request submitted by the deadline to add a service to the Medicare Telehealth Services List must include any supporting documentation the requester wishes CMS to consider. Because we use the annual PFS rulemaking process to make changes to the Medicare Telehealth Services List, requesters are advised that any information submitted as part of a request is subject to public disclosure for this purpose. For more information on submitting a request to add services to the Medicare Telehealth Services List, including where to send these requests, and to view the current Medicare Telehealth Service List, see our website at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

b. CMS Proposal To Add New Codes to the List

We are proposing to add HCPCS G-codes GACP1 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), first 20 minutes of clinical staff time with the patient, family member(s), directed by a treating physician or other treating qualified health care professional*), GACP2 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), each additional 20 minutes with the patient, family member(s), directed by a treating physician or other treating qualified health care professional (List separately in addition to code for primary procedure*)), GSMAS (*Voluntary, group-based medical session involving multiple patients with common medical condition(s), receiving medical care in a group setting; billed and led by a physician or qualified nonphysician practitioner and may include services provided by other qualified healthcare professionals, clinical staff, or auxiliary personnel under the direction of the supervising physician or other practitioner. Session integrates group education, counseling, and peer support with individualized patient clinical assessment and care, 2–10 patients, billed once per patient, per session.*), GSLPP (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual; for the pediatric population up to age 18 or 21*), and GADV1 (*Office or other outpatient evaluation and management service(s) for the diagnosis and treatment of vaccine adverse effects, new or established patient; each 15 minutes personally performed by the physician or qualified healthcare professional (list separately in addition to CPT codes 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350)*) to the Medicare Telehealth Services List. If finalized, these services will be separately payable under the PFS. These services will be subject to the provisions of section 1834(m) of the Act, as they are inherently face-to-face services and would serve as a substitute for an in-person encounter. We also believe that the elements of these services as described by the HCPCS codes are capable of being furnished using an interactive telecommunications system as defined in § 410.78(a)(3). We refer readers to the relevant proposal in section II.D. of this proposed rule for further background on these proposed codes.

2. Telehealth Flexibilities and Modifiers

As discussed in the CY 2021 PFS final rule (85 FR 84506), legislation enacted to address the PHE for COVID–19 provided the Secretary with new authorities under section 1135(b)(8) of the Act, as added by section 102 of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (Pub. L. 116–123, March 6, 2020) and subsequently amended by section 6010 of the Families First Coronavirus Response Act (Pub. L. 116–127, March 18, 2020) and section 3703 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020), to waive or modify Medicare telehealth payment requirements during the PHE for COVID–19.

We used these authorities to establish several flexibilities to accommodate changes in the delivery of care during the PHE. Through waiver authority under section 1135(b)(8) of the Act, in response to the PHE for COVID–19, we removed the geographic and site of service originating site restrictions in section 1834(m)(4)(C) of the Act, as well as restrictions in section 1834(m)(4)(E) of the Act on the types of practitioners who may furnish telehealth services, for the duration of the PHE for COVID–19. We also used waiver authority to allow certain telehealth services to be furnished via audio-only communication technology. At the end of the PHE for COVID–19, these waivers and interim policies were set to expire, and payment for Medicare telehealth services would have once again been limited by the requirements of section 1834(m) of the Act. These flexibilities have been extended by Congress numerous times since, most recently in the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75, February 3, 2026).

Section 6209(a) and (b) of the CAA, 2026 extends the flexibilities for Medicare telehealth services to remove the geographic restrictions, expand the list of acceptable originating sites, and expand the array of practitioners eligible

to furnish telehealth services from January 30, 2026 to the extended date of December 31, 2027. Section 6209(d) of the CAA, 2026 delays the in-person visit requirements for mental health services furnished through telehealth from January 30, 2026 to the extended date of January 1, 2028. Section 6209(e) of the CAA, 2026 extends the flexibilities to allow audio-only Medicare telehealth services from January 30, 2026 to the extended date of January 1, 2028. To align with these extensions, § 410.78 has been revised, detailed later in this proposed rule.

Additionally, section 6209(g) of the CAA, 2026, requires CMS to establish modifiers for telehealth services in certain instances, effective January 1, 2027. These modifiers do not affect payment and are required for claims for telehealth services that are furnished through a virtual telehealth platform by a physician or practitioner that contracts with an entity that owns such virtual platform; or for which a physician or practitioner has a payment arrangement with an entity for use of such virtual platform; and for claims for telehealth services that are furnished incident to a physician's or practitioner's professional service.

In accordance with section 6209(g) of CAA, 2026, we are creating modifiers BB and BC. Guidance on use of these modifiers will be available on the CMS website. Any updates to this policy will be issued via subregulatory guidance in accordance with section 6209(h) of the CAA, 2026, which authorizes the Secretary to implement section 6209 via program instruction or otherwise.

3. Telehealth Critical Care Consultations

In the CY 2017 PFS final rule (81 FR 80352 through 80353), we established HCPCS codes G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth*) and G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth*) to report telehealth consultations for a patient requiring critical care services. These services were modeled after CPT codes 99291 (*Critical care, evaluation and management of the critically ill or critically injured patient; first 30 to 74 minutes*) and 99292 (*Critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (list separately in addition to code for primary service)*).

When adding some services to the Medicare Telehealth Services List in the past, we have included certain frequency restrictions on how often physicians and other practitioners may furnish the service via telehealth. These include a limitation of one critical care consultation service furnished via telehealth per day, added in the CY 2017 final rule (81 FR 80198). In the CY 2026 PFS final rule, we finalized permanently removing frequency limitations on furnishing these services via telehealth (90 FR 49324 through 49325).

We continue to believe that physicians and other practitioners, who have the greatest familiarity and insight into the needs of individual beneficiaries, can use their complex professional judgment to determine whether they can safely furnish a service via telehealth, given the entirety of the circumstances, including the clinical profile and needs of the beneficiary, to determine the appropriate service modality. We strive to balance the goals of increasing physician or practitioner and patient choice of service modality with consideration of patient safety for all Medicare beneficiaries. As technology advances and more services may be safely furnished via telehealth and paid under the PFS, it is increasingly important for physicians and other practitioners to exercise their professional judgment in determining the generally appropriate service modality for their patients to receive a service.

Since the permanent removal of the frequency limitation of one critical care consultation service furnished via telehealth per day, we have received questions about language in the code descriptors for HCPCS codes G0508 (*Telehealth consultation, critical care, initial, physicians typically spend 60 minutes communicating with the patient and providers via telehealth*) and G0509 (*Telehealth consultation, critical care, subsequent, physicians typically spend 50 minutes communicating with the patient and providers via telehealth*) describing ''initial'' and ''subsequent'' consultations, as well as questions regarding the language about the typical time spent on the service. To clarify the requirements for billing these services, we are proposing the following revised code descriptors:

- G0508: *Telehealth consultation, critical care; first 30 to 74 minutes.*
- G0509: *Telehealth consultation, critical care; each additional 30 minutes (List separately in addition to code for primary service).*

We welcome comments on this proposal.

4. Changes To Teaching Physicians' Billing for Services Involving Residents or Teaching Physicians With Virtual Presence

In the CY 2021 PFS final rule (85 FR 84577 through 84585), we finalized a temporary policy that allowed the teaching physician to have a virtual presence in all teaching settings, but only in clinical instances when the service was furnished virtually (for example, a three-way telehealth visit, with all parties in separate locations). This permitted teaching physicians to have a virtual presence during the key portion of the Medicare telehealth service for which payment was sought, through audio/video real-time communications technology, in all residency training locations through December 31, 2024.

As summarized in the CY 2025 PFS final rule (89 FR 97764 through 97765), commenters encouraged CMS to establish this policy permanently and include in-person services to promote access to care, and stated that teaching physicians should be allowed to determine when their virtual presence would be clinically appropriate based on their assessment of the patient's needs and the competency level of the resident. In the CY 2026 PFS final rule, we finalized permanently allowing teaching physicians to have a virtual presence in all teaching settings, only in clinical instances when the service is a three-way telehealth visit, with the teaching physician, resident, and patient in different locations.

We have received feedback from interested parties that indicates that our current policy for teaching physicians and residents can, in somewhat rare cases, cause logistical complexities in scenarios where either the teaching physician or resident is already in the same physical location as the beneficiary. For CY 2027, we are proposing a modification to our previously finalized policy. Rather than requiring the teaching physician, resident, and patient to each be in a different location, we are proposing to allow teaching physicians to bill for services involving residents when either the teaching physician or resident is in the same physical location as the beneficiary. We would generally interpret physical presence to be defined as either the teaching physician or resident in the same room as the beneficiary, but we are seeking comment on other scenarios in which this may be appropriate. This would only be applicable to services that are on the Medicare Telehealth Services List. As always, documentation in the

medical record must continue to demonstrate whether the teaching physician was physically present or present through audio/video real-time communications technology at the time of the Medicare telehealth service, which includes documenting the specific portion of the service for which the teaching physician was present through audio/video real-time communications technology. In accordance with section 1842(b)(7)(A)(i)(I) of the Act, the teaching physician must have personal oversight and involvement over the management of the portion of the case for which the payment is sought. We are seeking comments on this proposal.

5. Telehealth Originating Site Facility Fee Payment Amount Proposed Update

Section 1834(m)(2)(B) of the Act established the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31, 2002 at $20.00, and specifies that, for telehealth services furnished on or after January 1 of each subsequent calendar year, the telehealth originating site facility fee is increased by the percentage increase in the Medicare Economic Index (MEI) as defined in section 1842(i)(3) of the Act. The proposed percentage increase in the MEI for CY 2027 is 2.5 percent and is based on the expected historical percentage increase of the 2017-based MEI. For the final rule, we propose to update the MEI increase for CY 2027 based on historical data through the second quarter of 2026. Therefore, for CY 2027, the proposed payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is $32.65. Table A–C1 shows the Medicare telehealth originating site facility fee and the corresponding MEI percentage increase for each applicable time period.

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TABLE A-C1: THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE

Time Period	MEI (%)	Facility Fee for Q3014
Oct. 1, 2001 to Dec. 31, 2002	n/a	$20.00
2003	3.0	$20.60
2004	2.9	$21.20
2005	3.1	$21.86
2006	2.8	$22.47
2007	2.1	$22.94
2008	1.8	$23.35
2009	1.6	$23.72
2010	1.2	$24.00
2011	0.4	$24.10
2012	0.6	$24.24
2013	0.8	$24.43
2014	0.8	$24.63
2015	0.8	$24.83
2016	1.1	$25.10
2017	1.2	$25.40
2018	1.4	$25.76
2019	1.5	$26.15
2020	1.9	$26.65
2021	1.4	$27.02
2022	2.1	$27.59
2023	3.8	$28.64
2024	4.6	$29.96
2025	3.5	$31.01
2026	2.7	$31.85
2027*	2.5	$32.65

*Reflects the most recent estimate of the CY 2027 MEI percentage increase and will be updated in the final rule based on historical data through the second quarter of 2026.

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D. Valuation of Specific Codes Including Potentially Misvalued Services Under the PFS

1. Background: Process for Valuing New, Revised, and Potentially Misvalued Codes

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since the inception of the PFS, it has also been a priority to revalue services regularly to make sure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the 5-year review

process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011, and revised MP RVUs in CY 2010, CY 2015, and CY 2020. Under the 5-year review process, revisions in RVUs were proposed and finalized via rulemaking. In addition to the 5-year reviews, beginning with CY 2009, CMS and the AMA's Relative Value Unit Update Committee (RUC) identified a number of potentially misvalued codes each year using various identification screens, as outlined in section II.C. of this proposed rule, Potentially Misvalued Services under the PFS. Historically, when we received RUC recommendations, our process had been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accepted public comments about those valuations. For services furnished during the calendar year following the publication of interim final rates, we paid for services based upon the interim final values established in the final rule. In the final rule with comment period for the subsequent year, we considered and responded to public comments received on the interim final values and typically made any appropriate adjustments and finalized those values.

In the CY 2015 PFS final rule with comment period (79 FR 67547), we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. Beginning with the CY 2017 PFS proposed rule (81 FR 46162), the new process was applicable to all codes, except for new codes that describe truly new services. For CY 2017, we proposed new values in the CY 2017 PFS proposed rule for the vast majority of new, revised, and potentially misvalued codes for which we received complete RUC recommendations by February 10, 2016. To complete the transition to this new process, for codes for which we established interim final values in the CY 2016 PFS final rule with comment period (81 FR 80170), we reviewed the comments received during the 60-day public comment period following release of the CY 2016 PFS final rule with comment period (80 FR 70886), and re-proposed values for those codes in the CY 2017 PFS proposed rule. We considered public comments received during the 60-day public comment period for the proposed rule before establishing final values in the CY 2017 PFS final rule. As part of our established process, we will adopt interim final values only in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

As part of our obligation to establish RVUs for the PFS, we thoroughly review and consider available information including recommendations and supporting information from the RUC, the Health Care Professionals Advisory Committee (HCPAC), public commenters, medical literature, Medicare claims data, comparative databases, comparison with other codes within the PFS, as well as consultation with other physicians and healthcare professionals within CMS and the Federal Government as part of our process for establishing valuations. Where we concur that the RUC's recommendations, or recommendations from other commenters, are reasonable and appropriate and are consistent with the time and intensity paradigm of physician work, we proposed those values as recommended. Additionally, we continually engage with interested parties, including the RUC, regarding our approach for accurately valuing codes, and as we prioritize our obligation to value new, revised, and potentially misvalued codes. We continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process.

2. Methodology for Establishing Work RVUs

a. Background

For each code identified in this section, we conduct a review that includes the current work RVU (if any), RUC-recommended work RVU, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our reviews of recommended work RVUs and time inputs generally include, but have not been limited to, a review of information provided by the RUC, the HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, consultation with other physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation (see the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329) for more information). When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process.

Components that we use in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could include the CPT codes that make up the bundled code and the inputs associated with those codes. We use the building block methodology to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Magnitude estimation refers to a methodology for valuing work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, we frequently utilize an incremental methodology in which we value a code based upon its incremental difference between another code and another family of codes. Section 1848(c)(1)(A) of the Act specifically defines the work component as the resources that reflect time and intensity in furnishing the service. Also, the published literature on valuing work has recognized the key role of time in overall work. For particular codes, we refine the work RVUs in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intraservice time.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently, there are preservice time packages for services typically furnished in the facility setting (for example, preservice time packages

reflecting the different combinations of straightforward or difficult procedure, and straightforward or difficult patient). Currently, there are three preservice time packages for services typically furnished in the non-facility setting.

We have developed several standard building block methodologies to value services appropriately when they have common billing patterns. For example, in cases where a service is typically furnished to a beneficiary on the same day as an E/M service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. Our longstanding adjustments have reflected a broad assumption that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit.

Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service multiplied by the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU.

Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time had already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, now addresses the overlap in time and work when a service is typically furnished on the same day as an E/M service.

The following paragraphs discuss our approach to reviewing RUC recommendations and developing proposed values for specific codes. When they exist, we also include a summary of interested party reactions to our approach. We noted that many commenters and interested parties have expressed concern over the years with our ongoing adjustment of work RVUs based on changes in the best information we had regarding the time resources involved in furnishing individual services. We have been particularly concerned with the RUC's and various specialty societies' objections to our approach given the significance of their recommendations to our process for valuing services and since much of the information we use to make the adjustments is derived from their survey process. We note that we are obligated under the statute to consider both time and intensity in establishing work RVUs for PFS services. As explained in the CY 2016 PFS final rule with comment period (80 FR 70933), we recognize that adjusting work RVUs for changes in time is not always a straightforward process, so we have applied various methodologies to identify several potential work values for individual codes.

We observed that for many codes reviewed by the RUC, recommended work RVUs have appeared to be incongruous with recommended assumptions regarding the resource costs in time. This has been the case for a significant portion of codes for which we recently established or proposed work RVUs that are based on refinements to the RUC-recommended values. When we adjusted work RVUs to account for significant changes in time, we started by looking at the change in the time in the context of the RUC-recommended work RVU. When the recommended work RVUs do not appear to account for significant changes in time, we employed different approaches (including survey data, building blocks, crosswalks to key reference or similar codes, and magnitude estimation) to identify potential values that reconcile the recommended work RVUs with the recommended time values. Many of these methodologies, such as survey data, building block, crosswalks to key reference or similar codes, and magnitude estimation have long been used in developing work RVUs under the PFS. In addition to these, we sometimes use the relationship between the old time values and the new time values for particular services to identify alternative work RVUs based on changes in time components.

In so doing, rather than ignoring the RUC-recommended value, we used the recommended values as a starting reference and then applied one of these several methodologies to account for the reductions in time that we believe were not otherwise reflected in the RUC-recommended value. If we believe that such changes in time are already accounted for in the RUC's recommendation, then we do not make such adjustments. Likewise, we do not arbitrarily apply time ratios to current work RVUs to calculate proposed work RVUs. We use the ratios to identify potential work RVUs and consider these work RVUs as potential options relative to the values developed through other options.

While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs, we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner. If the RUC's recommendation has appeared to disregard or dismiss the changes in time, without a persuasive explanation of why such a change should not be accounted for in the overall work of the service, then we generally used one of the aforementioned methodologies to identify potential work RVUs, including the methodologies intended to account for the changes in the resources involved in furnishing the procedure (such as building blocks or crosswalks to key reference or similar codes).

Several interested parties, including the RUC, have expressed general objections to our use of these methodologies and suggested that our actions in adjusting the recommended work RVUs are inappropriate; other interested parties have also expressed general concerns with CMS refinements to RUC-recommended values in general. In the CY 2017 PFS final rule (81 FR 80272 through 80277), we responded in detail to several comments that we received regarding this issue. In the CY 2017 PFS proposed rule (81 FR 46162), we requested comments regarding potential alternatives to making adjustments that would recognize overall estimates of work in the context of changes in the resource of time for particular services; however, we did not receive any specific potential alternatives. As described earlier in this section, crosswalks to key reference or similar codes are one of the many methodological approaches we employed to identify potential values that reconcile the RUC-recommended work RVUs with the recommended time values when the RUC-recommended work RVUs did not appear to account for significant changes in time.

We have historically relied on survey data provided by the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC) to estimate practitioner time, work intensity, and practice expense for the purpose of establishing RVUs for the codes used for payment under the PFS. As described in section II.C. of this

proposed rule, CMS regularly revalues codes as part of its potentially misvalued codes initiative, as required by section 1848(c)(2)(K) of the Act, using RUC survey data that shows clinicians' estimates of how long a particular service takes to complete. In the CY 2025 PFS final rule, we summarized public comments that we had received expressing concerns with using RUC data as a source of valuation and identifying a need for empirical data in the context of valuing advanced primary care management services (89 FR 97898). In response to these comments, we indicated that we were open to alternative recommendations for how to price these and other services, and that we would consider all options presented to us with a preference for information with empirical evidence behind it. We also reminded commenters that we do not exclusively rely on RUC recommendations and can receive data and recommendations from other outside sources as well.

In the CY 2019 PFS final rule (83 FR 59515), in response to comments, we clarified that terms ''reference services,'' ''key reference services,'' and ''crosswalks'' as described by the commenters are part of the RUC's process for code valuation. These are not terms that we created, and we do not agree that we necessarily must employ them in the identical fashion for the purpose of discussing our valuation of individual services that come up for review. However, in the interest of minimizing confusion and providing clear language to facilitate feedback from interested parties, we stated that we would seek to limit the use of the term, ''crosswalk,'' to those cases where we made a comparison to a CPT code with the identical work RVU (83 FR 59515). We noted that we also occasionally make use of a ''bracket'' for code valuation. A ''bracket'' refers to when a work RVU falls between the values of two CPT codes, one at a higher work RVU and one at a lower work RVU.

We look forward to continuing to engage with interested parties and commenters, including the RUC, as we prioritize our obligation to value new, revised, and potentially misvalued codes; and we will continue to welcome feedback from all interested parties regarding valuation of services for consideration through our rulemaking process. We refer readers to the detailed discussion in this section of the valuation considered for specific codes. Table A–DX contains a list of codes and descriptors for which we proposed work RVUs for CY 2027; this includes all codes for which we received RUC recommendations by February 10, 2026. The proposed work RVUs, work time and other payment information for all CY 2027 payable codes are available on the CMS website under downloads for the CY 2027 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Feefor-ServicePayment/PhysicianFeeSched/index.html*).

b. Efficiency Adjustment

In the CY 2026 final rule, we finalized the establishment of an efficiency adjustment to the work RVUs, as well as corresponding updates to the intraservice portion of physician time inputs for non-time-based services, with refinements (90 FR 49334 through 49345). We finalized a policy to apply this efficiency adjustment to the intraservice portion of physician time and work RVUs every 3 years. To calculate the efficiency adjustment, we finalized the use of the MEI productivity adjustment over a 5-year look back period from CY 2022 to CY 2026. We noted that using more recent historical data from the BLS yielded an efficiency adjustment of 3.6 percent. As we discussed in the CY 2026 PFS proposed rule, our approach in applying an efficiency adjustment was to take into account changes in medical practice and to better reflect resources involved, and it was designed to be conservative in nature, as we were concerned about making too many changes at once to the current methodology. Therefore, we finalized the proposed efficiency adjustment of 2.5 percent. We also exempted additional codes, specifically time-based codes, services on the CMS telehealth list, and new codes for CY 2026, as reflected in the Codes Subject to Efficiency Adjustment file. This file with efficiency adjustment exemptions is issued annually and can be found in the public use files for CY 2027; the file is available on the CMS website under downloads for the CY 2027 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. For a full discussion of the efficiency adjustment, we direct readers to the CY 2026 PFS final rule (90 FR 49334 through 49345).

For CY 2027 rulemaking, the RUC made a number of work RVU recommendations prior to the finalization of the efficiency adjustment in the CY 2026 PFS final rule. In these cases, where the RUC's work RVU recommendation was based on a pre-adjusted work RVU, we have treated the recommendation as though the RUC had recommended the efficiency adjusted valuation. For example, the RUC initially recommended a work RVU of 0.35 for CPT code 95XX4 based on a crosswalk to the pre-adjusted work RVU of CPT code 95885. The work RVU of this crosswalk code became 0.34 after applying the efficiency adjustment, which we have used as the recommended valuation for CPT code 95XX4. This policy affected a relatively small number of the codes reviewed for CY 2027, and we have noted in the preamble where the efficiency adjustment affected a work valuation.

3. Methodology for the Direct PE Inputs To Develop PE RVUs

a. Background

On an annual basis, the RUC provides us with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code-by-code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the PFS, and consultation with physicians and health care professionals within CMS and the Federal Government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC's recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, are consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or non-facility direct PE inputs and refine the inputs accordingly.

Our review and refinement of the RUC-recommended direct PE inputs includes many refinements that are common across codes, as well as refinements that are specific to particular services. Table A–D11 details our refinements of the RUC's direct PE recommendations at the code-specific level. In section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), we address certain refinements that will be

common across codes. Refinements to particular codes are addressed in the portions of that section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We note that, on average, in any case where the impact on the direct cost for a particular refinement is $0.35 or less, the refinement has no impact on the PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU, as well as the impact on the indirect allocator for the average service. In this proposed rule, we also note that many of the refinements listed in Table A–D11 result in changes under the $0.35 threshold and would be unlikely to result in a change to the RVUs.

We note that the proposed direct PE inputs for CY 2027 are displayed in the CY 2027 direct PE input files, available on the CMS website under the downloads for the CY 2027 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. The inputs displayed there have been used in developing the CY 2027 PE RVUs as displayed in Addendum B (see *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates*).

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. The direct PE input recommendations generally correspond to the work time values associated with services. We believe that inadvertent discrepancies between work time values and direct PE inputs should be refined or adjusted in the establishment of proposed direct PE inputs to resolve the discrepancies.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We clarified this principle over several years of rulemaking, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items, as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up postoperative visits included in the global period for a service, the equipment time will also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the preservice or postservice tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of the clinical staff may be occupied with a preservice or postservice task related to the procedure. We also noted that we believe these same assumptions will apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items since any items in the room in question will be available if the room is not being occupied by a particular patient. For additional information, in that rule we referred readers to our discussion of these issues in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there is a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, we review the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to conform to the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the preservice clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

We refer readers to section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units (PE RVUs), for more information regarding the collaborative work of CMS and the RUC in improvements in standardizing clinical labor tasks.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC's recommendations include items that are not clinical labor, disposable supplies, or medical equipment or that cannot be allocated to individual services or patients. We addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use items included in these recommendations as direct PE inputs in the calculation of PE RVUs.

(5) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. However, some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2027 we received invoices for several new supply and equipment items. Tables A–D11 and A–D12 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.B. of this proposed rule, Determination of Practice Expense Relative Value Units, we encourage interested parties to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage

interested parties to submit invoices or other information to improve the accuracy of pricing for these items in the direct PE database by February 10th of the following year for consideration in future rulemaking, similar to our process for consideration of RUC recommendations.

We remind interested parties that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables A–D11 and A–D12 also include the number of invoices received and the number of non-facility allowed services for procedures that use these equipment items. We provide the non-facility allowed services so that interested parties will note the impact the particular price may have on PE relativity, as well as to identify items that are used frequently, since we believe that interested parties are more likely to have better pricing information for items used more frequently. A single invoice may not be reflective of typical costs, and we encourage interested parties to provide additional invoices so that we may identify and use accurate prices in the development of PE RVUs.

In some cases, we do not use the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we may use existing items as proxies for the newly recommended items. In other cases, we include the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the proposed PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(6) Service Period Clinical Labor Time in the Facility Setting

Generally speaking, our direct PE inputs do not include clinical labor minutes assigned to the service period because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs. We address code-specific refinements to clinical labor in the individual code sections.

(7) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the Outpatient Prospective Payment System (OPPS) Cap

We note that the list of services for the upcoming calendar year that are subject to the MPPR for diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services, and therapy services are displayed in the public use files for the PFS proposed and final rules for each year. In addition, the list of procedures that meet the definition of imaging under section 1848(b)(4)(B) of the Act, and therefore, are subject to the OPPS cap, are also displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2027 are available on the CMS website under downloads for the CY 2027 PFS final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. For more information regarding the history of the MPPR policy, we referred readers to the CY 2014 PFS final rule with comment period (78 FR 74261 through 74263).

Effective January 1, 2007, section 5102(b)(1) of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, enacted on February 8, 2006) amended section 1848(b)(4) of the Act to require that, for imaging services, if—(i) The technical component (TC) (including the TC portion of a global fee) of the service established for a year under the fee schedule without application of the geographic adjustment factor, exceeds (ii) The Medicare outpatient department (OPD) fee schedule amount established under the prospective payment system (PPS) for hospital OPD services under section 1833(t)(3)(D) of the Act for such service for such year, determined without regard to geographic adjustment under section 1833(t)(2)(D) of the Act, the Secretary shall substitute the amount described in clause (ii), adjusted by the geographic adjustment factor under the PFS, for the fee schedule amount for such TC for such year. As required by section 1848(b)(4)(A) of the Act, for imaging services furnished on or after January 1, 2007, we cap the TC of the PFS payment amount for the year (prior to geographic adjustment) by the Outpatient Prospective Payment System (OPPS) payment amount for the service (prior to geographic adjustment). We then apply the PFS geographic adjustment to the capped payment amount. Section 1848(b)(4)(B) of the Act defines imaging services as ''imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including PET), magnetic resonance imaging (MRI), computed tomography (CT), and fluoroscopy, but excluding diagnostic and screening mammography.'' For more information regarding the history of the cap on the TC of the PFS payment amount under the DRA (the ''OPPS cap''), we referred readers to the CY 2007 PFS final rule with comment period (71 FR 69659 through 69662).

For CY 2027, we identified new and revised codes to determine which services meet the definition of ''imaging services'' as defined at section 1848(b)(4)(B) of the Act for purposes of this cap. Beginning for CY 2027, we are proposing to include the following services in Table A–D1 on the list of codes to which the OPPS cap applies:

TABLE A-D1: CY 2027 PROPOSED CODE ADDITIONS TO THE OPPS CAP LIST

CPT Code	CPT Long Descriptor
70XX4	*Magnetic resonance angiography, head and neck, including image postprocessing; without contrast material(s)*
70XX5	*Magnetic resonance angiography, head and neck, including image postprocessing; with contrast material(s)*
70XX6	*Magnetic resonance angiography, head and neck; without contrast material(s) in one or both body regions, followed by contrast material(s) and further sequences in one or both body regions, including image postprocessing*
976XX	*Real-time fluorescence wound imaging with clinical darkness to identify presence, location, load of bacteria and measure wound size, per day*
92978	*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to code for primary procedure)*
92979	*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to code for primary procedure)*

We believe that these codes meet the definition of imaging services under section 1848(b)(4)(B) of the Act, and thus, should be subject to the OPPS cap.

c. Valuation of Specific Codes for CY 2027

(1) Fine Needle Aspiration (CPT Codes 10005 and 10006)

The RUC received notification of interest from a specialty society to re-review CPT codes 10005 (*Fine needle aspiration biopsy, including ultrasound guidance; first lesion*) and 10006 (*Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion*) at the January 2026 meeting.

We are proposing the RUC-recommended work RVUs of 1.35 for CPT code 10005 and 1.00 for 10006.

We are proposing the RUC recommended direct PE inputs for CPT codes 10005 and 10006 with one modification. The RUC submitted an invoice associated with this code family for an update in the price of the portable ultrasound (EQ250) equipment from its current price of $41,612.53 to $83,750.00. However, based on our review of current market pricing for portable ultrasounds, it appears that this type of equipment is becoming less expensive, not doubling in price over current . We also have reason to believe that the type of portable ultrasound listed on the submitted invoice represented the upper end of the market as opposed to the typical case. This invoice stated that the product in question constitutes ''a high-performance diagnostic ultrasound system'' including a 23-inch flat panel monitor. It is also not clear from the submitted invoice that the product in question is even a portable version of an ultrasound system.

Given that the price on this invoice was significantly higher than other portable ultrasounds available for purchase, we are not proposing to update the price of the EQ250 portable ultrasound which is used in many other HCPCS codes. Instead, we are proposing to create a new equipment item that describes a ''Fine Needle Aspiration portable ultrasound'' (ER130) which we propose to price at the submitted $83,750.00 price. The ER130 equipment is proposed to replace the previous EQ250 portable ultrasound at the same 37 minutes for CPT code 10005 and 17 minutes for CPT code 10006 as recommended by the RUC.

(2) Skin Cell Suspension Autograft (CPT Codes 15X19, 15X20, 15X21, and 15X22)

In September 2025, the CPT Editorial Panel created four codes to report skin cell suspension autograft (SCSA): CPT code 15X19 *(Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1% of body area of infants and children),* CPT code 15X20 *(Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)),* CPT code 15X21 *(Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children),* and CPT code 15X22 *(Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof (List separately in addition to code for primary procedure)).* The existing eight skin cell suspension autograft CPT codes (CPT codes 15011–15018) were deleted, and the ''Skin Cell Suspension Autograft'' guidelines were revised. The four new codes were surveyed for the January 2026 RUC meeting.

For CY 2027, we are proposing the RUC-recommended work RVUs of 10.97 for CPT code 15X19, 0.59 for CPT code 15X20, 11.28 for CPT code 15X21, and 0.98 for CPT code 15X22. We are proposing the RUC-recommended direct PE inputs for CPT codes 15X19, 15X20, 15X21, and 15X22 without refinement.

(3) Computer Assisted Surgical Navigation (CPT Code 20985)

CPT code 20985 *(Computer-assisted surgical navigational procedure for musculoskeletal procedures, image-less (List separately in addition to code for primary procedure))* was first identified via the high-volume growth screen in April 2024.[1] The RUC's Relativity Assessment Workgroup (RAW) reviewed the action plan for 20985 and recommended that the RUC refer CPT code 20985 to the CPT Editorial Panel for revision, to modify the descriptor and address overlap with codes 0054T and 0055T. At the February 2025 CPT Editorial Panel meeting, CPT code 20985 was revised to remove ''image-less'' for reporting computer-assisted surgical navigational procedures for musculoskeletal procedures.

We are proposing the RUC-recommended work RVU of 2.44, which is the current work RVU of CPT code 20985 after the efficiency adjustment was applied at the start of CY 2026. The RUC did not recommend and we are not proposing direct PE inputs for CPT code 20985.

(4) Ablation Therapy—Bone Tumors (CPT Code 209XX)

In February 2025, the CPT Editorial Panel approved new Category I add-on code 209XX (*Ablation therapy for reduction or eradication of bone tumor, including adjacent soft tissue when involved by tumor extension, cryoablation, open*) to describe and report cryoablation during an open

[1] *https://www.ama-assn.org/system/files/raw-progress-report.pdf.*

surgical procedure where the bone is frozen after a tumor resection. CPT code 209XX was surveyed for the April 2025 meeting where the specialty recommended an interim value; the code was resurveyed at the September 2025 RUC meeting and recommendations submitted to CMS.

We are proposing the RUC-recommended work RVU of 2.70 for CPT code 209XX. The RUC did not recommend and we are not proposing any direct PE inputs for this code.

(5) Intraosseous Fiducial Marker Placement (CPT Codes 209X1 and 209X2)

At the May 2025 CPT Editorial Panel Meeting, CPT approved the addition of two codes and guidelines to report percutaneous intraosseous fiducial marker placement for the first target site and each additional target site, respectively: CPT codes 209X1 (*Placement of localization marker(s)* (*e.g.*, fiducial marker[s]), *intraosseous, percutaneous, including imaging guidance, when performed; first target site)* and 209X2 *(Placement of localization marker(s)* (*e.g.*, fiducial marker[s]), *intraosseous, percutaneous, including imaging guidance, when performed; each additional target site)* . The specialties clarified that these codes are not new technology but are new codes to more accurately describe existing technology. These codes were surveyed for the October 2025 RUC meeting.

We are proposing the RUC-recommended work RVU of 3.00 for CPT code 209X1 and the RUC-recommended work RVU of 1.76 for CPT code 209X2.

We are proposing the RUC-recommended direct PE inputs for both codes in the family without refinement.

(6) Osteotomy—Spine (CPT Codes 22210, 22212, 22214, and 22216)

In CY 2025 rulemaking, CPT codes 22210 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical*), 22212 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic*), 22214 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar*), and 22216 (*Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (List separately in addition to primary procedure)*) were nominated as potentially misvalued services.

At the September 2025 CPT Editorial Panel Meeting, CPT revised the existing codes and guidelines to clarify that the codes include complete resection of the interspinous ligament and the entirety of the ligamentum flavum (*i.e.*, laminar and subarticular) to allow deformity correction through spinal column realignment. The osteotomy includes resection of the inferior portion of the lamina, the inferior facet of the cranial vertebra, the superior portion of the lamina, and the superior facet of the caudal vertebra. Following the revisions to the CPT guidelines and parentheticals for the code family, CPT codes 22210, 22212, 22214, and 22216 were surveyed for the January 2026 RUC meeting.

We disagree with the RUC's recommended work RVU for CPT codes 22210, 22212, and 22214 and we are proposing lower work RVUs in all three cases. We reviewed the RUC's recommended work valuations and found them to be high, relative to other codes with the same or similar times. We note that although the surveyed intraservice work time decreased substantially for all three of these codes, the RUC recommended either maintaining the current work RVU (for CPT code 22210) or increasing the work RVU (for CPT codes 22212 and 22214), stating that there was compelling evidence for increased work valuation based on a change in the patient population and a change in technology. However, these services maintained the same code descriptors, with only minor changes to their billing guidelines, indicating that despite the changes in technology and patient population the underlying procedure remains significantly similar. Therefore, we do not agree with the RUC that there has been an increase in intensity which would account for these recommended work RVUs. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs, we do believe that since the two components of work are time and intensity, absent an obvious or explicitly stated rationale why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner.

In the case of CPT codes 22210, 22212, and 22214, we believe that the work RVUs should be reduced to account for the significant decreases in surveyed intraservice work time.

Additionally, the postoperative office visit levels in this code family are increasing from three level 2 evaluation and management visits to one level 4 and two level 3 office visits. The shifting of the post-operative visits in this code family to higher level office visit codes that require more time, maintains the total time and thus reflects a higher intensity and can contribute to a higher work RVU which highlights our overall concerns with visits during the global period and how we believe that all of these visits are not typically occurring. We refer readers to section II.B. of this proposed rule under ''b. Global Surgical Packages'' for that discussion.

We disagree with the RUC recommended value of 24.75 for CPT code 22210 and we are instead proposing a work RVU of 23.12 based on a crosswalk to CPT code 34701 (*Endovascular repair of infrarenal aorta by deployment of an aorto-aortic tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, all endograft extension(s) placed in the aorta from the level of the renal arteries to the aortic bifurcation, and all angioplasty/stenting performed from the level of the renal arteries to the aortic bifurcation; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, penetrating ulcer)*). This code has a lower intraservice time and a similar total time. We noticed that the surveyed intraservice time for CPT code 22210 is decreasing by nearly an hour, from 170 minutes to 120 minutes, indicating that the procedure typically takes much less time to perform than it did at the time of last review. Although the RUC has recommended significantly more postoperative time in the inpatient and outpatient visits, which has caused the total time of the procedure to increase slightly, we note that this postoperative care should take place at a significantly lower intensity than the 50 minutes of intraservice time being removed from the code. We are concerned that, while the intraservice time for CPT code 22210 is decreasing from 170 to 120 minutes, this intraservice work time is being replaced with higher levels of post operative care to result in the total time being maintained similar to the current time. We believe that with the intraservice time going down, this reflects that the procedure has a lesser intensity than before and therefore it does not makes sense that the intensity of the post operative visit levels would increase. Separately, we continue to have concern with the post-operative visits in general and we do not believe the post-operative visits are happening and therefore would not justify the higher value.

We believe that it better serves relativity to propose a work RVU of 23.12, which maintains the current intensity of CPT code 22210, as opposed to proposing the RUC's recommended

work RVU of 24.75 which results in an intensity increase for this code. We are supporting this proposed work RVU of 23.12 with a pair of other 90-day global codes with similar work time values: CPT code 34718 *(Endovascular repair of iliac artery, not associated with placement of an aorto-iliac artery endograft at the same session, by deployment of an iliac branched endograft, including pre-procedure sizing and device selection, all ipsilateral selective iliac artery catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally in the internal iliac, external iliac, and common femoral artery(ies), and treatment zone angioplasty/stenting, when performed, for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation, penetrating ulcer), unilateral),* valued at a work RVU of 23.40 with an intraservice time of 120 minutes, and CPT code 34707 *(Endovascular repair of iliac artery by deployment of an ilio-iliac tube endograft including pre-procedure sizing and device selection, all nonselective catheterization(s), all associated radiological supervision and interpretation, and all endograft extension(s) proximally to the aortic bifurcation and distally to the iliac bifurcation, and treatment zone angioplasty/stenting, when performed, unilateral; for other than rupture (e.g., for aneurysm, pseudoaneurysm, dissection, arteriovenous malformation)),* valued at a work RVU of 21.72 with an intraservice time of 120 minutes.

We disagree with the RUC recommended value of 23.20 for CPT code 22212 and we are instead proposing a work RVU of 21.72 based on a crosswalk to CPT code 34707. This code has a lower intraservice time and a slightly lower total time. We noticed that the surveyed intraservice time for CPT code 22212 is also decreasing significantly, from 147 minutes to 120 minutes, which is offset by the RUC's recommendation of significantly more time in the postoperative visits. We do not agree with the RUC that the work RVU should be increasing by nearly 3.00 RVUs for a procedure where the intraservice time, which is likely to be the most difficult and dangerous part of the procedure, is going down by approximately half an hour. We believe that the RUC's recommended work RVU of 23.20 results in an intensity increase for this code and therefore it better serves relativity to propose a work RVU of 21.72, which maintains the current intensity of CPT code 22212. This proposed work RVU of 21.72 accounts for the decrease in intraservice time and change in the level of the postoperative office visits and is well bracketed by CPT code 34701, valued at a work RVU of 23.12 work with an intraservice time of 120 minutes, and CPT code 38115 *(Repair of ruptured spleen (splenorrhaphy) with or without partial splenectomy),* valued at a work RVU of 21.33 with an intraservice time of 120 minutes.

We disagree with the RUC recommended value of 21.72 for CPT code 22214 and we are instead proposing a work RVU of 19.53 based on a crosswalk to CPT code 44125 (*Enterectomy, resection of small intestine; with enterostomy*). This code has a lower intraservice time and a higher total time and its use as a crosswalk code maintains the current intensity of CPT code 22214. As was the case with the first two codes, we noticed that the surveyed intraservice time for CPT code 22214 is decreasing significantly, from 163 minutes to 120 minutes, which is offset by the RUC's recommendation of significantly more time in the postoperative visits. We do not agree with the RUC that the work RVU should be increasing for a procedure where the intraservice time, the most difficult and dangerous part of the procedure, is going down by more than half an hour. We believe that it better serves relativity to propose a work RVU of 19.53, which maintains the current intensity of CPT code 22214, as opposed to proposing the RUC's recommended work RVU of 21.72 which results in an intensity increase for this code. This proposed work RVU of 19.53 accounts for the decrease in intraservice time and change in the level of the postoperative office visits and is well bracketed by CPT code 38115, valued at a work RVU of 21.33 with an intraservice time of 120 minutes, and CPT code 42890 *(Limited pharyngectomy),* valued at a work RVU of 18.65 with an intraservice time of 120 minutes.

We are proposing the RUC recommended work RVU of 3.00 for CPT code 22216, as this code maintains its current intensity at the RUC's recommended valuation and maintains relativity with other similar add-on codes.

We are proposing the RUC recommended direct PE inputs for all the codes in this family without refinement.

(7) Arthroplasty—Shoulder (CPT Codes 23470 and 23472)

In April 2025, the RAW identified CPT code 23472 as having a site of service anomaly where Medicare data from 2021–2023 indicated it was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital E/M services within the global period. The RAW concluded that CPT code 23472 represented a site of service anomaly and identified CPT code 23470 as part of this family of services. The RUC therefore surveyed CPT codes 23470 (*Arthroplasty, glenohumeral joint; hemiarthroplasty*) and 23742 (*Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (e.g., total shoulder))*) for the September 2025 meeting.

We disagree with the RUC's recommended work RVU of 15.60 for CPT code 23470 and we are instead proposing a work RVU of 13.81 based on a crosswalk to CPT code 27416 (*Osteochondral autograft(s), knee, open (e.g., mosaicplasty) (includes harvesting of autograft[s])*). The RUC recommended a work RVU of 15.60, which is the current work RVU of the RUC's crosswalk code 67107 (*Repair of retinal detachment; scleral buckling (such as lamellar scleral dissection, imbrication or encircling procedure), including, when performed, implant, cryotherapy, photocoagulation, and drainage of subretinal fluid*) after the efficiency adjustment was applied at the start of CY 2026. In reviewing CPT code 23470, we note that the recommended intraservice time is decreasing from 113 minutes to 90 minutes (20 percent reduction), and the recommended total time is decreasing from 390 minutes to 330 minutes (22 percent reduction); however, the RUC-recommended work RVU is only decreasing from 17.44 to 15.60, which is a reduction of just over 10 percent. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner.

More specifically, CPT code 23470 was identified by the RAW as having a site of service anomaly in which the service was performed less than 50 percent of the time in the inpatient

setting yet included inpatient hospital Evaluation and Management services within the global period. The RUC has recommended the removal of five inpatient hospital visits along with recommending a decrease of 23 minutes to the intraservice work time based on the survey. We do not believe that the RUC's recommended work decrease of fewer than two RVUs appropriately captures this decrease in procedure time and physician work for CPT code 23470. We also noticed that the RUC's recommended work RVU of 15.60 results in an intensity increase for CPT code 23470. We disagree that an increase in intensity for this code is warranted, particularly given that the typical case for the procedure is moving from the inpatient to outpatient setting. The code descriptor for CPT code 23470 also remains unchanged which suggests that there has been no significant change in the procedure's performance or intensity. Furthermore, we also found that the recommended work RVU of 15.60 was higher than nearly all of the other 90 day global codes with similar time values, and we do not believe that this type of shoulder arthroplasty procedure, which is typically done on a routine and elective basis, would warrant an intensity and work valuation at the very top of the scale relative to other 90 day globals with similar time values. Because the PFS uses a relative value system, we believe it is important to highlight that these codes fail to maintain relativity with related surgical services. We are therefore proposing a work RVU of 13.81 based on a crosswalk to CPT code 27416 which preserves the current intensity of CPT code 23470 and better maintains relativity with the rest of the PFS.

We disagree with the RUC's recommended work RVU of 19.35 for CPT code 23472 and we are instead proposing a work RVU of 17.49 based on a crosswalk to CPT code 67414 (*Orbitotomy without bone flap (frontal or transconjunctival approach); with removal of bone for decompression*). The RUC recommended a work RVU of 19.35, which is the current work RVU of the RUC's crosswalk code 61798 (*Stereotactic radiosurgery (particle beam, gamma ray, or linear accelerator); 1 complex cranial lesion*) after the efficiency adjustment was applied at the start of CY 2026. In reviewing CPT code 23472, we note that the recommended intraservice time is decreasing from 140 minutes to 120 minutes (15 percent reduction), and the recommended total time is decreasing from 448 minutes to 348 minutes (24 percent reduction); however, the RUC-recommended work RVU is only decreasing from 21.58 to 19.35, which is a reduction of just over 10 percent. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner.

More specifically, CPT code 23472 was identified by the RAW as having a site of service anomaly in which the service was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RUC has recommended the removal of 3 inpatient hospital visits, one outpatient E/M visit, a decrease from a full to a half discharge visit, along with recommending a decrease of 20 minutes to the intraservice work time based on the survey. We do not believe that the RUC's recommended work decrease of just over two RVUs appropriately captures this decrease in procedure time and practitioner work for CPT code 23472. We also noticed that the RUC's recommended work RVU of 19.35 results in an intensity increase for CPT code 23472. We disagree that an increase in intensity for this code is warranted, particularly given that the typical case for the procedure is moving from the inpatient to outpatient setting. The code descriptor for CPT code 23472 also remains unchanged which suggests that there has been no significant change in the procedure's performance or intensity. Furthermore, we also found that the recommended work RVU of 19.35 was higher than nearly all of the other 90 day global codes with similar time values, and we do not believe that this type of total shoulder arthroplasty procedure, which is typically done on a routine and elective basis, would warrant an intensity and work valuation at the very top of the scale relative to other 90 day globals with similar time values. We are therefore proposing a work RVU of 17.49 based on a crosswalk to CPT code 67414 which preserves the current intensity of CPT code 23472 and better maintains relativity with the rest of the PFS.

We are proposing the RUC-recommended direct PE inputs for CPT codes 23470 and 23472 without refinement.

(8) Arthroplasty—Hip (CPT Code 27130)

In April 2025, the RAW identified CPT code 27130 as having a site of service anomaly where Medicare data from 2021–2023 indicated it was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RAW concluded that the code represented a site of service anomaly, and the RUC therefore surveyed CPT code 27130 (*Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft*) for the September 2025 meeting.

We disagree with the RUC's recommended work RVU of 16.70 for CPT code 27130 and we are instead proposing a work RVU of 15.37 based on a crosswalk to CPT code 43774 (*Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device and subcutaneous port components*). The RUC recommended a work RVU of 16.70, which is the current work RVU of the RUC's crosswalk code 67108 (*Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique*) after the efficiency adjustment was applied at the start of CY 2026. In reviewing CPT code 27130, we noted that the recommended total time is decreasing from 377 minutes to 305 minutes (19 percent reduction); however, the RUC-recommended work RVU is only decreasing from 19.11 to 16.70, which is a reduction of 13 percent. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner.

More specifically, CPT code 27130 was identified by the RAW as having a site of service anomaly in which the service was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RUC has recommended the removal of 2 inpatient hospital visits, a decrease from

a full to a half discharge visit, along with recommending a decrease of 10 minutes to the intraservice work time based on the survey. We do not believe that the RUC's recommended work decrease of just over two RVUs appropriately captures this decrease in procedure time and practitioner work for CPT code 27130. We also noticed that the RUC's recommended work RVU of 16.70 results in an intensity increase for CPT code 27130. We disagree that an increase in intensity for this code is warranted, particularly given that the typical case for the procedure is moving from the inpatient to outpatient setting. The code descriptor for CPT code 27130 also remains unchanged which suggests that there has been no significant change in the procedure's performance or intensity. Furthermore, we also found that the recommended work RVU of 16.70 was higher than nearly all of the other 90 day global codes with similar time values, and we do not believe that this type of total hip arthroplasty procedure, which is typically done on a routine and elective basis, would warrant an intensity and work valuation at the very top of the scale relative to other 90 day globals with similar time values. We are therefore proposing a work RVU of 15.37 based on a crosswalk to CPT code 43774 which preserves the current intensity of CPT code 27130 and better maintains relativity with the rest of the PFS.

We are proposing the RUC-recommended direct PE inputs for CPT code 27130 without refinement.

(9) Sacroiliac Joint Arthrodesis (CPT Codes 27278 and 27279)

At the May 2025 CPT Editorial Panel meeting. CPT code 27278 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive, including imaging guidance, unilateral; placement of intra-articular structural bone graft, metal and/or synthetic device(s) without cortical piercing, including use of osteopromotive material and/or obtaining bone graft, when performed*) was revised to include imaging guidance, placement of intra-articular structural bone graft, metal, and/or synthetic device(s) without cortical piercing and CPT code 27279 (*Arthrodesis, sacroiliac joint, percutaneous or minimally invasive, including imaging guidance, unilateral; placement of transarticular and/or intra-articular device(s) that engage bone with intrinsic fixation (e.g., screw[s], flange[s], blade[s]) piercing the lateral cortex of the sacrum and the medial cortex of the ilium (with or without piercing the lateral cortex of the ilium), including use of osteopromotive material and/or obtaining bone graft, when performed*) was revised to include placement of transarticular and/or intra-articular device(s) that engage bone with intrinsic fixation (*e.g.,* screw(s), flange(s), blade(s)) piercing the lateral cortex of the sacrum and the medial cortex of the ilium. CPT codes 27278 and 27279 were surveyed for the September 2025 RUC meeting.

We are proposing the RUC-recommended work RVUs of 7.66 for CPT code 27278 (which is the current work RVU of the code after the efficiency adjustment was applied at the start of CY 2026) and 11.00 for CPT code 27279. We are also proposing the RUC-recommended direct PE inputs for CPT codes 27278 and 27279 without refinement.

(10) Arthroplasty—Knee (CPT Code 27447)

In April 2025, the RAW identified CPT code 27447 as having a site of service anomaly where Medicare data from 2021–2023 indicated it was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RAW concluded that the code represented a site of service anomaly, and the RUC therefore surveyed CPT code 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*) for the September 2025 meeting.

We disagree with the RUC's recommended work RVU of 16.70 for CPT code 27447 and we are instead proposing a work RVU of 15.94 based on a crosswalk to CPT code 65730 (*Keratoplasty (corneal transplant); penetrating (except in aphakia or pseudophakia)*). The RUC recommended a work RVU of 16.70, which is the current work RVU of the RUC's crosswalk code 67108 (R*epair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique*) after the efficiency adjustment was applied at the start of CY 2026. In reviewing CPT code 27447, we noted that the recommended total time is decreasing from 374 minutes to 305 minutes (19 percent reduction); however, the RUC-recommended work RVU is only decreasing from 19.11 to 16.70, which is a reduction of 13 percent. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner.

More specifically, CPT code 27447 was identified by the RAW as having a site of service anomaly in which the service was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period. The RUC has recommended the removal of two inpatient hospital visits, a decrease from a full to a half discharge visit, along with recommending a decrease of 7 minutes to the intraservice work time based on the survey. We do not believe that the RUC's recommended work decrease of just over two RVUs appropriately captures this decrease in procedure time and practitioner work for CPT code 27447. We also noticed that the RUC's recommended work RVU of 16.70 results in an intensity increase for CPT code 27447. We disagree that an increase in intensity for this code is warranted, particularly given that the typical case for the procedure is moving from the inpatient to outpatient setting. The code descriptor for CPT code 27447 also remains unchanged which suggests that there has been no significant change in the procedure's performance or intensity. Furthermore, we also found that the recommended work RVU of 16.70 was higher than nearly all of the other 90 day global codes with similar time values, and we do not believe that this type of total knee arthroplasty procedure, which is typically done on a routine and elective basis, would warrant an intensity and work valuation at the very top of the scale relative to other 90 day globals with similar time values. We are therefore proposing a work RVU of 15.94 based on a crosswalk to CPT code 65730 which preserves the current intensity of CPT code 27447 and better maintains relativity with the rest of the PFS.

We are proposing the RUC-recommended direct PE inputs for CPT code 27447 without refinement.

(11) Implantation of Extra-Articular Shock Absorber—Medial Knee (CPT Code 27X05)

At the September 2025 CPT Editorial Panel Meeting, CPT created a new Category I code to describe the implantation of a medial knee extra-articular shock absorber. CPT code

27X05 (*Implantation of medial knee extra-articular shock absorber, including fluoroscopic guidance)* was surveyed at the January 2026 RUC meeting.

We are proposing the RUC-recommended work RVU of 13.16 for CPT code 27X05. We are proposing the RUC-recommended direct PE inputs for CPT code 27X05 without refinement.

(12) Osteochondral Acellular Scaffold Implantation, Knee (CPT Code 27XX8)

At the September 2025 CPT Editorial Panel Meeting, CPT created a new Category I CPT code 27XX8 (*Acellular scaffold(s) (e.g., aragonite) implant(s), for osteochondral lesion(s), knee, open*), which describes open cartilage knee repair procedures with an acellular scaffold implant. Based on the inorganic nature of these implants, the CPT Editorial Panel included the term ''acellular scaffold'' in the code descriptor for 27XX8, as it is a more comprehensive term and further defines the types of regenerative implants being used that are neither autologous nor allogenic. The CPT Editorial Panel did not request deletion for existing Category III code 0737T, which is currently being reported for this procedure, since it may appropriately describe procedures with this type of implant joints other than the knee. CPT code 27XX8 was surveyed for the January 2026 RUC meeting.

We are proposing the RUC-recommended work RVU of 9.53 for CPT code 27XX8.We are proposing the RUC-recommended direct PE inputs for CPT code 27XX8 without refinement.

(13) Cardiac Contractility Modulation (CPT Codes 33X01, 33X02, 33X03, 33X04, 33X05, 33X06, 33X07, 33X08, 33X09, 33X10, 33X11, 93X01, 93X02, 93X03, and 93X04)

In May 2025, the CPT Editorial Panel approved a new family of 11 Category I CPT codes for insertion, removal, and replacement of cardiac contractility modulation (CCM) systems, generators, and leads in several combinations. A separate set of four codes was created to describe the corresponding CCM programming, interrogation, and remote interrogation services. All 11 of the insertion, removal, and replacement/repositioning/revision CCM codes, as well as three programming, interrogation, and remote interrogation CCM services that involve physician work, were surveyed for the September 2025 RUC meeting.

The specialty societies detailed the four code subsets within the CCM code family. These include CCM insertion services: CPT codes 33X01 (*Insertion of permanent cardiac contractility modulation system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; pulse generator and transvenous electrodes*), 33X02 (*Insertion of permanent cardiac contractility modulation system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; pulse generator only*), 33X03 (*Insertion of permanent cardiac contractility modulation system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; transvenous electrode, single*), and 33X04 (*Insertion of permanent cardiac contractility modulation system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; transvenous electrode, dual*); CCM removal services: CPT code 33X05 (*Removal of a permanent cardiac contractility modulation system; pulse generator and transvenous electrodes*), 33X06 (*Removal of a permanent cardiac contractility modulation system; pulse generator only*), 33X07 (*Removal of a permanent cardiac contractility modulation system; transvenous electrode, single*), and 33X08 (*Removal of a permanent cardiac contractility modulation system; transvenous electrode, dual*); CCM replacement, repositioning, and revision services: CPT code 33X09 (*Removal and replacement of permanent cardiac contractility modulation system, pulse generator only*), 33X10 (*Repositioning of previously implanted cardiac contractility modulation transvenous electrode(s), including fluoroscopic guidance and programming of sensing and therapeutic parameters*), and 33X11 (*Relocation or revision of skin pocket for implanted cardiac contractility modulation pulse generator*); and CCM programming, interrogation, and remote interrogation services: CPT code 93X01 (*Programming of the cardiac contractility modulation system (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report by a physician or other qualified health care professional*), 93X02 (*Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified healthcare professional, includes connection, recording and disconnection per patient encounter, implantable cardiac contractility modulation system*), 93X03 (*Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation system with interim analysis, review and report(s) by a physician or other qualified health care professional*), and 93X04 (*Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation system, remote data acquisition(s), receipt of transmissions, technician review, technical support, and distribution of results*).

We are proposing the RUC-recommended work RVU for all of the codes in this family. We are proposing a work RVU of 8.83 for CPT code 33X01, work RVU of 5.66 for CPT 33X02, work RVU of 6.00 for CPT 33X03, work RVU of 6.23 for CPT 33X04, work RVU of 9.90 for CPT 33X05, work RVU of 4.79 for CPT 33X06, work RVU of 7.30 for CPT 33X07, work RVU of 8.39 for CPT 33X08, work RVU of 6.00 for CPT 33X09, work RVU of 5.00 for CPT 33X10, work RVU of 5.12 for CPT 33X11, work RVU of 0.90 for CPT 93X01, work RVU of 0.80 for CPT 93X02, and work RVU of 0.59 for CPT 93X03. We note that several of these work RVUs were affected by the efficiency adjustment which was applied at the start of CY 2026, as the RUC recommendations were based on pre-adjustment work valuations. The RUC did not recommend, and we are not proposing, a work RVU for CPT code 93X04.

We are proposing the RUC-recommended direct PE inputs for CPT codes 33X01–33X11 as well as for CPT codes 93X01–93X04 without refinement.

(14) Insertion and Removal of Surgical Ventricular Assist Device (CPT Codes 33X12, 33X13, and 33X15)

At the September 2025 CPT Editorial Panel meeting, the CPT Editorial Panel created three new category I CPT codes to describe the insertion and removal of a left heart ventricular assist device (VAD), specifically using an open arterial with conduit surgical approach. These new category I CPT codes include the insertion CPT codes 33X15 *(Insertion of left heart ventricular assist device, including radiological supervision and interpretation, open; axillary, subclavian or innominate artery exposure with creation of conduit by infraclavicular or supraclavicular incision, unilateral)* and 33X12 *(Insertion of left heart ventricular assist device, including radiological supervision and interpretation, open; aorta exposure with creation of conduit*

by transthoracic (e.g., median sternotomy, thoracotomy) incision) as well as the removal CPT code 33X13 *(Removal of left heart ventricular assist device with resection and stapling of graft conduit and skin closure (e.g., infraclavicular, supraclavicular).*

We are proposing the RUC-recommended work RVU of 13.65 for CPT code 33X15, work RVU of 17.52 for CPT 33X12, and work RVU of 6.58 for CPT 33X13.

We are proposing the RUC-recommended direct PE inputs for CPT codes 33X15, 33X12, and 33X13 without refinement.

(15) Transcatheter Tricuspid Valve Implant, Edge-to-Edge Repair (CPT Codes 33X50, 33X51, and 33X52)

In September 2025, the CPT Editorial Panel approved the addition of CPT codes 33X50 *(Transcatheter tricuspid valve implantation (TTVI)/replacement with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed),* CPT code 33X51 *(Transcatheter tricuspid valve edge-to-edge repair (T–TEER), percutaneous approach; initial clip),* and CPT code 33X52 *(Transcatheter tricuspid valve edge-to-edge repair (T–TEER), percutaneous approach; each additional clip during same session).* These codes were surveyed for the January 2026 RUC meeting.

The RUC recommended the inclusion of an inpatient hospital visit (CPT code 99233) within the global period of CPT codes 33X50 and 33X51, despite the fact that both codes were recommended with 0 day global periods. We disagree that this inpatient hospital visit should be included within the valuation of these services, as 0 day global periods are specifically defined to include only postoperative care that takes place on the day of the procedure itself without incorporating any postoperative days. We are therefore proposing to remove the inpatient hospital visit (CPT code 99233) from both CPT codes 33X50 and 33X51, including the removal of 55 minutes of associated work time from each procedure.

We disagree with the RUC-recommended work RVU of 24.38 for CPT code 33X50 and we are instead proposing a work RVU of 17.52 based on a crosswalk to CPT code 95391 *(Percutaneous transcatheter closure of paravalvular leak; initial occlusion device, aortic valve).* Our review of CPT code 33X50 found that the RUC's recommended work RVU of 24.38 placed it far higher than any other 0-day global code with similar time values on the PFS, especially after accounting for the removal of the work time associated with the inpatient hospital visit described earlier in this section. Most codes with 120 minutes of intraservice time and approximately 220 minutes of total time were valued around a work RVU of 13.00–15.00 and there were zero codes valued higher than a work RVU of 17.52. While we concur that CPT code 33X50 is a difficult and intensive procedure to perform, we do not believe it is accurately valued at 7 RVUs higher than any other code with comparable time values. We are instead proposing a work RVU of 17.52 based on a crosswalk to CPT code 95391, the highest 0-day global valuation with comparable work times, as this will avoid distorting relativity with other services on the PFS. We also note that CPT code 33X50 has comparable intensity at our proposed work RVU to the top reference code from the survey, CPT code 33477, which we believe better serves relativity than the RUC's recommended work RVU. The RUC's recommended work RVU of 24.38 would result in an intensity for CPT code 33X50 nearly 50 percent higher than the already complex and difficult transcatheter pulmonary valve implantation procedure described in the reference code, which we do not believe would be typical.

For CPT code 33X51, we disagree with the RUC's recommended work RVU of 23.92 and we are instead proposing a work RVU of 17.06. Although we disagree with the RUC-recommended work RVU for CPT 33X51, we concurred that the relative difference in work between CPT codes 33X50 and 33X51 is equivalent to the recommended interval of 0.46 RVUs. Therefore, we are proposing a work RVU of 17.06 for CPT code 33X51, based on the recommended interval of 0.46 below our proposed work RVU of 17.52 for CPT code 33X50.

For CPT code 33X52, we disagree with the RUC-recommended work RVU of 8.00 and we are instead proposing a work RVU of 6.34 based on a crosswalk to CPT 22552 *(Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (List separately in addition to code for primary procedure).* Our review of CPT code 33X52 found that the RUC's recommended work RVU of 8.00 placed it far higher than almost any other add-on code with similar time values on the PFS, with the sole exception of CPT code 61642 (Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in different vascular territory which is an outlier valuation at a work RVU of 8.66. Most add-on codes with approximately 50 minutes of total time were valued around a work RVU of 3.00–5.00 and there was only a single code valued higher than a work RVU of 6.34. While we concur that CPT code 33X52 is a difficult and intensive procedure to perform, we do not believe it is accurately valued at nearly two RVUs higher than other codes with comparable time values. We are instead proposing a work RVU of 6.34 based on a crosswalk to CPT code 22522, the highest non-outlier add-on code valuation with comparable work times, as this will avoid distorting relativity with other services on the PFS. We note that this valuation will also maintain relative intensity between CPT code 33X52 and the first two codes in the family at our proposed work RVUs.

The RUC did not recommend and we are not proposing any direct PE inputs for the three codes in this family.

(16) Percutaneous Transcatheter Closure (CPT Code 33340)

In April 2025, the RAW identified CPT code 33340 (*Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation)* as a code that has Medicare utilization of 10,000 or more that has increased by at least 100 percent from 2018 through 2023. The specialty societies indicated and the RUC agreed that CPT code 33340 be surveyed for the January 2026 RUC meeting.

We disagree with the RUC's recommendation of the current work RVU of 9.99 for CPT code 33340 and we are instead proposing a work RVU of 9.00 based on crosswalk to CPT code 37271 *(Revascularization, endovascular, open or percutaneous, femoral and popliteal vascular territory, with transluminal atherectomy, including transluminal angioplasty when performed, including all maneuvers necessary for accessing and selectively catheterizing the artery and crossing the lesion, including all imaging guidance and radiological supervision and interpretation necessary to perform the atherectomy and angioplasty when performed, within the same artery, unilateral; straightforward lesion, initial vessel).* The RUC survey indicated that the typical time needed to perform CPT code 33340 has decreased, with the

intraservice time decreasing from 70 minutes to 62 minutes and the total time decreasing from 165 minutes to 154 minutes. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner. The RUC's recommendation to maintain the current work RVU of 9.99 for CPT code 33340 can only be justified if the intensity to perform the service has increased over time. However, there has been no change to the code descriptor for CPT code 33340 and no apparent change in clinical practice which would warrant the roughly 15 percent increase in intensity as recommended by the RUC. Since we do not believe that there is evidence indicating that CPT code 33340 has typically become more intense to perform, we are therefore proposing a work RVU of 9.00 which maintains the current intensity of the service. This valuation is based on a crosswalk to CPT code 37271, a recently reviewed service from CY 2026 that has a higher intraservice time and nearly identical total time.

We are proposing the direct PE inputs for CPT code 33340 as recommended by the RUC without refinement.

(17) Treatment of Incompetent Veins (CPT Codes 36470, 36471, 36465, 36466, 36473, and 36474)

In April 2025, the RAW identified CPT code 36465 (*Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (e.g., great saphenous vein, accessory saphenous vein*), as a code that has Medicare utilization of 10,000 or more that has increased by at least 100 percent from 2018 through 2023. The RAW reviewed the action plan and the RUC recommended CPT code 36465 along with the family of services be surveyed for the January 2026 RUC meeting.

The RUC reviewed this family of services at the January 2026 meeting including all sclerosant treatment of incompetent veins. These services are: CPT code 36465; CPT code 36466 (*Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (e.g., great saphenous vein, accessory saphenous vein), same leg*); CPT code 36470 (*Injection of sclerosant; single incompetent vein (other than telangiectasia)*); CPT code 36471 (*Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg*); CPT code 36473 (*Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated*); and CPT code 36474 (*Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure)*).

For CY 2027, we are proposing the RUC-recommended work RVUs for five of the six codes in this family. We are proposing the RUC-recommended work RVU of 2.29 for CPT code 36465, 0.73 for CPT code 36470, 1.18 for CPT code 36471, 3.41 for CPT code 36473, and 1.71 for CPT code 36474.

We disagree with the RUC recommended work RVU of 2.93 for CPT code 36466. Instead, we are proposing a work RVU of 2.62 based on a crosswalk to CPT code 57156 (*Insertion of a vaginal radiation afterloading apparatus for clinical brachytherapy*). In reviewing CPT code 36466, we noted that the recommended intraservice time is decreasing from 35 minutes to 30 minutes (14 percent reduction), and the recommended total time is decreasing from 76 minutes to 68 minutes (11 percent reduction); however, the RUC recommended maintaining the current work RVU of 2.93. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner. The RUC's recommendation to maintain the current work RVU of 2.93 for CPT code 36466 can only be justified if the intensity to perform the service has increased over time. However, there has been no change to the code descriptor for CPT code 36466 and no apparent change in clinical practice which would warrant the roughly 17 percent increase in intensity as recommended by the RUC. Since we do not believe that there is evidence indicating that CPT code 36466 has typically become more intense to perform, we are therefore proposing a work RVU of 2.62 which maintains the current intensity of the service. This valuation is based on a crosswalk to CPT code 57156, which has the same intraservice work time of 30 minutes and higher total time.

We are proposing the RUC-recommended direct PE inputs for all CPT codes in this family without refinement.

(18) Microvascular Bypass, Lymphatic Vessels (CPT Codes 38X03 and 38X04)

In September 2025, the CPT Editorial Panel approved two new Category I codes to describe microvascular bypass of lymphatic vessels, a microsurgical procedure. This newly created Category I CPT code family describes two services: a base code for the initial anastomosis, CPT code 38X03 (*Microvascular anastomosis between a single vein opening and any number of lymphatic vessels, per limb; initial anastomosis*), and the add-on code for each additional anastomosis, CPT code 38X04 (*Microvascular anastomosis between a single vein opening and any number of lymphatic vessels, per limb; initial anastomosis; each additional anastomosis (List separately in addition to code for primary procedure)*). CPT codes 38X03 and 38X04 were surveyed for the January 2026 RUC meeting.

We reviewed the RUC's recommended work valuations and found the RUC's recommended work RVU of 16.00 for CPT code 38X03 to be high, based on a search of similarly timed codes in the RUC database. For CY 2027 we are proposing a work RVU of 14.00, based on the RUC survey 25th percentile, for CPT code 38X03. We are proposing the RUC recommended work RVU of 6.00 for CPT code 38X04. We are proposing the RUC-recommended direct PE inputs for both CPT codes without refinement.

(19) Diaphragmatic Hernia Repair (CPT Codes 39540, 39541, 39XX3, 39XX4, 39XX5, 39XX7, 39XX8, 39XX9, 39X11, 39X12, and 39X13)

At the September 2025 CPT Editorial Panel, the committee revised two existing CPT codes, CPT code 39540 *(Repair, diaphragmatic hernia (other than neonatal), via laparotomy; traumatic, acute)* and CPT code 39541 *(Repair, diaphragmatic hernia (other than neonatal), via laparotomy; traumatic, chronic),* describing diaphragmatic hernia repair. They also created nine new Category I codes, CPT

codes 39XX3 *(Repair, diaphragmatic hernia (other than neonatal), via laparotomy; nontraumatic (ie, Bochdalek, Morgagni*)), 39XX4 *(Repair, diaphragmatic hernia (other than neonatal), via thoracotomy; traumatic, chronic),* 39XX5 *(Repair, diaphragmatic hernia (other than neonatal), via thoracotomy; nontraumatic (ie, Bochdalek, Morgagni)),* 39XX7 *(Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, acute),* 39XX8 *(Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, chronic),* 39XX9 *(Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); nontraumatic (ie, Bochdalek, Morgagni)),* 39X11*(Thoracoscopy surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, chronic),* 39X12 *(Thoracoscopy surgical, with repair of diaphragmatic hernia (other than neonatal); nontraumatic (ie, Bochdalek, Morgagni)),* and 39X13 *(Implantation of mesh or other prosthesis with open, laparoscopic, or thoracoscopic diaphragmatic hernia repair (List separately in addition to code for primary procedure))* that expanded the range of surgical interventions included in this code family. The RUC reviewed these services at the January 2026 meeting.

For CY 2027, we are proposing the RUC recommended work RVUs of 24.00 for CPT code 39540, 26.00 for CPT code 39541, 25.75 for CPT code 39XX3, 26.41 for CPT code 39XX4, 25.94 for CPT code 39XX5, 22.04 for CPT code 39XX7, 26.60 for CPT code 39XX8, 27.00 for CPT code 39XX9, 25.44 for CPT code 39X11, 25.94 for CPT code 39X12, and 3.00 for CPT code 39X13.

We are proposing the RUC-recommended direct PE inputs for all CPT codes in this family without refinement.

(20) Diaphragm Repair (CPT Codes 39545 and 395X2)

In May 2025, the CPT Editorial Panel revised CPT code 39545 (*Plication of diaphragm for eventration or paralysis, via thoracotomy*) to specify plication of the diaphragm for eventration or paralysis, via thoracotomy, and created CPT code 395X2 (*Thoracoscopy, surgical, with plication of diaphragm for eventration or paralysis*) to report thoracoscopic plication of the diaphragm for eventration or paralysis.

For CY 2027, we are proposing the RUC recommended work RVUs of 18.45 for CPT code 39545 and 20.00 for CPT code 395X2. We are proposing the RUC-recommended direct PE inputs for both CPT codes without refinement.

(21) Division of Median Arcuate Ligament (CPT Codes 39XX1 and 39XX2)

In February 2025, the CPT Editorial Panel created two new codes to report open and laparoscopic median arcuate ligament syndrome (MALS) treatment: CPT code 39XX1 (*Division of median arcuate ligament and release of celiac trunk, with ganglionectomy, when performed*) and CPT code 39XX2 (*Laparoscopy, surgical, with division of median arcuate ligament and release of celiac trunk, with ganglionectomy, when performed*). The two new codes were surveyed for the April 2025 RUC meeting.

We are proposing the RUC-recommended efficiency adjusted work RVUs of 26.41 for CPT code 39XX1 and 25.94 for CPT code 39XX2. We are proposing the RUC-recommended direct PE inputs for CPT codes 39XX1 and 39XX2 without refinement.

(22) Endoscopic Submucosal Dissection (CPT Codes 4XX01 and 4XX02)

At the May 2025 CPT Editorial Panel Meeting, two new CPT codes were created for reporting endoscopic submucosal dissection (ESD) of both the upper and lower GI tract, including mucosal closure: CPT codes 4XX01 (*Endoscopic submucosal dissection (ESD) of upper gastrointestinal tract, including mucosal closure, when performed)* and 4XX02 *(Endoscopic submucosal dissection (ESD) of lower gastrointestinal tract, including mucosal closure, when performed).* These new CPT codes were surveyed at the September 2025 AMA RUC meeting.

For CY 2027, we are proposing the RUC-recommended work RVUs of 15.00 for CPT code 4XX01 and 16.38 for CPT code 4XX02. We are proposing the RUC-recommended direct PE inputs for CPT codes 4XX01 and 4XX02 without refinement.

(23) Transoral Oropharyngeal Procedures (CPT Codes 42808, 42XX1, and 42XX2)

In February 2025, the CPT Editorial Panel approved two new Category I codes that describe transoral endoscopic surgery under magnification for the removal of tumors in the oropharynx, including robotic assistance when performed: CPT code 42XX1 (*Transoral removal of oropharyngeal and/or pharyngeal neoplasm under magnification (e.g., microscope or telescope), includes robotic assistance, when performed, tongue base*) and CPT code 42XX2 (*Transoral removal of oropharyngeal and/or pharyngeal neoplasm under magnification (e.g., microscope or telescope), includes robotic assistance, when performed; tongue base; lateral pharyngeal wall, including tonsil*). CPT code 42808 (*Excision or destruction of lesion of pharynx, without magnification, any method*) was revised to clarify that it is done without magnification, and it was surveyed along with the two new codes at the April 2025 RUC meeting.

We are proposing the RUC-recommended work RVU for all three codes in this family. We are proposing a work RVU of 2.29 for CPT code 42808 (which is the current work RVU of the code after the efficiency adjustment was applied at the start of CY 2026), a work RVU of 20.00 for CPT code 42XX1, and a work RVU of 20.05 for CPT code 42XX2. We note that the RUC's recommended work RVU of 2.29 for CPT code 42808 assigns an intensity value of zero for this service; we are seeking comment from interested parties as to whether an alternate work valuation, such as the survey 25th percentile work RVU of 2.70, would be more appropriate.

We are proposing the RUC-recommended direct PE inputs for all three codes without refinement.

(24) Congenital Duodenal Obstruction Repair (CPT Codes 44XX1 and 44XX2)

At the May 2025 CPT Editorial Panel Meeting, two new CPT codes were created for reporting surgical treatment for congenital duodenal obstruction via an open or laparoscopic approach, that were previously reported using unlisted codes: CPT codes 44XX1 *(Duodenoduodenostomy or duodenojejunostomy for congenital duodenal obstruction)* and 44XX2 *(Laparoscopy, surgical; duodenoduodenostomy or duodenojejunostomy for congenital duodenal obstruction).* These new CPT codes were surveyed at the September 2025 AMA RUC meeting.

For CY 2027, we are proposing the RUC-recommended work RVUs of 50.00 for CPT code 44XX1 and 52.60 for CPT code 44XX2. We are proposing the RUC-recommended direct PE inputs for CPT codes 44XX1 and 44XX2 without refinement.

(25) Irreversible Electroporation of Tumor, Pancreas (CPT Code 48XXX)

In May 2025, the CPT Editorial Panel approved the addition of a new CPT code 48XXX (*Ablation, irreversible electroporation of tumor(s) of the pancreas, open, including imaging guidance)* to report open irreversible electroporation (IRE) ablation of tumors of the pancreas.

We are proposing the RUC-recommended work RVU of 25.19 for CPT code 48XXX, and the RUC-recommended direct PE inputs without refinement.

(26) Prostate Biopsy Services (CPT Codes 55705, 55707, 55708, 55709, 55710, 55711, 55712, 55714, and 55715)

This service was identified via the April 2022 RAW review of services performed by the same physician on the same date of service 75 percent of the time or more and was surveyed for the September 2024 RUC meeting. The data from the September 2024 survey indicated that the long descriptors did not adequately describe these services. While the codes were valued for the CPT 2026 cycle, the specialties and the RUC agreed that a new coding change application should be developed for the CPT Editorial Panel for restructuring in the CPT 2027 cycle. CPT revised the prostate biopsy code family in 2026 and it was surveyed for the January 2026 RUC meeting. The revisions to the family are as follows: CPT codes 55705 (*Biopsy, prostate, any approach, non-imaging guided*), 55707 (*Biopsy, prostate, transrectal, including imaging guidance, regional*), 55708 (*Biopsy, prostate, transrectal, including imaging guidance, regional and fusion-targeted lesion(s)*), 55709 *(Biopsy, prostate, transperineal, including imaging guidance, regional),* 55710 *(Biopsy, prostate, transperineal, including imaging guidance, regional and of fusion-targeted lesion(s),* 76872 *(ultrasound, transrectal),* and 55714 *(Biopsy, prostate, including imaging guidance, in-bore-CT-or-MRI-guided; first targeted lesion)* have work RVUs that were reaffirmed from CY 2026 by the RUC. CPT codes 55711 *(Biopsy, prostate, transrectal or transperineal, including imaging guidance, fusion),* 5XX14 *(Biopsy, prostate, transrectal or transperineal, including imaging guidance, fusion-targeted lesion(s) without regional; each additional targeted lesion (List separately in addition to code for primary procedure)* and 55715 *(Biopsy, prostate, including imaging guidance, in-bore CT- or MRI-guided; each additional targeted lesion (List separately in addition to code for primary procedure))* are new and/or revised codes for CY2027.

For CY 2027, we are proposing the RUC-recommended work RVU for eight of the nine codes in the family. We are proposing the RUC-recommended work RVUs of 1.88 for CPT code 55705, 2.63 for CPT code 55707, 3.39 for CPT code 55708, 3.23 for CPT code 55709, 3.81 for CPT code 55710, 2.37 for CPT code 55711, 3.62 for CPT code 55714, and 1.80 for CPT 55715.

For CPT code 5XX14, we disagree with the RUC-recommended work RVU of 0.80. In the interest of maintaining relativity with similarly timed codes, we are instead proposing a work RVU of 0.68 based on a crosswalk to CPT code 93567 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for supravalvular aortography (List separately in addition to code for primary procedure)*). CPT code 55X14 was surveyed with only 6 minutes of intraservice and total work time, yet the RUC recommended a work RVU of 0.80. We compared this recommended valuation against CPT code 55715, another add-on code within this same family, which was surveyed at 35 minutes of intraservice and total work time but with a recommended work RVU of 1.80. This results in CPT code 55X14 having an intensity nearly triple that of CPT code 55715 which we do not believe would be typical. We also found that there were no other add-on codes in the RUC database with comparable time values to CPT code 55X14 which had a work RVU approaching 0.80. The closest was CPT code 77063 (*Screening digital breast tomosynthesis, bilateral*) at a work RVU of 0.59, with that code having 8 minutes of work time instead of 6 minutes, and all other comparable add-on codes had a work RVU of 0.37 or lower. Although we agree that CPT code 55X14 is a difficult and intensive procedure, we believe that the RUC's recommended work RVU of 0.80 assigns too much work valuation and intensity to the service, and does not maintain relativity with other related codes on the PFS.

We are instead proposing a work RVU of 0.68 for CPT code 5XX14 based on a crosswalk to CPT code 93567. Our proposed work RVU of 0.68 is also supported with add-on CPT codes with similar work time values. CPT code 93566 (*Injection procedure during cardiac catheterization including imaging supervision, interpretation, and report; for selective right ventricular or right atrial angiography (List separately in addition to code for primary procedure)*) is valued at a work RVU of 0.49 with an intraservice time of 10 minutes and CPT code 64484 (*Injection(s), anesthetic agent(s) and/or steroid; transforaminal epidural, with imaging guidance (fluoroscopy or CT), lumbar or sacral, each additional level (List separately in addition to code for primary procedure)*) is valued at a work RVU of 0.98 with an intraservice time of 10 minutes.

We are proposing the RUC-recommended direct PE inputs for all CPT codes in this family without refinement.

(27) Maternity Care Services (CPT Codes 59320, 59325, 59412, 59871, 59XX1, 59XX2, 59XX3, 59XX4, 59030, 59051, 59XX5, 59XX6, 59414, 59300, 59XX7, 59XX8, 59XX9, 59X10, 59X11, 59X12, and 59160)

a. Background and Proposal

At the January 2026 AMA RUC meeting, the maternity global codes were revised to delete 17 legacy CPT codes, create 12 new CPT codes, and revise 9 CPT codes describing maternity care services. See Table A–D2 for a summary of the codes and their long descriptors. These codes were restructured from the MMM global period to individual codes to reflect changes in practice. The previous MMM global period included 12 prenatal E/M visits bundled into CPT codes 59400, 59510, 59610, and 59618. In May 2025, the American College of Obstetricians and Gynecologists (ACOG) published new clinical guidelines, recommending that obstetrician-gynecologists and other maternity care professionals tailor the visit frequency and monitoring schedule to the needs of the pregnant woman. These new clinical guidelines provide a sample schedule for prenatal care services and visit frequency, which describes 8 visits for average-risk pregnant women without medical or pregnancy complications, and 13 visits for pregnant women with greater-than-average risk. This sample schedule specifies that additional services may be offered as needed throughout the pregnancy.

When the RUC reviewed these codes, they included 12 prenatal E/M visits (two level 2 established patient office visits, eight level 3 established patient office visits, and two level 4 established patient office visits) in the calculations to make these changes budget-neutral despite the revisions to the clinical guidelines suggesting that 12 visits would no longer be typical. As the clinical guidelines have changed to reflect a revised assumption about the typical number of visits, estimating work neutrality based on the assumption that all 12 prenatal E/M visits in the base year would be reported in the predictive year overestimates the total utilization and as a result, undervalues the work RVUs as recommended by the RUC. To improve payment accuracy of the new codes, we are proposing to refine the RUC's recommended utilization crosswalk to remove four E/M visits (two level 2

established patient office visits and two level 4 established patient office visits) from the utilization estimate calculation and reallocate those RVUs within the code family to the new labor and delivery codes. This would mean reallocating 11,810 additional work RVUs to the new labor and delivery codes (CPT codes 59XX1–59XX8). Since the RUC provided a utilization estimate of 12,791 for CPT codes 59XX1–59XX8, this would result in a 15 percent increase in work RVUs for each labor and delivery code. We would like to emphasize that we are not endorsing a reduced number of prenatal visits for pregnant women. Our recalculation of the utilization estimates in the valuation of these services should not be used to determine the appropriate number of visits to provide reasonable and necessary care to beneficiaries. As with all PFS services, maternity services should be furnished when medically reasonable and necessary.

There are no RUC-recommended direct PE inputs for these CPT codes. Table A–D2 also shows the RUC-recommended and CMS proposed work RVUs for the 21 CPT codes.

TABLE A-D2: CPT LONG DESCRIPTORS AND PROPOSED WORK RVUS FOR MATERNITY SERVICES

CPT Code	Long Descriptors	RUC Recommended Work RVUs	CMS Proposed Work RVUs
Antepartum Care			
59320	*Cerclage of cervix, during pregnancy; vaginal*	3.02	3.02
59325	*Cerclage of cervix, during pregnancy; abdominal*	6.34	6.34
59412	*External cephalic version*	2.63	2.63
59871	*Removal of cerclage suture under anesthesia (other than local)*	2.15	2.15
Labor Management and Delivery			
59XX1	*Initial day labor management; straightforward, per day*	3.50	4.03
59XX2	*Initial day labor management; complex, per day*	4.50	5.18
59XX3	*Subsequent day labor management; straightforward, per day*	3.00	3.45
59XX4	*Subsequent day labor management; complex, per day*	4.20	4.83
59XX5	*Vaginal delivery, with or without episiotomy;*	8.00	9.20
59XX6	*Vaginal delivery, with or without episiotomy; after previous cesarean delivery*	9.00	10.35
59XX7	*Cesarean delivery; primary*	12.00	13.80
59XX8	*Cesarean delivery; repeat*	14.66	16.86
Labor Procedures, Other Procedures, and Postpartum			
59030	*Fetal scalp blood sampling*	0.90	0.90
59051	*Fetal monitoring during labor by consulting physician (ie, non-attending physician) or other qualified health care professional, with interpretation and report*	0.93	0.93
59414	*Delivery of placenta only (separate procedure)*	1.61	1.61
59300	*Repair of first or second-degree episiotomy or laceration, by other than attending physician or other qualified health care professional performing vaginal delivery care (separate procedure)*	1.76	1.76
59X11	*Repair of episiotomy or laceration; third-degree laceration*	2.47	2.47
59X12	*Repair of episiotomy or laceration; fourth-degree laceration*	4.14	4.14
59XX9	*Subtotal or total hysterectomy after cesarean delivery*	15.56	15.56
59X10	*Uterine tamponade (eg, balloon, catheter, vacuum, packing material)*	2.15	2.15
59160	*Curettage, postpartum*	2.93	2.93

b. Comment Solicitation on Maintaining Current Coding Through Creation of HCPCS G-codes

We are interested in thinking about different approaches to how maternity care codes are valued and paid under the PFS. Although the RUC asserts that these proposed coding changes discussed above reflect clinical consensus, we have concerns that our adoption of the new codes would be disruptive based on how the longstanding existing code structure is currently accounted for in clinical practice patterns. We are seeking comment on whether CMS should create HCPCS G-codes that would maintain the current coding and payment for maternity services to ameliorate this concern, while we continue to consider the potential impact that changes in the maternity care code family have on clinical outcomes for maternal care. These codes would be used in lieu of adoption of the new CPT codes for purposes of Medicare payment. We are specifically interested in additional information to support or oppose this concern, as well as additional information to support or oppose the use of the creation of HCPCS G-codes in lieu of adoption of the new CPT codes.

Specifically, for payment for maternity care services under the PFS, we are considering, and are seeking comment on, the creation of 15 new HCPCS G-Codes for CY 2027 that reflect the previous MMM global code structure, with the code descriptors and work RVUs detailed in Table A–D3, as an alternative to the revaluation of the codes as discussed in Section (a), of this preamble. We are seeking public comment on these HCPCS G-codes and, after consideration of public comment, could finalize payment for these codes. We are seeking comment on these HCPCS G-codes and are also seeking comment on any other HCPCS G-codes that may be needed to reflect the necessary service elements for this code family. These HCPCS G-codes would adopt all current conditions of payment for the MMM global codes, as well as maintain the MMM global period, if finalized.

TABLE A-D3: POTENTIAL G CODES TO MAINTAIN PREVIOUS CODE SET

HCPCS G-Code	Long Descriptors	G-Code Work RVUs
GMAT1	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care	37.00
GMAT2	Vaginal delivery only (with or without episiotomy and/or forceps);	14.37
GMAT3	Vaginal delivery only (with or without episiotomy and/or forceps); including postpartum care	18.76
GMAT4	Antepartum care only; 4-6 visits	7.8
GMAT5	Antepartum care only; 7 or more visits	14.3
GMAT6	Postpartum care only (separate procedure)	3.22
GMAT7	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care	41.05
GMAT8	Cesarean delivery only;	16.13
GMAT9	Cesarean delivery only; including postpartum care	22.79
GMA10	Routine obstetric care including antepartum care, vaginal delivery (with or without episiotomy, and/or forceps) and postpartum care, after previous cesarean delivery	38.71
GMA11	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	16.09
GMA12	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps); including postpartum care	20.48
GMA13	Routine obstetric care including antepartum care, cesarean delivery, and postpartum care, following attempted vaginal delivery after previous cesarean delivery	41.57
GMA14	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery;	16.66
GMA15	Cesarean delivery only, following attempted vaginal delivery after previous cesarean delivery; including postpartum care	23.32

(28) Stereotactic Computer-Assisted Volumetric Navigation (CPT Codes 61781, 61782, and 61783)

In April 2024, CPT code 61783 (*Stereotactic computer-assisted (navigational) procedure; spinal (List separately in addition to code for primary procedure)*) was identified via the high-volume growth screen. In January 2025, the RAW reviewed the action plan for CPT code 61783 and determined that this service should be surveyed with the appropriate family of codes. The RUC recommended that CPT code 61781 be surveyed with CPT codes 61782 (*Stereotactic computer-assisted (navigational) procedure; cranial, extradural (List separately in addition to code for primary procedure)*) and 61783 (*Stereotactic computer-assisted (navigational) procedure; spinal (List separately in addition to code for primary procedure)*) for September 2025.

We are proposing the RUC-recommended work RVU of 3.66 for CPT codes 61781 and 61783, and the RUC-recommended RVU of 2.06 for CPT code 61782. We note that all three of these RUC-recommended RVUs reflect the application of the CY 2026 efficiency adjustment described in the CY 2026 PFS final rule (90 FR 49334 through 49345).

We are proposing the RUC's recommended direct PE inputs for CPT code 61782. Since CPT codes 61781 and 61783 are performed in the facility setting only, the RUC did not recommend, and we are not proposing, any direct PE inputs for these two codes.

(29) Percutaneous Lumbar Decompression (CPT Code 62287)

At the January 2025 RUC meeting, the surveying societies requested deletion of CPT code 62287 *(Decompression, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar)* due to declining Medicare utilization. At the May 2025 CPT Editorial Panel meeting, CPT reviewed additional utilization estimates, and requests from neurosurgery and radiology were received to resurvey and retain the code. CPT code 62287 was surveyed at the September 2025 AMA RUC meeting since it was not deleted in January 2025 with the other codes in the family.

We disagree with the RUC's recommended work RVU of 7.06 for CPT code 62287 and we are instead proposing a work RVU of 6.23 based on a crosswalk to CPT code 46707 *(Repair of anorectal fistula with plug (e.g., porcine small intestine submucosa [SIS]))*. We believe that the RUC's recommended work RVU of 7.06 is an overestimation based on a comparison to other codes with similar time values, particularly the key reference code CPT code 22869 (*Insertion of interlaminar/interspinous process stabilization/distraction device, without open decompression or fusion, including image guidance when performed, lumbar; single level*). There was a decrease in the surveyed work times, such as the intraservice time decreasing from 60 minutes to 37 minutes, which was not fully accounted for in the RUC's recommended work RVU of 7.06. We also note that the procedure does not seem to have become more intense, as the code descriptor did not change.

In the interest of maintaining relativity with similarly timed codes, we are instead proposing a work RVU of 6.23 based on a crosswalk to CPT code 46707. This code has an almost identical intraservice time and similar total time. The proposed work RVU accounts for the decrease in both intraservice time and total time and is well bracketed by CPT code 67912 *(Correction of lagophthalmos, with implantation of upper eyelid lid load (e.g., gold weight))*, valued at a work RVU of 6.20 with an intraservice time of 40 minutes, and CPT code 24358 *(Tenotomy, elbow, lateral or medial (e.g., epicondylitis, tennis elbow, golfer's elbow); debridement, soft tissue and/or bone, open)*, valued at a work RVU of 6.49 with an intraservice time of 40 minutes.

We are proposing the RUC-recommended direct PE inputs for all of the codes in this family.

(30) Laminectomy (CPT Codes 63045, 63046, 63047, and 63048)

In April 2025, the RAW identified CPT code 63047 (*Laminectomy, facetectomy and foraminotomy*

(unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar) as a site of service anomaly where Medicare data from 2021 to 2023 indicated it was performed less than 50 percent of the time in the inpatient setting yet included inpatient hospital Evaluation and Management services within the global period with 2023 Medicare utilization over 10,000. The RAW also worked with the specialty societies and identified other codes 63045 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical*), 63046 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; thoracic*) and 63048 (*Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional vertebral segment, cervical, thoracic, or lumbar (List separately in addition to code for primary procedure)*) as part of this family of services. These services were surveyed for September 2025.

We are proposing the RUC-recommended work RVUs for all four CPT codes in this family. We are proposing a work RVU of 17.25 for CPT code 63045, a work RVU of 16.71 for CPT code 63046, a work RVU of 14.99 for CPT code 63047, and a work RVU of 3.38 for CPT code 63048. We note that several of these work RVUs were affected by the efficiency adjustment which was applied at the start of CY 2026, as the RUC recommendations were based on pre-adjustment work valuations.

We are proposing the RUC recommended direct PE inputs for CPT codes 63045, 63046, 63047, and 63048 without refinement.

(31) Injection Anesthetic Agent (CPT Codes 64400 and 64405)

The RUC identified CPT code 64400 *(Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (i.e., ophthalmic, maxillary, mandibular))* via their database flag, ''Do not use to validate physician work'', and recommended to survey this CPT code and the related CPT code 64405 *(Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve)* for the September 2025 meeting.

For CY 2027, we are proposing the RUC-recommended work RVUs of 0.73 for CPT code 64400 (which is the current work RVU of the code after the efficiency adjustment was applied at the start of CY 2026) and 0.84 for CPT code 64405.

We are proposing the RUC-recommended direct PE inputs for both CPT codes without refinement.

(32) MRA—Head, Neck (CPT Codes 70544, 70545, 70546, 70547, 70548, 70549, 70XX4, 70XX5, and 70XX6)

In April 2024, the RAW noted that the rate at which CPT codes 70547 (currently described as *Magnetic resonance angiography, neck; without contrast material(s)*) and 70544 (currently described as *Magnetic resonance angiography, head; without contrast material(s)*) are reported together continued to increase after the initial identification of the trend in April 2022 and a 2-year delay in review to allow practice patterns in the inpatient and outpatient setting go back to how they were prior to the COVID–19 pandemic. At the September 2025 CPT Editorial Panel, six CPT codes were revised to include ''image postprocessing'': CPT codes 70544 (*Magnetic resonance angiography, head, including image postprocessing; without contrast material(s)*), 70545 (*Magnetic resonance angiography, head, including image postprocessing; with contrast material(s)*), 70546 (*Magnetic resonance angiography, head, including image postprocessing; without contrast material(s), followed by contrast material(s) and further sequences*), 70547 (*Magnetic resonance angiography, neck, including image postprocessing; without contrast material(s)*), 70548 (*Magnetic resonance angiography, neck, including image postprocessing; with contrast material(s)*), and 70549 (*Magnetic resonance angiography, neck, including image postprocessing; without contrast material(s), followed by contrast material(s) and further sequences*). Three additional codes were created to bundle magnetic resonance angiography (MRA) head and neck with/without contrast: CPT codes 70XX4 (*Magnetic resonance angiography, head and neck, including image postprocessing; without contrast material(s)*), 70XX5 (*Magnetic resonance angiography, head and neck, including image postprocessing; with contrast material(s)*), and 70XX6 (*Magnetic resonance angiography, head and neck; without contrastmaterial(s) in one or both body regions, followed by contrast material(s) and further sequences in one or both body regions, including image postprocessing*). The code family was surveyed for the January 2026 RUC meeting.

We are proposing the RUC-recommended work RVU for all nine codes in the family. We are proposing the RUC-recommended work RVUs of 1.17, 1.17, 1.44, 1.17, 1.46, 1.76, 1.77, 2.10, and 2.23 for CPT codes 70544, 70545, 70546, 70547, 70548, 70549, 70XX4, 70XX5, and 70XX6, respectively. We are proposing the RUC recommended direct PE inputs for CPT codes 70544, 70545, 70546, 70547, 70548, 70549, 70XX4, 70XX5, and 70XX6 without refinement.

(33) Computed Tomography-Upper Extremity With Contrast (CPT Codes 73200, 73201, and 73202)

In April 2025, the RAW identified CPT code 73201 (*Computed tomography, upper extremity; with contrast material(s)*) via the CMS/Other source and 2023 Medicare utilization over 20,000 screen. The family of services was surveyed for the January 2026 RUC meeting, including CPT codes 73200 *(Computed tomography, upper extremity; without contrast material*) and 73202 *(Computed tomography, upper extremity; without contrast material, followed by contrast material(s) and further sections).*

We are proposing the RUC-recommended work RVUs of 1.00, 1.16, and 1.24 for CPT codes 73200, 73201, and 73202, respectively. We are proposing the RUC recommended direct PE inputs for CPT codes 73200, 73201, and 73202 without refinement.

(34) Biofeedback Training (CPT Codes 90901, 90X03, 90912, and 90913)

CPT codes 90901 (*Biofeedback training by any modality (e.g., EMG, EEG, ECG); initial 15 minutes of direct patient contact by physician or other qualified health care professional*), 90912 (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient*) and 90913 (*Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)*) were surveyed at the January 2026 RUC meeting after having gone through revision at the September 2025 CPT Editorial Panel. CPT revised code 90901 to describe the

initial 15 minutes of biofeedback training by a physician or other qualified health care professional with direct patient contact and created one new code, CPT code 90X03 (*Biofeedback training by any modality (e.g., EMG, EEG, ECG); each additional 15 minutes of direct patient contact by physician or other qualified health care professional (List separately in addition to code for primary procedure)),* to describe each additional 15 minutes. CPT codes 90912 and 90913 were surveyed for the January 2026 RUC meeting since they are part of the same code family. CPT codes 90901 and new code 90X03 were surveyed for the January 2026 RUC HCPAC Review Board meeting.

We are proposing the HCPAC-recommended work RVUs of 0.61 for CPT code 90901 and 0.48 for CPT code 90X03. We are proposing the RUC-recommended work RVUs of 0.90 for CPT code 90912 and 0.50 for CPT code 90913.

We are proposing the direct PE inputs recommended by the HCPAC and the RUC for all four codes in the family without refinement.

CPT codes 90901, 90912, and 90913 are all designated as sometimes therapy services, as such we are proposing to designate 90X03 as a sometimes therapy service.

(35) Radiation Oncology Treatment Delivery (CPT Codes 77402, 77407, and 77412)

In the CY 2026 PFS final rule (90 FR 49379 through 49383), we finalized our proposal to utilize the relationship between the Hospital Outpatient Prospective Payment System (OPPS) Ambulatory Payment Classifications (APC) relative weights for APCs 5621, 5622, and 5623 to inform the valuation of PE-only CPT codes 77402 (*Radiation treatment delivery; Level 1 (e.g., single-electron field, multiple-electron fields, or 2D photons), including imaging guidance, when performed*), 77407 (*Radiation treatment delivery; Level 2, single-isocenter (e.g., 3D or IMRT), photons, including imaging guidance, when performed*), and 77412 (*Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (e.g., 2D, 3D, or IMRT) or a single-isocenter photon therapy (e.g., 3D or IMRT) with active motion management, or total skin electrons, or mixed-electron/photon field(s), including imaging guidance, when performed*) when paid under the PFS. We also stated that we calculated the RVUs for these codes so that the overall PE and MP RVUs for these services represent the same share of total PE and MP RVUs in CY 2025 and CY 2026. To accomplish this, we developed PE and MP RVUs using the assumed distribution of services indicated in the utilization crosswalk.

We proposed to utilize the RUC-recommended crosswalk for these services, which assumed that 45 percent of the billed charges would be reported with CPT code 77412. Some commenters stated that CPT code 77412 would represent only 15 percent of the volume for these services. We stated in the CY 2026 PFS final rule that it is difficult to ascertain how services furnished in the past would be most accurately reported using a future code set (90 FR 49385). In response to comments and considering the disparate information we received, we finalized a modified crosswalk that adjusted downward the estimated portion that CPT code 77412 would be reported compared to CPT code 77407 based on commenters who represent those who provide care in the non-facility setting. Specifically, we modified the utilization crosswalk to crosswalk 35 percent of the utilization to CPT code 77412 and 55 percent of the utilization to CPT code 77407. Since the publication of the CY 2026 PFS final rule, interested parties have reported that the 35 percent utilization assumption for CPT code 77412 was still overstated despite our downward adjustment in the CY 2026 PFS final rule, and that the actual utilization for CPT code 77412 is approximately 18 percent. Given the importance of the assumed distribution of services in ensuring that we achieved our target of maintaining the same share of total PE and MP RVUs, we reviewed the claims data to evaluate the actual distribution of utilization among CPT codes 77402, 77407, and 77412. We noted that during the first 3 months of 2026, CPT code 77412 comprised approximately 18 of the total volume of these services.

Given that we valued these services by utilizing the relative relationship between the OPPS APC relative weights rather than our standard PE methodology, shifts in utilization over time are not automatically incorporated into the annual development of PE RVUs for these services over time. Consequently, we are proposing to refine the relativity within this family of codes for CY 2027 based on available claim data that corroborates the information submitted to us by outside parties. We are not proposing to change the assumptions about the total number of services, but rather, to revalue the PE RVUs using the observed distribution of services, such that the PE and MP RVUs for these services represent the same share of total PE and MP RVUs as they did in CY 2025.

(36) Proton Beam Treatment Delivery (CPT Codes 77520, 77522, 77523, and 77525)

Payment amounts for proton beam treatment delivery services described by CPT codes 77520 (*Proton treatment delivery; simple, without compensation*), 77522 (*Proton treatment delivery; simple, with compensation*), 77523 (*Proton treatment delivery; intermediate*), and 77525 (*Proton treatment delivery; complex*) are currently determined by local Medicare Administrative Contractors (MACs). We have not previously established RVUs for these services due to the unique nature of the equipment costs associated with these services compared to other capital costs addressed by our usual PE methodology. In the CY 2026 PFS proposed rule, we sought comment on establishing national payment rates for proton beam treatment delivery services. In the CY 2026 final rule (90 FR 49390), we indicated our intent to establish national pricing for proton beam treatment delivery services in future rulemaking.

Interested parties have raised concerns about wide geographic payment disparities with the current contractor pricing that are unrelated to the cost of providing care and have requested that CMS nationally price proton beam treatment delivery services. For example, 2024 claims data for CPT code 77525, which has the second highest utilization of the code family, reflects allowed charges that ranged from $122.15 to $1,374.26. Interested parties recommended that CMS establish identical payment rates for PFS and OPPS, calculating a weighted average of the payment rates to maintain budget neutrality across the PFS and OPPS. Other interested parties expressed concern about reliance on OPPS cost data to value proton beam treatment delivery services, as the substantial capital outlays required by freestanding centers could be greater than those faced by hospital systems and the freestanding centers lack the purchasing power or amortization flexibility that hospitals may have.

After considering the comments we received in response to the CY 2026 PFS rule regarding establishing national payment rates for proton beam treatment, similar to the policy we finalized for CY 2026 for radiation treatment delivery services, we are proposing to calculate the PE RVUs for these services as follows:

- Use the total allowed charges paid by the MACs for CPT codes 77520,

77522, 77523, and 77525 to establish the pool of PE RVUs to allocate to the services in this code family.

- Allocate PE RVUs to the individual services using the relationship between the APC relative weights for APCs 5625 (to which CPT codes 77522, 77523, and 77525 are assigned) and APC 5623 (to which CPT code 77520 is assigned) under the OPPS. We believe our proposal appropriately balances interested parties' requests to establish national payment rates with the difficulties we have faced when considering the capital-intensive and specialized resources for services like proton beam therapy services.

(37) Intracoronary Drug Delivery Balloon Services (CPT Codes 9XX04 and 9XX07)

In May 2025, the CPT Editorial Panel created two new codes, CPT code 9XX04 (*Percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloon (e.g., drug-coated, drug-eluting), including mechanical dilation by nondrug-delivery balloon angioplasty, single major coronary artery and/or its branch(es)*) and CPT code 9XX07 (*Percutaneous transcatheter therapeutic drug-delivery by intracoronary drug-delivery balloon (e.g., drug-coated, drug-eluting), single major artery and/or its branches (List separately in addition to code for primary procedure)*) to describe percutaneous transcatheter therapeutic drug delivery by intracoronary drug-delivery balloons. The RUC reviewed these two new CPT codes at the September 2025 RUC meeting.

We reviewed the RUC's recommended work valuations and found the RUC's recommended work RVU of 10.00 for CPT code 9XX04 to be high, based on a search of 000 global day codes with between 45 and 75 minutes of intraservice time and between 109 and 149 minutes of total time in the RUC database. For CY 2027 we are proposing a work RVU of 8.05, based on the RUC survey 25th percentile, for CPT code 9XX04. We are proposing the RUC-recommended work RVU of 4.38 for CPT code 9XX07. The RUC did not recommend, and we are not proposing any direct PE inputs for these codes.

(38) Rotational Vestibular Assessment (CPT Codes 92XX5 and 92XX6)

At the September 2025 CPT Editorial Panel Meeting, CPT code 92546 was deleted, and replaced with two new codes to report rotational vestibular assessment. The two new codes, CPT code 92XX5 (*Rotational vestibular assessment by sinusoidal harmonic acceleration (SHA) testing with calibrated, computer-controlled chair, with interpretation and report (do not report 92XX5 in conjunction with 92270)*) and 92XX6 (*Rotational vestibular assessment by sinusoidal harmonic acceleration (SHA) testing with calibrated, computer-controlled chair, with interpretation and report; with velocity step testing (VST) (List separately in addition to code for primary procedure)*) were surveyed for the September 2025 RUC meeting.

We are proposing the RUC-recommended work RVU of 0.92 for CPT code 92XX5.

We disagree with the RUC's recommended value of 0.48 for CPT code 92XX6 and we are instead proposing a work RVU of 0.35 which is the survey 25th percentile valuation. As valued by the RUC, the work RVU for add-on CPT code 92XX6 is half of the RUC's recommended work RVU of the base code (92XX5), despite the fact that CPT code 92XX6 has only 12 minutes of work time as compared with 45 minutes of work time for CPT code 92XX5. This leads to the intensity of CPT code 92XX6 being valued at double that of the base code, which we do not believe would be typical given that the same SHA testing is taking place in both services. We disagree with the RUC that valuing the work RVU of the add-on CPT code 92XX6 at half the work of the base CPT code 92XX5 would be appropriate, as this does not account for the substantial preservice and postservice work time contained in CPT code 92XX5, which together account for 20 of the 45 total minutes. We agree with the RUC that the intensity of this code is higher than the base code, and our proposed work RVU of 0.35 assigns a higher intensity to CPT code 92XX6 than CPT code 92XX5, but we disagree that the intensity of the add-on service would be double that of the base code.

We are proposing the RUC recommended direct PE inputs for CPT codes 92XX5 and 92XX6 without refinement.

Additionally, in the CY 2023 PFS final rule (87 FR 69656 through 69663) we created an exception to the physician order requirement at 42 CFR 410.32(a)(4) to allow patients to directly access audiologists. We also delineated the vestibular function tests as those not applicable for use with the AB modifier (for direct access)—see Audiology Services on the PFS website at *https://www.cms.gov/medicare/payment/fee-schedules/physician/audiology-services*. Based on the foregoing, for the new Rotational Vestibular Assessment Codes, CPT codes 92XX5 and 92XX6 will be added to the audiology services code list but they will not be eligible to be billed with the AB modifier.

(39) Video Head Impulse—Vestibular Function (CPT Codes 92X10 and 92X11)

At the September 2025 CPT Editorial Panel, the committee approved the addition of new CPT codes, 92X10 *(Video head impulse testing (vhit) with recording, interpretation and report of lateral semicircular canal function)* and 92X11 (*Video head impulse testing (vhit) with recording, interpretation and report of lateral and vertical semicircular canal function)* to report video head impulse testing (vHIT) and a corresponding parenthetical note. The RUC reviewed these services at the January 2026 meeting.

For CY 2027, we are proposing the RUC-recommended work RVUs of 0.53 for CPT code 92X10 and 0.84 for CPT code 92X11. We are proposing the RUC-recommended direct PE inputs for both CPT codes without refinement.

(40) Speech-Language Pathology Services (CPT Codes 92X0X, 92X1X, 92X2X, 92X3X, 92X4X, 92X5X, 92X6X, 92X7X, 92X8X, 92X9X, and 92508)

At the September 2025 CPT Editorial Panel meeting, CPT code 92507 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual*) was replaced with 10 new codes to report fluency disorder, speech sound production disorder, language comprehension and expression disorder, speech sound production disorder and language comprehension and expression disorder, and voice, upper airway dysfunction and/or resonance disorders. CPT codes 92X0X (*Treatment of fluency disorder (e.g., stuttering and cluttering), direct (one-on-one) patient contact; initial 30 minutes*), 92X1X (*Treatment of fluency disorder (e.g., stuttering and cluttering), direct (one-on-one) patient contact; each additional 15 minutes (list separately in addition to code for primary service)*), 92X2X (*Treatment of speech sound production disorder (e.g., articulation, phonological process, apraxia, dysarthria), direct (one-on-one) patient contact; initial 30 minutes*), 92X3X (*Treatment of speech sound production disorder (e.g., articulation, phonological process, apraxia, dysarthria), direct (one-on-one) patient contact; each additional 15 minutes (list separately in addition to code for primary service)*), 92X4X (*Treatment of language comprehension and expression disorder (e.g., receptive and expressive language), direct (one-on-one) patient contact; initial 30 minutes*), 92X5X (*Treatment of language comprehension*

and expression disorder (e.g., receptive and expressive language), direct (one-on-one) patient contact; each additional 15 minutes (list separately in addition to code for primary service)), 92X6X (*Treatment of speech sound production disorder (e.g., articulation, phonological process, apraxia, dysarthria) and language comprehension and expression disorder (e.g., receptive and expressive language), direct (one-on-one) patient contact; initial 30 minutes*), 92X7X (*Treatment of speech sound production disorder (e.g., articulation, phonological process, apraxia, dysarthria) and language comprehension and expression disorder (e.g., receptive and expressive language), direct (one-on-one) patient contact; each additional 15 minutes (list separately in addition to code for primary service)*), 92X8X (*Treatment of voice, upper airway dysfunction, and/or resonance disorders, direct (one-on-one) patient contact; initial 30 minutes*), 92X9X (*Treatment of voice, upper airway dysfunction, and/or resonance disorders, direct (one-on-one) patient contact; each additional 15 minutes (list separately in addition to code for primary service)*), and 92508 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder, group, 2 or more individuals*) are new and/or revised codes for CY 2027. Additionally, the introductory guidelines were revised to clarify reporting of the services. The code family was surveyed for the January 2026 RUC HCPAC Review Board meeting.

For CY 2027, we are proposing the RUC-recommended work RVU for all 11 codes in the family. We are proposing the RUC-recommended work RVUs of 0.92 for CPT code 92X0X, 0.44 for CPT code 92X1X, 0.90 for CPT code 92X2X, 0.44 for CPT code 92X3X, 1.00 for CPT code 92X4X, 0.48 for CPT code 92X5X, 1.00 for CPT code 92X6X, 0.50 for CPT code 92X7X, 0.98 for CPT code 92X8X, 0.48 for CPT code 92X9X, and 0.28 for CPT code 92508).

We are proposing the RUC-recommended direct PE inputs for all the codes in the family without refinement.

We are proposing to designate these codes as always therapy services which means they must be furnished under a therapy plan of care regardless of who provides them and billed with a therapy modifier (this includes physicians and NPPs when they furnish the service or therapists furnish the services incident to the physician/NPP). We are also proposing to designate the new CPT codes that each represent the initial 30 minutes—92X0X, 92X2X, 92X4X, 92X6X, and 92X8X—as subject to the multiple procedure payment reduction (MPPR) for therapy services. The new CPT codes that represent each additional 15 minutes—92X1X, 92X3X, 92X5X, 92X7X and 92X9X—are not subject to the MPPR as they are all add-on codes which we excluded in the CY 2011 PFS final rule along with contractor-priced and bundled codes (75 FR 73240) and noted in section 10.7 of chapter 5 of the Medicare Claims Processing Manual (MCPM).

(a) Pediatric G-Code for Speech-Language Pathology Services

We have heard from interested parties the need to preserve CPT code 92507 (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual)* specifically related to the pediatric population. Interested parties stated that the 10 new CPT codes do not accurately capture the time and intensity of work as it relates to pediatric patients. In an effort to be responsive to interested parties, we are proposing to create and pay separately for a new HCPCS code, HCPCS code GSLPP, to accurately reflect the time and resources spent in providing these services to pediatric patients.

We propose the following code and descriptor for the proposed code: HCPCS code GSLPP (*Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual; for the pediatric population up to age 21*). We are proposing that HCPCS code GSLPP would be reported by a speech language pathologist performing these services specific to the pediatric population.

We are proposing that this code could be billed only once per patient per day. We are proposing to assign a XXX global period payment indicator for HCPCS code GSLPP. The XXX global period payment indicator would indicate that the global period does not apply to this service.

As previously discussed in this section, we are proposing to designate HCPCS code GSLPP as an always therapy service and add it to the list of codes that are subject to the MPPR for therapy services.

(b) Proposed Valuation for HCPCS Code GSLPP

We note that the proposed valuation of HCPCS code GSLPP is meant to reflect the time and resource costs, for speech-language pathology services inherent to the pediatric population. Therefore, we believe that CPT code 92507 serves as an appropriate reference for the purposes of valuing HCPCS code GSLPP. We believe there will be relatively the same work involved for HCPCS code GSLPP when compared to the work of CPT code 92507 as it relates to pediatric patients, considering the amount of time needed to furnish the elements discussed earlier in this section. Therefore, we are proposing a work RVU of 1.30, which represents the assigned work for 60 minutes of CPT code 92507. Additionally, we are proposing a work time of 60 minutes established for CPT code 92507, personally performed by the billing practitioner.

We are proposing the same direct PE inputs for HCPCS code GSLPP as CPT code 92507, as we believe that the relative resource costs for this service will remain the same. To help inform whether our proposed valuation reflects the typical service for the pediatric population, we are seeking comment on the typical time and intensity practitioners spend furnishing these services.

(41) Endoluminal Coronary Intravascular Ultrasound (IVUS) (CPT Codes 92978 and 92979)

In April 2025, the RAW identified CPT code 92978 (*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel (List separately in addition to code for primary procedure)*) as a code that has Medicare utilization of 10,000 or more that has increased by at least 100 percent from 2018 through 2023. CPT codes 92978 and 92979 (*Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel (List separately in addition to code for primary procedure)*) were surveyed for the January 2026 RUC meeting.

We disagree with the RUC-recommended work RVUs for these codes and instead we are proposing work RVUs of 1.40 for CPT code 92978 and 1.04 for CPT code 92979 to account for the significant decreases in physician intraservice time for both codes. The RUC's recommendation to maintain current work RVUs for these codes does not appear to fully account for these intraservice time decreases. While we do not believe that the decrease in time as reflected in survey values should always equate to a one-to-

one or linear decrease in newly valued work RVUs we do believe that, since the two components of work are time and intensity, absent an obvious or explicitly stated rationale for why the relative intensity of a given procedure has increased, significant decreases in time should be reflected in decreases to work RVUs although not necessarily in a linear manner, and we do not believe it is appropriate to decrease physician time while maintaining the current work RVUs.

We reviewed the RUC recommendations and found them to be high, relative to other codes with the same or similar work times. Based on a search of similarly timed codes in the RUC database, the RUC-recommended work RVU of 1.76 for CPT code 92978 is higher than 44 of 47 add-on codes with 15 minutes of physician intraservice time. Similarly, the RUC-recommended work RVU of 1.40 for CPT code 92979 would be the second highest work RVU for add-on codes with 12 to 14 minutes of physician intraservice time. Therefore, we disagree with the RUC recommended work RVU of 1.76 for CPT code 92978 and we are instead proposing a work RVU of 1.40 based on a crosswalk to CPT code 93572 (*Intravascular Doppler velocity and/or pressure derived coronary flow reserve measurement (coronary vessel or graft) during coronary angiography including pharmacologically induced stress, when performed; each additional vessel (List separately in addition to code for primary procedure)*). This proposed work RVU is higher than the reverse building block work RVU of 1.06 and results in a higher intensity for the code than its current work RVU and physician time. The resulting increase in intensity more accurately accounts for the RUC's assertion that the intensity and complexity has increased with the evolution of these services because a higher proportion of the skin-to-skin time is now dedicated to more intense activities and interventions.

We also disagree with the RUC recommendation to maintain the current work RVU of 1.40 for CPT code 92979 and are proposing a work RVU of 1.04 based on the RUC-recommended increment of 0.36 work RVUs between CPT codes 96978 and 96979. Similarly, this represents an increase in intensity compared to the code's current work RVU and work time to account for the increased intensity that has occurred with the evolution of these services. The RUC did not recommend and we are not proposing any direct PE inputs for CPT codes 92978 and 92979.

(42) Autonomic Function Testing (CPT Codes 95921, 95XX4, 95922, 95923, 95XX5, 95XX6, 95924, 95XX7, 95XX8, and 95XX9)

In February 2025, the CPT Editorial Panel created six new codes to report autonomic function testing with the use of a tilt table, sudomotor tests, and combined procedures to address an earlier RUC referral: CPT code 95XX4 (T*esting of autonomic nervous system function, with interpretation and report; use of tilt table*), CPT code 95XX5 (*Testing of autonomic nervous system function, with interpretation and report; sudomotor, thermoregulatory sweat test*), CPT code 95XX6 (*Testing of autonomic nervous system function, with interpretation and report; sudomotor, assessing the sympathetic skin response (SSR) potential*), CPT code 95XX7 (*Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint*), CPT code 95XX8 (*Testing of autonomic nervous system function, with interpretation and report; combined sympathetic adrenergic with at least 5 minutes of passive tilt (ie, tilt table) and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint*), and CPT code 95XX9 (*Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic, sympathetic adrenergic function with at least 5 minutes of passive tilt (ie, tilt table), and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint*). The CPT Editorial Panel also revised four existing codes to include interpretation and report and clarification on tilt table use: CPT code 95921 (T*esting of autonomic nervous system function, with interpretation and report; cardiovagal innervation (parasympathetic function), including 2 or more of the following: heart rate response to deep breathing with recorded R–R interval, Valsalva ratio, and 30:15 ratio*), CPT code 95922 (*Testing of autonomic nervous system function, with interpretation and report; vasomotor adrenergic innervation (sympathetic adrenergic function), including beat-to-beat blood pressure and R–R interval changes during Valsalva maneuver and at least 5 minutes of passive tilt (ie, tilt table)*), CPT code 95923 (*Testing of autonomic nervous system function, with interpretation and report; sudomotor, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint*), and CPT code 95924 (*Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt (ie, tilt table)*). This code family was surveyed for the April 2025 RUC meeting.

We are proposing the RUC-recommended work RVU for seven of the ten codes in this family. We are proposing a work RVU of 0.34 for CPT code 95XX4, a work RVU of 0.96 for CPT code 95922, a work RVU of 0.88 for CPT code 95923, a work RVU of 1.00 for CPT code 95XX5, a work RVU of 0.50 for CPT code 95XX6, a work RVU of 1.50 for CPT code 95924, and a work RVU of 1.17 for CPT code 95XX7. We note that several of these work RVUs were affected by the efficiency adjustment which was applied at the start of CY 2026, as the RUC recommendations were based on pre-adjustment work valuations.

We disagree with the RUC-recommended work RVU of 0.88 for CPT code 95921 and we are instead proposing a work RVU of 0.74 based on a crosswalk to CPT code 97813 (*Acupuncture, 1 or more needles; with electrical stimulation, initial 15 minutes of personal one-on-one contact with the patient*). When reviewing this code family, we noticed that CPT code 95921 had one of the highest intensities in the family at the RUC-recommended work RVU of 0.88 despite having some of the shortest surveyed work times and describing one of the seemingly least intensive procedures. The revised code descriptor for CPT code 95921 describes a single test for cardiovagal innervation, and we do not agree that this service should be valued with a higher intensity than some of the other codes in this family that contain multiple kinds of autonomic function testing. The RUC's recommended work RVU would also value CPT code 95921 at the same 0.88 as CPT code 95923 despite the latter code having significantly more total work time (32 minutes as compared to 25 minutes). We are aware that these codes share the same current work RVU, however the new surveyed work times indicate that CPT code 95921 typically takes less time to perform than CPT code 95923, and, since the two components of work are time and intensity, we believe that CPT code 95921 should be valued at a lower rate. Therefore we are proposing a work RVU of 0.74 based on a crosswalk to CPT code 97813, an acupuncture procedure with the identical intraservice and total work time as CPT code 95921. We also note that this valuation of CPT code 95921 maintains the current intensity of

the procedure, as well as better maintaining relativity with the other codes in the family.

We disagree with the RUC-recommended work RVU of 1.75 for CPT code 95XX8 and we are instead proposing a work RVU of 1.56 based on a crosswalk to CPT code 77047 (*Magnetic resonance imaging, breast, without contrast material; bilateral*). We disagree with the RUC's recommended work RVU of 1.75, based on the survey median result, as it represents a significant increase in work valuation and intensity over the other codes in this family. For example, the RUC recommended a work RVU of 1.50 for CPT code 95924 in comparison to 1.75 for this code, despite CPT code 95XX8 having only 5 minutes of additional intraservice time and 3 minutes of additional total time (50 minutes as compared with 47 minutes). CPT code 95XX8 would require an anomalously high intensity relative to the rest of the family to justify the recommended work valuation of 1.75, which we do not agree would be warranted here given that this code is performing the same autonomic function tests that take place in CPT code 95922 and 95923. Therefore we are proposing a work RVU of 1.56 based on a crosswalk to CPT code 77047, a breast MRI procedure with the identical intraservice time and similar total work time as CPT code 95XX8. We believe that this valuation of CPT code 95XX8 better maintains relativity with the other codes in the family instead of requiring an anomalously high intensity as was the case at the RUC's recommended work RVU.

We disagree with the RUC-recommended work RVU of 1.91 for CPT code 95XX9 and we are instead proposing a work RVU of 1.77 based on a crosswalk to CPT code 78831 (*Radiopharmaceutical localization of tumor, inflammatory process or distribution of radiopharmaceutical agent(s) (includes vascular flow and blood pool imaging, when performed); tomographic (SPECT), minimum 2 areas (e.g., pelvis and knees, chest and abdomen) or separate acquisitions (e.g., lung ventilation and perfusion), single day imaging, or single area or acquisition over 2 or more days*). As was the case with CPT code 95XX8, we believe that the RUC's recommended work RVU of 1.91 for CPT code 95XX9, based on the survey 25th percentile result, represents a significant increase in work valuation and intensity over the other codes in this family. While we do agree with the RUC that CPT code 95XX9 includes the most autonomic function tests and should have the highest intensity within the code family, we disagree that CPT code 95XX9 should be valued at a work RVU that results in an intensity approximately 50 percent higher than the rest of this family. To use the same example again, the RUC recommended a work RVU of 1.50 for CPT code 95924 in comparison to 1.91 for this code, despite CPT code 95XX9 having only 5 minutes of additional intraservice time and 7 minutes of additional total time (52 minutes as compared with 47 minutes). We believe that the work valuation and intensity are simply too high at the RUC's recommended work RVU of 1.91 as this does not maintain relativity with the other codes in this family, given that the same tests are being performed. Therefore, we are proposing a work RVU of 1.77 based on a crosswalk to CPT code 78831, a radiopharmaceutical procedure with the identical intraservice time and similar total work time as CPT code 95XX9. We note that this work valuation still assigns the highest intensity in the family to CPT code 95XX9, while bringing it more in accordance with its peer codes. We believe that this valuation of CPT code 95XX9 better maintains relativity with the other codes in the family instead of requiring an anomalously high intensity as was the case at the RUC's recommended work RVU.

We are proposing the RUC-recommended direct PE inputs for CPT codes 95921, 95XX4, 95922, 95923, 95XX5, 95XX6, 95924, 95XX7, 95XX8, and 95XX9 without refinement.

(43) Unattended Sleep Testing (CPT Codes 95X18, 95X19, 95X20, 95X21, 95X22, and 95X23)

At the February 2025 CPT Editorial Panel meeting, CPT codes 95800 (*Sleep study, unattended, simultaneous recording; heart rate, oxygen saturation, respiratory analysis* (*e.g.,* by airflow or peripheral arterial tone), *and sleep time*), 95801 (*Sleep study, unattended, simultaneous recording; minimum of heart rate, oxygen saturation, and respiratory analysis* (*e.g.*, by airflow or peripheral arterial tone)) and 95806 (*Sleep study, unattended, simultaneous recording of, heart rate, oxygen saturation, respiratory airflow, and respiratory effort* (*e.g.*, thoracoabdominal movement)) were deleted. They were replaced with six new CPT codes: 95X18 (*Unattended sleep study, set-up, data acquisition and technical analysis; low complexity of 3–4 channels that generate at least 3–5 parameter categories*), 95X19 (*Unattended sleep study, set-up, data acquisition and technical analysis; moderate complexity of 5–10 channels that generate at least 6–8 parameter categories*), 95X20 (*Unattended sleep study, set-up, data acquisition and technical analysis; high complexity of 11 or more channels that generate at least 9 parameter categories*), 95X21 (*Unattended sleep study, interpretation and report by a physician or other qualified health care professional; low complexity of 3–4 channels that generate at least 3–5 parameter categories*), 95X22 (*Unattended sleep study, interpretation and report by a physician or other qualified health care professional; moderate complexity of 5–10 channels that generate at least 6–8 parameter categories*), and 95X23 (*Unattended sleep study, interpretation and report by a physician or other qualified health care professional; high complexity of 11 or more channels that generate at least 9 parameter categories*). This code family describes the reporting of unattended sleep studies with set-up, data acquisition, and technical analysis, and with interpretation and report by a physician or other qualified health care professional. These new codes were surveyed for the April 2025 RUC meeting.

For CY 2027, the RUC recommended a work RVU of 0.81 for CPT code 95X21, a work RVU of 1.05 for CPT code 95X22, and a work RVU of 1.60 for CPT code 95X23. These codes are professional component only services and have no direct PE inputs; we also note that the RUC recommendations for CPT codes 95X21 and 95X22 were affected by the efficiency adjustment which was applied at the start of CY 2026, as the RUC recommendations were based on pre-adjustment work valuations. For CPT code 95X21, we are proposing the RUC's recommended work RVU of 0.81 and for CPT code 95X22, we are proposing the RUC's recommended work RVU of 1.05.

However, we disagree with the RUC's recommended work RVU of 1.60 for CPT code 95X23 and we are instead proposing a work RVU of 1.42 based on a crosswalk to CPT code 92014 (*Ophthalmological services: medical examination and evaluation, with initiation or continuation of diagnostic and treatment program; comprehensive, established patient, 1 or more visits*), which has 24 minutes of intraservice time and 37 minutes of total time. CPT code 95X23 is a similarly timed code with 20 minutes of intraservice time and 39 minutes of total time. We are aware that the RUC's recommended work RVU is lower than the survey 25th percentile work RVU and further understand that the increase in intensity from moderate complexity of 5 to 10 channels that generate at least 6 to 8 parameter

categories to complexity of 11 or more channels that generate at least 9 parameter categories may not be linear. The additional parameters could be more complex, which could result in higher intensity and may not be fully captured in the previous two codes. We agree that the intensity for CPT code 95X23 should be higher; however, we do not believe that the intensity associated with the RUC recommended RVU of 1.60 is typical for this service since it would be nearly double the intensity of CPT codes 95X21 and 95X22. Therefore, we believe that CPT code 92014 is an appropriate crosswalk compared to the RUC's recommended crosswalk to CPT code 99203 (*Office or other outpatient visit for the evaluation and management of a new patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 30 minutes must be met or exceeded.*). We believe that our proposed valuation of 1.42, based on the crosswalk from 92014, more accurately values CPT code 95X23 since it does not result in the sizable increase in intensity as recommended by the RUC. In addition, we have maintained relativity between the codes in this family with similarly timed codes.

For CPT codes 95X18, 95X19, and 95X20, which are Practice Expense (PE) only codes, we are proposing the RUC-recommended direct PE inputs. However, we note concerns regarding two direct PE inputs: CA021 (Perform procedure/service—NOT directly related to physician work time) and CA042 (Perform procedure/service in post-service period—NOT directly related to physician work time). For CPT codes 95X18 and 95X19, the RUC recommended 15 minutes for the CA021 activity, and 25 minutes for CPT code 95X20. The rationale for this increase from 15 minutes for CPT codes 95X18 and 95X19 to 25 minutes for CPT code 95X20 was not clearly stated in the PE Summary of Recommendations although this is an increase of 66.7 percent. Similarly, for the CA042 activity, the RUC recommended 40 minutes for CPT code 95X18, 50 minutes for CPT code 95X19, and 70 minutes for CPT code 95X20. We note that there is a 10-minute increase from CPT code 95X18 to CPT code 95X19, and a 20-minute increase from CPT code 95X19 to CPT code 95X20. The rationale for these 10-minute and 20-minute increases was also not clearly stated. We appreciate that explanations for the direct PE inputs were provided in the PE Summary of Recommendations, given that this is a non-standard clinical labor activity. However, as CPT code 95X18 describes a low-complexity study, CPT code 95X19 describes a moderate-complexity study, and CPT code 95X20 describes a high-complexity study, we welcome public comments providing additional information, particularly regarding the increases in time for these direct PE inputs across these three CPT codes.

Also, for CPT codes 95X18, 95X19, and 95X20, the RUC recommended use of the ''other'' formula for three new equipment items and based the time assumption of 960 minutes (that is, 16 hours). We are soliciting comments on whether it would be typical for the equipment in question to be worn for the full 16 hours. According to the PE Summary of Recommendations, patients typically arrive later in the day (for example, around 4 p.m.) for an appointment to perform a test run with the equipment, then take the equipment home and return it the following morning (typically around 9 a.m.). Therefore, the RUC recommended a 16-hour period, representing two nights, as this duration currently exists in the RUC database and is generally consistent with clinical practice. However, we are seeking public comments on whether two nights of use are required and typical for home sleep testing, as the reported equipment time may represent the total period the patient has the device outside the office rather than the time it is actually in use.

Lastly, we received invoices for a new supply item and three new equipment items for CPT codes 95X18, 95X19, and 95X20. The new supply item is SA143 (Nox A1 Sensor Kit adult), and the new equipment items are EQ417 (Nox A1s System with SpO2, US), EQ418 (Apnea Link Air), and EQ419 (Apnea Trak Legacy). However, a single invoice for each supply or piece of equipment may not be reflective of typical costs, we encourage interested parties to submit invoices to improve the accuracy of pricing for these items in the direct PE database.

We are proposing the RUC-recommended direct PE inputs for CPT codes 95X18, 95X19, and 95X20 without refinement.

(44) Laser Treatment for Inflammatory Skin Diseases (CPT Codes 96920, 96921, and 96922)

In May 2025, the CPT Editorial Panel revised three codes to reflect the intended use for inflammatory or auto-immune skin diseases (*e.g.*, psoriasis): CPT codes 96920 *(Laser treatment, 308–312 nanometer wavelengths, for inflammatory or auto-immune skin diseases* (*e.g.*, psoriasis); *total area less than 250 sq cm),* 96921 *(Laser treatment, 308–312 nanometer wavelengths, for inflammatory or auto-immune skin diseases* (*e.g.*, psoriasis); 250 sq cm to 500 sq cm), and 96922 *(Laser treatment, 308–312 nanometer wavelengths, for inflammatory or auto-immune skin diseases* (*e.g.*, psoriasis); over 500 sq cm). These codes were last discussed in the CY 2025 PFS final rule (89 FR 97797 through 97801). These revisions were based on flaws in the prior valuation process and a change in the patient population. The specialty society surveyed the code family for the September 2025 RUC meeting.

For CY 2027, we are proposing the RUC-recommended work RVUs of 1.00 for CPT code 96920, 1.24 for CPT code 96921, and 1.50 for CPT code 96922. We are proposing the RUC-recommended direct PE inputs for CPT codes 96920, 96921, and 96922 without refinement.

(45) Real-Time Fluorescence Wound Imaging (CPT Code 976XX)

In September 2025, the CPT Editorial Panel created a new code to report real-time florescence wound imaging, CPT code 976XX (*Real-time fluorescence wound imaging with clinical darkness to identify presence, location, load of bacteria and measure wound size, per day*). The specialty society did not conduct a survey for CPT code 976XX because they determined it would be unable to conduct a successful survey that met the RUC's minimum survey threshold, and therefore, the RUC recommended contractor pricing for CY 2027.

Due to persistent payment variability for the predecessor CPT codes 0598T and 0599T, and limited geographical uptake of the technology, the device manufacturer requested that CMS actively price CPT code 976XX and provided work RVU and direct PE input recommendations. After consideration of the manufacturer's recommendations, we are proposing a work RVU of 0.80 and physician pre-evaluation time of 6 minutes, intraservice time of 15 minutes, and immediate post service time of 5 minutes, totaling 26 minutes of physician time. For direct PE in the non-facility, we are proposing a direct crosswalk of clinical labor activities and time from CPT code 97610 (*Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day*), with the addition of 10 minutes for CA026 Clean surgical instrument package for CPT code 976XX, for a total of 42 minutes of

clinical labor time. Additionally, we are proposing the following supply items and quantities in the non-facility for CPT code 976XX.

TABLE A-D4: PROPOSED SUPPLY ITEMS FOR CPT CODE 976XX

Supply Code	Supply Description	Supply Quantity in the Nonfacility
SA043	pack, cleaning, surgical instruments	1
SB007	drape, sterile barrier 16in x 29in	1
SB019	drape-towel, sterile 18in x 26in	1
SB022	gloves, non-sterile	2
SB028	gown, surgical, sterile	1
SB044	underpad 2ft x 3ft (Chux)	1
SC056	syringe 50-60ml	1
SF007	blade, surgical (Bard-Parker)	1
SG018	bandage, Kling, non-sterile 3in	1
SG035	dressing, 3in x 4in (Telfa, Release)	2
SG051	gauze, non-sterile 4in x 4in	8
SG052	gauze, self-adherent roll 0.5in to 2in (Fabco, Gauztex)	72
SG079	tape, surgical paper 1in (Micropore)	12
SH069	sodium chloride 0.9% irrigation (500-1000ml uou)	1
SJ046	silver nitrate applicator	2
SB061	MolecuLight DX Eco Dark Drapes	1

Additionally, we are proposing the following equipment items and equipment minutes in the non-facility to correspond with the 30 and 36 minutes of clinical labor time included in the default and instrument pack equipment formulas, respectively, for CPT code 976XX. The MolecuLight DX System (ER131) was added to the direct PE database for inclusion in CPT code 976XX assuming a 5-year useful life and purchase price of $21,500 based on the provided invoices. We are not proposing to include the MolecuLight carrying case in CPT code's 976XX's equipment costs as recommended by the device manufacturer. We have a longstanding policy that medical equipment must be at least $500 and all equipment inputs under $500 are considered indirect expense. We welcome public comment on the appropriateness of our proposed work RVU and the typicality of our proposed physician work times and direct PE inputs.

TABLE A-D5: PROPOSED EQUIPMENT ITEMS FOR CPT CODE 976XX

Equipment Code	Equipment Description	Equipment Minutes in the Nonfacility
EF015	mayo stand	30
EF031	table, power	30
EQ137	instrument pack, basic ($500-$1499)	36
EQ168	light, exam	30
ER131	MolecuLight DX System	30

We are seeking comment on whether this service will typically be billed alongside wound debridement codes (that is, greater than 50 percent of the time), and if so, which of the proposed direct PE inputs may be duplicative of those already included in the wound debridement codes, such as CPT codes 11042 (*Debridement, subcutaneous tissue (includes epidermis and dermis, if performed); first 20 sq cm or less)* and 97597 (*Debridement (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), open wound, (e.g., fibrin, devitalized epidermis and/or dermis, exudate, debris, biofilm), including topical application(s), wound assessment, use of a whirlpool, when performed and instruction(s) for ongoing care, per session, total wound(s) surface area; first 20 sq cm or less)*). We note that CPT code 976XX's predecessor codes, CPT codes 0598T and 0599T, were billed with wound debridement codes 35.1 percent and 46.6 percent of the time, respectively. However, we understand that such concurrent billing with wound debridement may become more common as adoption of this technology increases. For example, we are seeking comment on whether the following proposed supply items are duplicative of debridement codes if it is anticipated that these codes will be typically billed together: SB007, SB019, SB044, SC056, SF007, SF018, SG035, SG051, SG052, SG079, SH069 and SJ046. We are also seeking comment on whether these wound care supply items are typical for CPT code 976XX, given that the code descriptor specifies wound imaging but does not include any wound care elements. Finally, we note that the direct PE crosswalk code, CPT code 97610, is billed alone 64.4 percent of the time and with debridement CPT code 11042 only 4.3 percent of the time. Therefore, we are seeking comment on the appropriateness of this code as a direct PE crosswalk considering the different billing patterns of CPT code 97610 and 976XX based on its predecessor codes.

(46) Lactation Care Services (CPT Codes 978XX and 978X1)

At the May 2025 CPT Editorial Panel meeting, two new CPT codes were created for reporting lactation care directed by a physician or qualified health care professional (QHP): CPT codes 978XX (*Lactation care directed by a physician or other qualified health care professional, including history, assessment, training, and report; first 30*

minutes) and 978X1 (*Lactation care directed by a physician or other qualified health care professional, including history, assessment, training, and report; each additional 15 minutes*). These new CPT codes were surveyed at the September 2025 AMA RUC Meeting.

For CY 2027, we are proposing the RUC-recommended work RVU of 0.18 for CPT code 978XX. The RUC did not recommend, and we are not proposing a work RVU for CPT code 978X1, which has been designed as a PE only service.

We are proposing the RUC-recommended direct PE inputs for CPT codes 978XX and 978X1, including the creation of a new clinical staff type for Lactation Consultant (L076A) and a new EF052 equipment item (scale, infant, digital, fine gradation). We are adopting CPT language and requirements for the Lactation Consultant: ''The qualifications of the lactation consultant/counselor must be recognized by a physician society, nonphysician health care professional society/association, or other appropriate source.'' We are proposing to value this new clinical staff type at the same 0.76 rate per minute currently used by the RN (L051A) clinical staff type as recommended by the RUC; we are seeking comment regarding this new clinical staff type and whether there may be a more appropriate crosswalk than the RN clinical staff type. We are proposing the RUC-recommendation of the RN clinical staff type as a proxy for pricing purposes, but are seeking comment on whether Lactation Consultants are typically RNs with additional credentialing/certification to be qualified to serve as a lactation consultant.

(47) Adaptive Behavior Services (CPT Codes 97151, 97152, 97X1X, 97X2X, 97X3X, 97153, 97154, 97X4X, 97X5X, 97155, 97X6X, 97156, 97157, 97158)

At the September 2025 CPT Editorial Panel meeting, the CPT Editorial Panel deleted CPT codes 0362T (*Behavior identification supporting assessment, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.*) and 0373T (*Adaptive behavior treatment with protocol modification, each 15 minutes of technicians' time face-to-face with a patient, requiring the following components: administration by the physician or other qualified health care professional who is on site; with the assistance of two or more technicians; for a patient who exhibits destructive behavior; completion in an environment that is customized to the patient's behavior.*), revised eight existing CPT codes: 97151 (*Behavior identification assessment, administered by a physician or other QHP, each 15 minutes of the physician's or other QHP's time face-to-face with patient and/or caregiver(s) administering assessments and discussing findings and recommendations, and non- face-to-face analyzing past data, scoring and/or interpreting the assessment, and preparing the report and/or treatment plan*), 97152 (*Behavior identification-supporting assessment, administered by technician, face-to-face with the patient, each 15 minutes*), 97153 (*Adaptive behavior treatment by protocol, administered by technician, face-to-face with one patient, each 15 minutes*), 97154 (*Group adaptive behavior treatment by protocol, administered by technician, face-to-face with two or more patients, each 15 minutes*), 97155 (*Adaptive behavior direction of technician and analysis by physician or other QHP, face-to-face with a patient, each 15 minutes*), 97156 (*Family adaptive behavior treatment guidance with analysis, administered by physician or other QHP (with or without the patient present), including discussing protocols and treatment targets and/or training the caregiver(s) to implement assessment or treatment protocols with the patient, face-to-face with caregiver(s) for 1 patient, each 15 minutes*), 97157 (*Multiple-family group adaptive behavior treatment guidance with analysis, administered by physician or other QHP (without the patient present), face-to-face with multiple sets of caregivers for multiple patients, each 15 minutes*) and 97158 (*Group adaptive behavior treatment with analysis, administered by physician or other QHP, face-to-face with multiple patients, each 15 minutes*), and created six new CPT codes: 97X1X (*Behavior identification supporting assessment of harmful behavior, each 15 minutes of technician time face-to-face with a patient, requiring the following components: delivered by two technicians, for a patient who exhibits harmful behavior, conducted in an environment that is customized to the patient's behavior,*), 97X2X (*Behavior identification supporting assessment of harmful behavior, each 15 minutes of technician time face-to-face with a patient, requiring the following components: delivered by two technicians, for a patient who exhibits harmful behavior, conducted in an environment that is customized to the patient's behavior, additional technicians present, each 15 minutes (list separately in addition to code for primary procedure)*), 97X3X (*Adaptive behavior non-face-to-face services, personally performed by a physician or other QHP, each 15 minutes, with any of the following elements, when performed: review and analysis of data and session notes on patient treatment targets, clinical decision making regarding the need to modify treatment targets, goals, or protocols and/or making those modifications, clinical decision making regarding the need for additional assessment and developing or modifying assessment protocols, developing discharge or transition plan, reviewing treatment targets and/or revised assessment or treatment protocols with technician(s).*), 97X4X (*Adaptive behavior treatment of harmful behavior, each 15 minutes of technician time with a patient, requiring the following components: delivered by two technicians, for a patient who exhibits harmful behavior, conducted in an environment that is customized to the patient's behavior.*), 97X5X (*Adaptive behavior treatment of harmful behavior, each 15 minutes of technician time with a patient, requiring the following components: delivered by two technicians, for a patient who exhibits harmful behavior, conducted in an environment that is customized to the patient's behavior, each additional technician present, each 15 minutes (List separately in addition to code for primary procedure)*), and 97X6X (*Adaptive behavior treatment with analysis, administered by physician or other qualified health care professional, face-to-face with 1 patient, each 15 minutes*), to better specify appropriate time, define terms, address reporting gaps, and clarify reporting for technician and physician/QHP face-to-face and non-face-to-face adaptive behavior services. The RUC HCPAC Review Board reviewed the 14 codes in the revised code family at the January 2026 RUC HCPAC.

The RUC is recommending contractor pricing for all twelve codes in the family. The existing CPT codes 97151 through 97158 are currently contractor priced. We propose to contractor price the six new codes and make no change to the status indicator for the eight revised existing codes that are already contractor priced.

(48) Remote Monitoring (CPT Codes 98975, 98976, 98977, 98978, 98980, 98981, 98984, 98985, 98986, 98979, 99091, 99453, 99454, 99457, 99458, 99473, 99474, 99445, and 99470)

(a) Background and Overview

In recent years, we have established payment for two code families that describe certain remote monitoring services: remote physiologic monitoring (RPM) and remote therapy monitoring (RTM). In the CY 2018 PFS final rule, we summarized feedback from a comment solicitation aimed at informing new payment policies that would allow for separate payment for remote monitoring services (82 FR 53014). In the CY 2019 PFS final rule (83 FR 59574 through 59576), we established valuations and payment policy for the RPM code family. In the CY 2020 PFS final rule (84 FR 62697 through 62698), we explained that the RPM code family describes chronic care RPM services that involve the collection, analysis, and interpretation of digitally collected physiologic data, followed by the development of a treatment plan and the managing of a patient under the treatment plan (84 FR 62697). In the CY 2020 PFS final rule, we finalized that CPT codes 99457 and 99458 would be included as designated care management services, allowing RPM services to be furnished under the general supervision of the physician or other qualified health care professional (who is qualified by education, training, licensure/regulation and facility privileging) (84 FR 62698). In the CY 2023 PFS final rule, in response to comments, we clarified that RTM or RPM services could be billed concurrently with Chronic Care Management (CCM), Transitional Care Management (TCM), Principal Care Management (PCM), Chronic Pain Management (CPM), or Behavioral Health Integration (BHI) (86 FR 69528 through 69539).

In September 2024, the Current Procedural Terminology (CPT) Editorial Panel added one code and made code revisions to report RPM device supply for 2 to 15 days and 16 to 30 days within a 30-day period; created one new code and code revisions to report RPM treatment management services for the first 10 minutes, first 20 minutes, and each additional 20 minutes thereafter; added three RTM device supply codes to report respiratory, musculoskeletal and cognitive behavioral therapy for 2 to 15 days and 16 to 30 days within a 30-day period; created one new code and made code revisions to report RTM treatment management services for the first 10 minutes, first 20 minutes, and each additional 20 minutes thereafter; and revised remote monitoring guidelines. We reviewed the RUC recommendations for these services in the CY 2026 PFS final rule (90 FR 49394 through 49404). In response to recent reports and recommendations from the Office of the Inspector General (Additional Oversight of Remote Patient Monitoring in Medicare Is Needed [2] and Billing for Remote Patient Monitoring in Medicare [3]), for CY 2027, we are proposing refinements to the policies surrounding remote physiologic and remote therapeutic monitoring, as detailed later in this section.

(b) Established Patient Requirements

In the CY 2021 PFS final rule (85 FR 84542 through 84546), we established that, when the PHE for COVID–19 ended, we again required that RPM services be furnished only to an established patient. Patients who received initial remote monitoring services during PHE were considered established patients for purposes of the new patient requirements that were effective after the last day of the PHE for COVID–19.

For CY 2027, we are proposing to require that RTM services also be furnished only to established patients. We are proposing this condition of payment because we believe that a practitioner with an established relationship with a patient would likely have had the opportunity to collect relevant patient history and conduct a physical exam, as appropriate. As a result, the practitioner would possess information needed to understand the current medical status and needs of the patient prior to ordering RTM services to collect and analyze the patient's data and use the results of remote therapeutic monitoring to manage the patient under a specific treatment plan or therapy plan of care.

This proposal would also assist in resolving OIG's findings that some practices did not have a prior relationship with patients for whom they billed remote monitoring services for (Billing for Remote Patient Monitoring in Medicare [4]).

(c) Initiating Visit Requirements

For CY 2027, we are proposing that practitioners reporting RPM or RTM services must furnish a separately reportable initiating visit in association with the onset of RPM or RTM services, since these services require a level of care coordination that cannot be effective without appropriate evaluation of the patient's needs. The initiating visit would also ensure the billing practitioner assesses the beneficiary to determine clinical appropriateness of RPM or RTM and provide an opportunity to obtain the required beneficiary consent to receive RPM or RTM services. We are proposing that RPM or RTM services must be initiated by the billing practitioner during a face-to-face (in-person or telehealth) visit. CPT codes that do not involve a face-to-face visit by the billing practitioner or are not separately payable under Medicare cannot be used as the visit for RPM or RTM initiation. If RPM or RTM is not discussed with the patient at that visit, that visit cannot count as the initiating visit for RPM or RTM. The RPM or RTM initiating visit can be separately billed.

(d) Supervision Requirements

Currently, RPM or RTM services may be outsourced to third-party companies that provide services via telephone and online contact only, using staff who have little to no established relationship with the beneficiary or other members of the care team and have little to no interaction with the office staff and billing practitioner. After reviewing the findings discussed in recent OIG reports, such as companies ''cold calling'' beneficiaries to solicit them for remote monitoring services they may not need (Additional Oversight of Remote Patient Monitoring in Medicare Is Needed [5]) and working to improve the transparency of ''incident to'' services, we believe outsourcing RPM/RTM services to a third party can fragment care, lead to insufficient involvement and oversight of the billing practitioner, or result in services that do not actually represent or facilitate all required aspects of RPM or RTM services. Provision of these services by entities having only a loose association with the treating practitioner can detract from longitudinal, patient-centered care. We do not believe that RPM or RTM services provided by clinical staff contracted by a third party can ensure the billing practitioner has adequate oversight, management, or collaboration

[2] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/*.

[3] *https://oig.hhs.gov/reports/all/2025/billing-for-remote-patient-monitoring/*.

[4] See the eCQI Resource Center description of the US Quality Core Implementation Guide (*https://ecqi.healthit.gov/qi-core/about*) and version 0.5.0 of the 2026 US Quality Core Implementation Guide (*http://fhir.org/guides/onc/us-quality-core/ImplementationGuide/fhir.onc.us-quality-core*).

[5] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/*.

to bill RPM or RTM services. If there is little oversight by the billing practitioner or a lack of clinical integration between a third-party providing RPM/RTM and the billing practitioner, we do not believe that the full scope of service elements required to bill these codes are being met.

We are proposing to only allow payment for RPM or RTM services when furnished by clinical staff employed by the practice. To count the time spent by clinical staff providing aspects of RPM or RTM services, the clinical staff must be a direct employee of the practitioner or the practitioner's practice. If finalized, this will mean that for the purposes of billing Medicare, beginning January 1, 2027, the RPM and RTM codes could not be billed in cases where the service is not performed by clinical staff of the billing practitioner and will not allow contracting out to third-party companies. This does not mean the clinical staff must necessarily always be physically located within the practice, nor does it require that the beneficiary be on-site for the provision of remote monitoring services. Under our proposed revised policy, the time spent by clinical staff providing RPM or RTM services can be counted, provided that the clinical staff are under the general supervision of the billing practitioner, all other requirements of the ''incident to'' regulations at § 410.26 are met, and the clinical staff is a direct employee of the practitioner or the practitioner's practice. We are seeking comment on this proposal, specifically on how often third-party billing currently occurs and how this policy, if finalized, could impact access to remote monitoring services.

(e) Valuation

Remote physiologic monitoring (RPM) represents the remote monitoring of parameters such as weight, blood pressure, and pulse oximetry to monitor a patient's condition and inform their management. The remote physiologic monitoring code set currently includes CPT codes 99091, 99445, 99453, 99454, 99457, 99458, 99470, 99473, and 99474 (code descriptors in Table A–D6). Remote therapeutic monitoring (RTM) represents the monitoring of adherence to at-home therapeutic interventions. For RTM, there are distinct device supply codes for three types of therapeutic monitoring: respiratory system, cognitive behavioral therapy, and musculoskeletal system monitoring. The remote therapeutic monitoring code set currently includes CPT codes 98975, 98976, 98977, 98978, 98979, 98980, 98981, 98984, and 98985 (code descriptors in Table A–D6). There are three components of RPM and RTM services: education and setup, device supply, and treatment management.

TABLE A-D6: CY 2027 REMOTE MONITORING CODES

CPT Code	Long Descriptor
98975	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); initial set-up and patient education on use of equipment
98976	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 16-30 days in a 30-day period
98977	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 16-30 days in a 30-day period
98979	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 10 minutes
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; first 20 minutes
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least one interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes (List separately in addition to code for primary procedure)
98984	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period
98985	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 2-15 days in a 30-day period
98986	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 2-15 days in a 30-day period
99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days
99445	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial: device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; first 20 minutes
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring interactive communication with the patient/caregiver during the month; each additional 20 minutes (List separately in addition to code for primary procedure)
99470	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 10 minutes
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient

For CPT codes 99453 and 98975, which are PE-only codes describing RPM and RTM initial set-up and patient education on use of equipment, respectively, we are proposing to crosswalk the direct PE inputs from CPT code 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*), as we believe the existing valuation of CPT codes 99453 and 98975 may not accurately reflect the resource costs involved in those services. Specifically, we are concerned that, due to lack of information regarding the typical device used to perform these procedures, these services are overvalued. We believe that

the typical device used for these procedures in the physician office setting may not be accurately captured in the data previously used for valuation, as we have received very little invoice or pricing information from interested parties for the specific devices used in RTM and RPM services. We believe that a crosswalk to the direct PE inputs associated with CPT code 99473 may more accurately capture the resource costs associated with a typical device set-up and patient education on use of equipment. We are seeking comment on this proposal, specifically information regarding the typical clinical workflow for the initial set-up and patient education on use of equipment services used in furnishing RPM or RTM and their associated costs.

For CPT codes 99445 and 99454, which are PE-only codes describing RPM device(s) supply with daily recording(s) or programmed alert(s) transmission, we are proposing to crosswalk the direct PE inputs from CPT code 99474 (*Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient*). For CPT codes 98976, 98977, 98978, 98984, 98985, and 98986, which are PE-only codes describing RTM device(s) supply for data access or data transmissions, we are proposing to crosswalk the direct PE inputs from CPT code 93270 (*External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)).* We believe the existing valuation of CPT codes 99445, 99454, 98976, 98977, 98978, 98984, 98985, and 98986 may not accurately reflect the resource costs involved in these services, especially since we continue to lack data surrounding the typical RPM and RTM devices and the costs associated with them. Specifically, we are concerned that, due to lack of information regarding the typical device used to perform these procedures, these services are overvalued. We believe that the typical device used for these procedures in the physician office setting may not be accurately captured in the data previously used for valuation, as we have received very little invoice or pricing information from interested parties for the specific devices used in RTM and RPM services. We believe that the crosswalk to the direct PE inputs associated with the proposed codes discussed earlier may more accurately capture the resource costs associated with a typical device. We are soliciting comments on this proposal, specifically information regarding the typical devices used in furnishing RPM or RTM, not just their associated costs and invoices, but robust evidence detailing what providers are actually paying for these devices, including discounts or other typical pricing details. We are seeking other types of pricing data and information for RPM or RTM devices, including if the costs include software, hardware, or both, as well as more information about the typical devices.

For CPT codes 99470, 99457, 99458, 98979, 98980, and 98981, which describe the physician/QHP work associated with treatment management, we are proposing to eliminate PE inputs for these codes, as we believe resource costs for these services are accurately captured in the work RVUs, and we do not believe the typical clinical workflow for these services would involve clinical staff time. We are proposing that the current work RVUs and current work times for these codes be maintained. We welcome information regarding the typical clinical workflow for these services.

We are soliciting comments on these proposals, as well as requesting general feedback from the public that may be useful in further development of our payment policies for remote monitoring services that are currently separately payable under the PFS.

(f) Comment Solicitation

We have concerns about the administrative burden of the numerous remote monitoring codes and proliferation of this code family. We also continue to work to implement recommendations from the recent OIG reports that we are concerned cannot be fully resolved with the current coding structure of the remote monitoring code family, such as ensuring that beneficiaries receive all components of the remote monitoring service. For example, the OIG report found that, ''About 43 percent of enrollees who received remote patient monitoring did not receive all 3 components of it, raising questions about whether the monitoring is being used as intended.'' (Additional Oversight of Remote Patient Monitoring in Medicare Is Needed [6]).

We are also considering, and are seeking comment on, bundling CPT codes 99453, 99445, 99454, 99091, 99470, 99457, 99458, 98975, 98984, 98976, 98985, 98977, 98986, 98978, 98979, 98980, and 98981 through the creation of new codes that describe initial set up and monthly monitoring/management for RPM and RTM, respectively. For payment for remote monitoring services under the PFS, we are also considering, and are seeking comment on, the creation of four new HCPCS G-Codes:

- GRPM1: RPM initial set-up and patient education.
- GRPM2: Remote monitoring of physiologic parameter(s) (*e.g.,* weight, blood pressure, pulse oximetry, respiratory flow rate), per calendar month, including:

++ Device(s) supply with daily recording(s) or programmed alert(s) transmission.

++ 2 or more days of data transmission.

++ Treatment management services, requiring at least one real-time interactive communication with the patient/caregiver; time totaling at least 20 minutes.

- GRTM1: RTM initial set-up and patient education.
- GRTM2: Remote monitoring of therapeutic parameter(s) (*e.g.,* therapy adherence, therapy response, digital therapeutic intervention), per calendar month, including:

++ Device(s) supply for data access or data transmissions.

++ 2 or more days of data transmission.

++ Treatment management services, requiring at least one real-time interactive communication with the patient or caregiver; time totaling at least 20 minutes.

We are seeking comment on these HCPCS G-codes and are also seeking comment on any other revisions needed to the code descriptors to reflect the necessary service elements for this code family. These HCPCS G-codes would adopt all current conditions of payment for the remote therapeutic and remote physiologic codes finalized in prior rulemaking, as well as the proposed established patient, initiating visit, or supervision or both requirements outlined earlier in this section, if finalized. As drafted, all service elements outlined in the G-code descriptors would be required each

[6] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/.*

calendar month. We are seeking public comment on these HCPCS G-codes and, after consideration of public comment, could finalize payment for these codes.

The creation of these G-codes could alleviate administrative burden, as this would reduce the number of remote monitoring codes from 17 to four. These HCPCS G-codes would also ensure that beneficiaries receive treatment management services when receiving remote monitoring services. According to the OIG Reports, billing for Remote Patient Monitoring in Medicare [7] and Additional Oversight of Remote Patient Monitoring in Medicare Is Needed,[8] some beneficiaries do not regularly receive treatment management services. The OIG Report, Additional Oversight of Remote Patient Monitoring in Medicare Is Needed,[9] also stated that forty-three percent of enrollees who received remote patient monitoring did not receive at least one of the three components (patient education and set-up, device supply, and treatment management). Although we have not required that providers bill for all three components, this data from the OIG Report raises questions about how these services are being used. By incorporating device supply, data transmission, and treatment management into one code, we could ensure that those service elements are always provided.

In the CY 2024 PFS final rule (88 FR 79071 through 79073), we finalized the policy to add the suite of services that comprise RPM and RTM services to the general care management code, G0511 beginning January 1, 2024 as the requirements for RPM and RTM services are similar to the non-face-to-face requirements for the general care management services furnished in RHCs and FQHCs. Beginning January 1, 2025, RHCs and FQHCs are required to bill the individual codes that make up the general care management HCPCS code, G0511 (89 FR 97998 through 98010). Accordingly, we are seeking comment on implementing these HCPCS G-codes in RHCs and FQHCs.

We are seeking comment on valuation for these HCPCS G-codes. For GRPM1 and GRTM1, which could be PE-only codes describing RPM and RTM initial set-up and patient education on use of equipment, respectively, we could crosswalk the direct PE inputs from CPT code 99473 (*Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration*). We are seeking comment on this valuation, specifically information regarding the typical clinical workflow for the initial set-up and patient education on the use of equipment services used in furnishing RPM or RTM and their associated costs.

For GRPM2, we could crosswalk the work RVU input of 0.61 RVUs from CPT code 99457 and the direct PE inputs from CPT code 99474 (*Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient*).

For GRTM2, we could crosswalk the work RVU input of 0.62 RVUs from CPT code 98980 and the direct PE inputs from CPT code 93270 (*External patient and, when performed, auto activated electrocardiographic rhythm derived event recording with symptom-related memory loop with remote download capability up to 30 days, 24-hour attended monitoring; recording (includes connection, recording, and disconnection)).*

(49) National Payment for Non-Sheet Form Skin Substitutes

In the CY 2026 PFS final rule (90 FR 49500), we finalized contractor pricing for non-sheet form skin substitutes. We stated that these products have the potential to be payable as skin substitutes; but that the units, as expressed in a product's coding, are difficult to standardize for payment purposes. Therefore, we finalized that we would maintain the current coding mechanism for these products and would direct the Medicare Administrative Contractors (MACs) to determine appropriate payment, which is generally consistent with how these products are currently paid. We stated that we would continue to evaluate payments for these products to determine if an alternative payment methodology may be better suited to non-sheet products.

Based on ongoing analysis and feedback from internal and external interested parties, we have come to believe that, on the balance, the resource costs per cm^2 for non-sheet form skin substitutes is consistent with the resource costs associated with those associated with sheet form skin substitutes. For non-sheet skin substitute products, cm^2 reflects the wound surface area treated rather than the physical dimensions of the product. Therefore, for CY 2027, we are proposing to nationally price the non-sheet form skin substitutes consistent with the payment rates associated with the sheet form skin substitutes. For a list of the non-sheet form skin substitutes, please refer to the skin substitutes section located on the CMS website (*https://www.cms.gov/medicare/payment/fee-schedules/physician-fee-schedule/skin-substitutes*).

(50) Smoking and Tobacco Use Cessation (CPT Codes 99406, 99407) and Screening, Brief Intervention, and Referral to Treatment (SBIRT) (HCPCS Codes G2011, G0396, G0397)

The Trump Administration Executive Order, ''Establishing the President's Make America Health Again Commission'' [10] is a top priority for CMS, as such we continue to focus on the prevention and management of chronic disease. Chronic disease remains a significant public health concern, with three in four American adults having at least one chronic condition, and more than half having two or more chronic conditions. Many preventable chronic diseases are caused by a short list of risk behaviors, including smoking, poor nutrition, physical inactivity, and excessive alcohol use.[11] These patterns reinforce the need for accessible behavioral health services that can help individuals reduce these risk behaviors.

In the CY 2024 PFS final rule (88 FR 79006 through 79010), we finalized an increase in the valuation for timed behavioral health services under the PFS by applying an upward adjustment of 19.1 percent to the work RVUs for time-based psychotherapy codes payable under the PFS. This increase is being implemented over a 4-year transition period.

We believe similar adjustments are warranted for smoking and tobacco use cessation, CPT codes 99406 (*Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes*) and 99407 (*Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes*) and screening, brief intervention, and referral to treatment (SBIRT) services, HCPCS codes G2011

[7] *https://oig.hhs.gov/reports/all/2025/billing-for-remote-patient-monitoring/.*

[8] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/.*

[9] *https://oig.hhs.gov/reports/all/2024/additional-oversight-of-remote-patient-monitoring-in-medicare-is-needed/.*

[10] *https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/.*

[11] *https://www.cdc.gov/chronic-disease/about/index.html.*

(*Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention, 5–14 minutes*), G0396 (*Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and brief intervention 15 to 30 minutes*), and G0397(*Alcohol and/or substance (other than tobacco) misuse structured assessment (e.g., audit, dast), and intervention, greater than 30 minutes*).

Smoking and tobacco cessation and SBIRT services are evidence supported behavioral health interventions. Quitting smoking provides immediate health improvements including lowering the likelihood of developing lung cancer and other smoking-related cancers, and reduces the risks of coronary heart disease, stroke, and chronic obstructive pulmonary disease. Evidence based smoking and tobacco cessation treatments are effective, including the combination of behavioral counseling and medication therapy.[12] SBIRT effectively addresses substance use. In primary care and other clinical settings, SBIRT has been shown to help decrease unhealthy substance use and misuse.[13]

The smoking and tobacco cessation services (CPT codes 99406 and 99407) and SBIRT services HCPCS codes G0396 and G0397 were last valued in 2008, and the SBIRT service HCPCS code G2011 was created and last valued in 2019. Given the evidence supported role these services play in preventing and managing chronic disease and behavioral health conditions including alcohol and/or substance misuse, we believe that valuation should more accurately reflect the clinical intensity and work associated with these time-based services.

Therefore, we propose applying the same upward adjustment of 19.1 percent to the work RVUs for these time-based services aligning with the adjustments made to the time-based psychotherapy codes, in conjunction with the fourth and final year of the phase-in for time-based psychotherapy codes that we finalized in the CY 2024 PFS final rule (88 FR 79006 through 79010). Although the upward adjustment of 19.1 percent for the time-based psychotherapy codes has been implemented over a 4-year period, with CY 2027 being the fourth year, we are proposing to apply the full 19.1 percent to smoking and tobacco use cessation services and SBIRT services in this final year of the transition. This approach ensures that these services are brought into alignment with the psychotherapy codes at the completion of the 4-year phase-in timeline, rather than initiating a new multiyear phase-in period. We are proposing to refine the work RVU of smoking and tobacco use cessation services codes as follows: for CPT code 99406 by increasing the work RVU to 0.29 from the current 0.24, and CPT code 99407 by increasing the work RVU to 0.60 from the current 0.50; and for the SBIRT services codes, we are proposing to refine the work RVU as follows, for HCPCS code G2011 by increasing the work RVU to 0.39 from the current 0.33, for HCPCS code G0396 by increasing the work RVU to 0.77 from the current 0.65, and for HCPCS code G0397 by increasing the work RVU to 1.55 from the current 1.30.

(51) Psychiatric Collaborative Care Model (CoCM) (CPT codes 99492, 99493, 99494, G2214) and APCM BHI Add-On Codes (HCPCS Codes G0568, G0569)

Patients with chronic health conditions are ''more likely to have related behavioral health concerns and find it easier to improve chronic conditions when these concerns are also addressed.'' [14] Integrating behavioral health with primary care has been shown to improve outcomes like reductions in depression severity and enhancing patient's experience of care.[15]

In the CY 2017 PFS final rule (81 FR 80230), we established separate payment for three services, HCPCS codes G0502 (*Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional; initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan; review by the psychiatric consultant with modifications of the plan if recommended; entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant; and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies*), G0503 (*Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation; participation in weekly caseload consultation with the psychiatric consultant; ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers; additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant; provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies; monitoring of patient outcomes using validated rating scales; and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment*), and G0504 (*Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional (list separately in addition to code for primary procedure); (use G0504 in conjunction with G0502, G0503*), used to bill for monthly services furnished using the psychiatric collaborative care model (CoCM), an evidence-based approach to behavioral health integration that enhances ''usual'' primary care by adding care management support and regular psychiatric inter-specialty consultation. The G-codes were valued

[12] *https://progressreport.cancer.gov/prevention/tobacco/cessation-aids#jump-links-field-background.*

[13] *https://pmc.ncbi.nlm.nih.gov/articles/PMC5551279/.*

[14] *https://integrationacademy.ahrq.gov/about/integrated-behavioral-health#:~:text=Integrated%20behavioral%20health%20offers%20many,these%20concerns%20are%20also%20addressed.*

[15] Balasubramanian, Bijal, Deborah Cohen, Katelyn Jetelina, Miriam Dickinson, Melinda Davis, Rose Gunn, Kris Gowen, Frank DeGruy 3rd, Benjamin Miller, Larry Green. ''Outcomes of Integrated Behavioral Health with Primary Care.'' J Am Board Fam Med. 2017 Mar-Apr;30(2):130–139.doi: 10.3122/jabfm.2017.02.160234

to account for the work of the treating physician or other qualified health care professionals, based on a direct crosswalk to the work values for the complex Chronic Care Management (CCM) services, CPT codes 99487 (*Complex chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; first 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.*) and 99489 (*Complex chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored, moderate or high complexity medical decision making; each additional 30 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)*). The valuation also accounted for the work of the psychiatric consultant, based on an estimated 10 minutes of psychiatric consultant time per patient per month, such that the work RVU was based on a crosswalk to the work per minute of a level 3 established patient office visit. These G-codes were replaced by CPT codes 99492, 99493, and 99494, which we established for payment under the PFS in the CY 2018 PFS final rule (82 FR 53077 and 53078). In the CY 2021 PFS final rule (85 FR 84548 through 84574), we increased the work RVUs for certain CPT codes that rely upon or are analogous to office/outpatient evaluation and management (O/O) (E/M) visits, consistent with the increases in values finalized for O/O E/M visits for CY 2021, such that the CoCM services valuation were updated as follows: 99492 (work RVU increased from 1.70 to 1.88), 99493 (work RVU increased from 1.53 to 2.05) and 99494 (work RVU remained 0.82).

Interested parties have expressed concerns regarding the current valuation of CoCM and requested revaluation for these services. They stated that the current valuation undervalues the medical decision-making performed by the billing practitioner and psychiatric consultant and undervalues the labor rates assigned to the CoCM service. The interested parties recommend valuing the work RVUs for the two physicians or other qualified health care professional based on a blended rate based on level 4 and 5 O/O E/M visits based on medical decision-making, CPT codes 99204 and 99205 (for new patients), and 99214 and 99215 (for established patients), to account for the medical decision-making required for the CoCM service. CPT code 99492 would be adjusted from a work RVU of 1.88 to 3.67, 99493 from a work RVU of 2.05 to 2.99, and 99494 from a work RVU of 0.82 to 1.50. The interested parties noted that their recommendation would result in a higher work RVU for the initial psychiatric collaborative care management service, CPT code 99492, compared to the subsequent psychiatric collaborative care management service, CPT code 99493, since the initial month generally involves a new patient requiring more medical decision making. The interested parties recommend valuing CPT code 99494 at 50 percent of CPT code 99493. In addition, the interested parties requested refinements to the direct PE inputs, specifically for the Behavioral Health Care Manager clinical labor type (L057B). They recommend increasing the clinical labor value for Behavioral Health Care Manager (L057B) from a per minute rate of $0.57 to $0.70 per minute by crosswalking the valuation to CORF social worker/psychologist (L045C), rather than to the genetic counselors (L057A) which was used when the original CoCM G-codes were established.

After reviewing the feedback from the interested parties, we reviewed the valuation of the CoCM codes and considered Medicare claims data for levels 3 through 5 O/O E/M services. The Medicare claims data shows that level 5 E/M visits (CPT codes 99205 and 99215), which represent the highest complexity of evaluation and management services, are billed substantially less frequently than level 3 E/M services (CPT codes 99203 and 99213) and level 4 E/M services (CPT codes 99204 and 99214). Based upon this billing pattern, we believe that a blended level 3 and 4 E/M rate would be more appropriate to value CoCM. Therefore, we propose to refine the work RVUs of CoCM as follows: CPT codes 99492 would be adjusted from a work RVU of 1.88 to 2.75, 99493 from a work RVU of 2.05 to 2.26, and 99494 from a work RVU of 0.82 to 1.13, which is 50 percent of 99493.

We also propose conforming changes to the valuation of HCPCS codes G2214, G0568, and G0569, which also describe psychiatric collaborative care services. For HCPCS code G2214 (*Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional),* we propose to refine the work RVU from 0.77 to 1.13, representing one half of the time described by the existing code that describes subsequent months of CoCM services (CPT code 99493), consistent with how the code was valued in the CY 2021 PFS final rule (85 FR 84547 through 84548). For HCPCS code G0568 (*Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies (list separately in addition to the advanced primary care management code*)), we propose to refine the work RVU from 1.88 to 2.75, aligning with the direct crosswalk to the work RVU of CPT code 99492. For HCPCS code G0569 (*Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate*

documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment (list separately in addition to advanced primary care management code)), we propose to refine the work RVU from 2.05 to 2.26, as this code was valued based on a direct crosswalk to the work RVU of CPT code 99493.

Additionally, consistent with the changes proposed for CPT codes 99492–99494, we propose refinements to the direct PE inputs for HCPCS codes G2214, G0568, and G0569 by revaluing the rate of Behavioral Health Care Manager (L057B) with a per minute rate of $0.57 to $0.70. This proposed change is based on a crosswalk of valuing Behavioral Health Care Manager (L057B) to the clinical labor CORF social worker/psychologist (L045C), as opposed to basing the rates to genetic counselors as discussed in the CY 2017 final rule (81 FR 80350). We also note that HCPCS codes G2086 (*Office-based treatment for opioid use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month*), G2087 (*Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month),* and G2088 (*Office-based treatment for opioid use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (list separately in addition to code for primary procedure))* include clinical labor minutes for a Behavioral Health Care Manager (L057B), and therefore as part of this proposal, we are also proposing that that same increase in valuation for L057B from $0.57 to $0.70 would also apply to HCPCS codes G2086–G2088.

We welcome comments on these proposals.

(52) Tympanostomy (HCPCS Code G0561)

In January 2026, the Practice Expense (PE) Subcommittee reviewed the following practice expense only add-on HCPCS code G0561 (*Tympanostomy with local or topical anesthesia and insertion of a ventilating tube when performed with tympanostomy tube delivery device, unilateral)* on the Medicare Physician Fee Schedule which is currently contractor priced.

The RUC recommended one direct PE input for a new supply item, an Automated PE tube delivery device (SD395), and submitted invoices to price the supply at $497.50. We are proposing the RUC-recommended direct PE input for HCPCS code G0561 without refinement.

The RUC did not recommend, and we are not proposing a work RVU for HCPCS code G0561, which has been designed as a PE only service.

(53) Evaluation and Management (E/M) Visit Complexity Add-On (HCPCS Code G2211)

(a) Background

In the CY 2024 PFS final rule (88 FR 78970 through 78982), we finalized separate payment for the O/O E/M visit complexity add-on code, HCPCS code G2211 (*Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established)*). This policy was originally proposed in CY 2019, as part of a proposed overhaul to the E/M code set (83 FR 59628) where we proposed two codes, one for primary care and one for non-procedure specialty care. We learned that the CPT Editorial Panel and AMA RUC were planning to review and refine the O/O E/M code set, so we did not finalize this proposal or the other proposed changes to the E/M code set. The CPT Editorial Panel and AMA RUC reviewed and refined the O/O E/M code set, which were finalized by CMS in the CY 2021 PFS final rule (84 FR 62844 through 62856). We combined the two proposed complexity add-on codes into one, and we finalized separate coding and payment for HCPCS code add-on code GPC1X in the CY 2020 PFS final rule (84 FR 62854 through 62856). This became HCPCS code G2211 in the CY 2021 final rule (85 FR 84569). However, implementation of G2211 was delayed by Congress (section 113 of Division CC of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260, December 27, 2020) (CAA, 2021)), and we began actively paying for HCPCS code G2211 in CY 2024.

In the CY 2026 PFS final rule (90 FR 49462 through 49464), we finalized our proposal to allow HCPCS code G2211 to be billed as an add-on code with the home or residence E/M visits code family (CPT codes 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350). We finalized refinements to the code descriptor of HCPCS code G2211 *(Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition. (Add-on code, list separately in addition to home or residence or office/outpatient evaluation and management service, new or established)* to reflect this change.

This service is intended to recognize the longitudinal relationship between the patient and the practitioner, which differentiates the E/M visit from visits that are not longitudinal in nature. As discussed in section II.E. of this proposed rule, we are continuing to examine primary care in the PFS, and how we can appropriately recognize the resource costs of longitudinal and especially primary care, given the generality of E/M coding.

(b) Proposed Changes to the Billing Mechanism for Inherent Complexity

(i) Modifier MOD1

Since we began actively paying for HCPCS code G2211 in CY 2024, we have come to believe that the resource costs of furnishing longitudinal care for beneficiaries is not best characterized as a separate service requiring a separate code. Rather, we believe that since this work is an inherent part of the visit, it would be more accurately valued as a modifier to the base E/M code. We also believe that transitioning HCPCS code G2211 from an add-on code to a modifier will be more streamlined from an operational perspective. This should also reduce operational burden, as it will not require the submission of a separate claim line, because the modifier will be placed on the claim

line for the associated E/M code. We are therefore proposing to replace HCPCS code G2211 with a modifier, which we will refer to in this proposed rule as MOD1, which is a placeholder that would be replaced with a two-digit HCPCS modifier, if finalized.

We are proposing that modifier MOD1 will be billed under the same circumstances that HCPCS code G2211 is billed now. We discussed in the CY 2024 final rule (88 FR 78973) that HCPCS code G2211 was intended to characterize the associated E/M code as a service with a practitioner who serves as the continuing focal point for all needed health care services, or with medical care that is part of ongoing care related to a patient's single, serious, or complex condition. HCPCS code G2211 was meant to describe the inherent complexity of these visits that would otherwise be unaccounted for. The application of the add-on code is not based on the characteristics of particular patients (even though the rationale for valuing the code is based on recognizing the typical complexity of patient needs), but rather the relationship between the patient and the practitioner.

We are proposing to match the code descriptor for HCPCS code G2211 to MOD1, with some technical changes. The new proposed modifier descriptor is: *Visit complexity inherent to new or established office/outpatient or home or residence evaluation and management service, associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient's single, serious condition or a complex condition.*

(ii) Modifier MOD1 Valuation

When HCPCS code G2211 was finalized in the CY 2020 PFS final rule (84 FR 82854 through 82855), we crosswalked it to 100 percent of the valuation of CPT code 90785 *(Interactive complexity (List separately in addition to the code for primary procedure)),* which was created to capture additional work that occurs with certain psychiatric and psychotherapy codes. We believed that this service was analogous to the additional work involved in maintaining a longitudinal relationship with patients as described by CPT code 90785. CPT code 90785 has a work RVU of 0.33 and a physician time of 11 minutes. In reexamining this policy after a few years of utilization, we have come to believe that a flat rate as described by G2211 does not reflect the variation in work of the various E/M visit levels.

TABLE A-D7: COMPARISON OF HCPCS CODE G2211 WITH BASE CODES

Base CPT code	Total NF RVU of HCPCS code G2211	Total NF RVF of Base CPT code	HCPCS code G2211 as percentage of base-code
99212	0.52	1.78	0.52/1.78: **29%**
99215	0.52	5.76	0.52/5.76: **9%**

Table A–D7 illustrates that the addition of HCPCS code G2211 as an add-on to the associated E/M visit represents a higher increase in total value for base codes with lower total non-facility RVUs than it does for more intense services. For example, HCPCS code G2211 has a total RVU of 0.52 in the non-facility (NF) setting. CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code selection, 10 minutes must be met or exceeded.*) has a total NF RVU of 1.78. So, when HCPCS code G2211 is appended to CPT code 99212, the overall value of the service is increased by 29 percent. However, when HCPCS code G2211 is appended to CPT code 99215 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and high level of medical decision making. When using total time on the date of the encounter for code selection, 40 minutes must be met or exceeded.*) with a NF total RVU of 5.76, it only represents a 9 percent increase in the total value of the service. We believe that HCPCS code G2211 should reflect an increase to the base code that is proportional across all types of E/M visits. Therefore, we are proposing a modifier to replace HCPCS code G2211 with the valuation of 16 percent of the base E/M code. We established this percentage using a weighted average of the percentage increase that G2211 comprised relative to the O/O E/M code, weighted by HCPCS code G2211 utilization and adjusted to achieve budget neutrality.

(c) G2211 in Medicare Accountable Care Organizations (ACOs)

(i) Background

The Medicare Shared Savings Program (Shared Savings Program) established under section 1899 of the Act, offers doctors, hospitals, and other health care providers an opportunity to create an Accountable Care Organization (ACO). Shared Savings Program ACOs are groups of doctors, hospitals, and other health care professionals that work together to give patients high-quality, coordinated service and health care, improve health outcomes, and manage costs.[16] In Original Medicare, physicians are reimbursed for reasonable and necessary services necessary for diagnosis or treatment of illness or injury. In an ACO, the doctor-patient relationship in Original Medicare is expanded such that the doctors, hospitals and other health care professionals are not just providing services under the reasonable and necessary standard, but there is additional work conducted to manage the beneficiaries' overall health, considering their personal health goals and values. This is how CMS defines an ''accountable care relationship,'' and this relationship may lead patients to be less likely to get repeated medical tests or unnecessary services, since clinicians consider a patient's entire health history when developing a treatment plan, and the doctors and other health professionals communicate and collaborate to improve the patient's

[16] ''Accountable Care and Accountable Care Organizations.'' *Centers for Medicare & Medicaid Services,* CMS Innovation Center, *https://www.cms.gov/priorities/innovation/key-concepts/accountable-care-accountable-care-organizations.* Accessed 16 June 2026.

long-term health.[17] CMS believes accountable care supports the professional ethos of health professionals to take responsibility for their patients in a way that beneficiaries expect. When these accountable care relationships succeed and the ACO succeeds in delivering high-quality care and reducing expenditures, the ACO may be eligible to share in the savings. For more information on the Shared Savings Program and policies directly relating to Shared Savings Program, see section III.G. of this proposed rule.

The CMS Innovation Center recently announced the Long-term Enhanced ACO Design (LEAD) Model which will launch on January 1, 2027. LEAD builds upon previous accountable care work and was designed to attract health care providers that have previously had limited participation in ACOs. It also aims to encourage health care providers to deliver preventive care, empower beneficiaries to be more actively involved in their care, and support health care providers who serve high needs and dually eligible beneficiaries to improve care and reduce costs.

(ii) Modifier MOD2

In the PFS, we have established a complexity add-code (HCPCS code G2211) that we are proposing to change to a modifier (MOD1) that supports care relationships which may approximate but are not accountable care. This modifier is meant to recognize the additional complexity of services associated with providing ongoing, longitudinal care to a beneficiary. We are proposing that the complexity of care established in that longitudinal relationship fundamentally differs in Original Medicare where physicians are providing all reasonable and necessary care for diagnosis and treatment of a clinical condition versus when they are in an accountable care relationship. As previously discussed, we are proposing applying the complexity add-on (we are proposing to change this to a modifier) to reflect the ongoing resource costs associated with being the focal point for all needed health care services performed under this reasonable and necessary standard.

We believe this standard is distinct from care provided in an ACO, where in addition to being responsible for all needed health care services that are part of ongoing care, clinicians are also responsible for managing the accountable care relationship, which involves managing a beneficiary's overall health, personal goals, values, and coordinating care with responsibility for both quality and cost. We consider the complexity associated with serving as the focal point of care for all necessary services within an accountable care relationship, responsibility for the entire patient, and responsibility for quality and cost of care, to be inherently more complex than serving in this role outside of an accountable care relationship. We are therefore proposing two levels for this modifier to reflect the additional resource costs associated with accountable care.

For example, the most common condition for which HCPCS code G2211 was billed in 2024 in Original Medicare was hypertension.[18] Outside of an accountable care relationship, the complexity add-on (proposing in this rule to change to a modifier) would be billed by clinicians for E/M visits managing a beneficiary's hypertension over time. The additional time and resource costs for serving as this focal point in care may address a patient's reservations about initiating pharmacologic treatment for hypertension (for example, perhaps the beneficiary wishes to trial complementary or alternative medicine approaches, so the clinician and patient engage in shared decision-making to understand the risks and benefits of this approach preceding pharmacologic intervention).[19] They may also discuss risk factor reduction (for example, smoking cessation) and lifestyle changes (for example, following the dietary approaches to stop hypertension or 'DASH' diet and meeting physical activity recommendations), or perhaps engage in motivational interviewing to facilitate behavior change. While the current HCPCS code G2211 is meant to take into account the additional time and resource intensity for these services, we expect even more from clinicians participating in an ACO.

For example, a beneficiary has general anxiety disorder and hypertension and monitors their blood pressure at home. They have an instance in which their blood pressure exceeds 140/90mmHg, and they also feel panic or a sense of impending doom or chest pain. They decide to go to the emergency room, but the slightly elevated blood pressure may or may not be the physiologic trigger of their symptoms. This patient may continue to seek care at the emergency room for similar episodes indefinitely unless their practitioner identifies this trend on their own and provides education to the patient on distinguishing the symptoms of anxiety from hypertension, and when it may be appropriate to go to the emergency room. If this same patient was in an ACO, that ACO might have already established admission discharge transfer (ADT) notifications which would alert the team (near-real time) for the admission. This would allow for earlier intervention to ensure that both the patient's anxiety and blood pressure were being managed in the correct setting, and that the patient had the best information to understand their intersecting conditions.

The additional time and resources associated with coordinating care for this complex patient considering both quality and cost are distinct. We are proposing differentiating the resource costs associated with HCPCS code G2211 outside of and within an accountable care environment to account for the additional resource costs associated with serving as the focal point of care for the entire beneficiary within an accountable care relationship. We are clarifying that we do not believe every encounter a patient has within an ACO qualifies as longitudinal. For example, if instead of presenting to the ED, the patient calls the clinic and is able to see another ACO participant, ACO professional, ACO provider/supplier (as each is defined at § 425.20, for the Shared Savings Program), or LEAD Participant Provider who is available the same day, this encounter would not necessarily meet the criteria of inherent complexity, if that practitioner is not supporting the beneficiary's longitudinal care, and if this visit is not more inherently complex. Simply providing an E/M visit while being part of an ACO does not necessarily meet the threshold of inherent complexity.

We believe that MOD2 aligns with the goals of the Shared Savings Program and LEAD, which involve groups of health care providers working together to enhance beneficiary health through high quality, longitudinal primary and preventative care. One of the features of Shared Savings Program and LEAD ACOs is that beneficiaries benefit from ACO participants balancing goals of having total cost of care accountability and improving quality of care, while avoiding unnecessary services and

[17] ''Accountable Care and Accountable Care Organizations.'' *Centers for Medicare & Medicaid Services, https://www.cms.gov/priorities/innovation/innovation-models/aco.* Accessed 16 June 2026.

[18] Ganguli I, Daley NE, Hicks AL, McWilliams JM, Rosenthal MB. Billing of Medicare's G2211 Longitudinal Care Code Among Traditional Medicare Beneficiaries. *JAMA.* 2026;335(11):1003–1006. doi:10.1001/jama.2026.0424.

[19] ''Hypertension (High Blood Pressure).'' *National Center for Complementary and Integrative Health,* U.S. Department of Health and Human Services, July 2018, *https://www.nccih.nih.gov/health/hypertension-high-blood-pressure.* Accessed 16 June 2026.

medical errors. While the specifics vary between the Shared Savings Program and the LEAD model, in general, participating ACOs are required to report quality measures that align with these objectives, and they are measured against their past performance, and the performance of similar ACOs.[20]

While these measures span a broad area of topics, many measures are focused on longitudinal care and care coordination, such as chronic disease management, preventive care and screenings and reducing avoidable hospitalizations.[21] Current participation in the Shared Savings Program helps provide and future participation in LEAD will help provide a framework to allow health care providers to collaborate to give coordinated high-quality care, while also enabling investment to achieve those goals. For example, health care providers may join ACOs to help defray the costs of large capital investments such as electronic medical records.[22] Health care providers also cite help with care coordination and quality reporting as a reason to join, increasing their access to resources and expertise to help with these areas in their practice.[23] We also want to encourage health care providers to form and join ACOs to coordinate care for their beneficiaries. Similarly, ACO participants, ACO professionals, ACO providers/suppliers (as each is defined at § 425.20, for the Shared Savings Program), and LEAD Participant Providers often provide advanced primary care to beneficiaries regardless of whether a particular beneficiary is assigned, aligned, or attributed to their ACO. Advanced primary care is a patient-focused approach to care wherein health care providers take extra steps to actively manage a beneficiary's health care needs.[24] Further, additional beneficiaries to whom a health care provider provides care might be assigned to that ACO in the future, so encouraging similar care to be provided to all beneficiaries served by health care providers in ACOs would be in the interest of the ACO. This level of care coordination, which includes advanced primary care, is often inherent by virtue of participation in an ACO.[25]

We are proposing to match the descriptor of MOD2 to MOD1 and HCPCS G2211, with some small differences. The new proposed modifier descriptor is: *Visit complexity inherent to new or established office/outpatient or home or residence evaluation and management service, associated with medical care services furnished by a participant or practitioner participating in a Medicare accountable care organization. Services must serve as the continuing focal point for all needed health care services and/or be part of ongoing care related to a patient's single, serious condition or complex condition.*

(ii) Modifier Valuation for Medicare ACO Participants

With these goals in mind, we are proposing that, in place of reporting G2211, ACOs would have the option to report a modifier on a claim (referred to in this proposed rule as placeholder MOD2, which if finalized would be replaced with a two-digit HCPCS modifier), which will be valued at 32 percent of the associated E/M visit when performed by Shared Savings Program ACO participants, ACO professionals, and ACO providers/suppliers (as each is defined at § 425.20), as well as Participant Providers in the LEAD Model. We are proposing that MOD2 would pay twice the rate of MOD1 to better account for the inherent complexity of some visits in the ACO context, specifically applying to Shared Savings Program and LEAD ACOs in situations that require increased time and intensity. This increased valuation is meant to reflect the cognitive work of providing longitudinal care, follow-up discussions through an assigned care coordinator with the beneficiary or other providers, and expanded access to educational resources, care options, and provider communication methods. The value-based care provided through a Shared Savings Program or LEAD ACO puts greater emphasis on integrated care, meaning health care providers work together to address a person's physical, mental, behavioral and social needs. In this way, providers treat an individual as a whole person, rather than focusing on a specific health issue or disease.[26] [27]

The differential payment we propose to provide to Shared Savings Program ACO participants, ACO professionals, and ACO providers/suppliers (as each is defined at § 425.20) and to LEAD Participant Providers would further support the CMS Innovation Center 2025 Strategy to Make America Healthy Again which focuses on empowering Americans to achieve their health goals and live healthier lives.[28] We recognize that not all E/M visits represent longitudinal care and so we would not expect MOD2 to be included on all claims for E/M visits, only visits that have an increased visit complexity that requires an increased valuation, as described in the examples provided earlier in this section.

(iii) Use of MOD2 Modifier by ACOs

Modifier MOD2 would be exclusively available for ACO participants, ACO professionals, and ACO providers/suppliers (as each is defined at § 425.20, for the Shared Savings Program), as well as LEAD Participant Providers, when the visit complexity is met, provided the individual is a medical professional who can bill office and outpatient E/M visits or home visit services, regardless of specialty. Utilization and claims of either modifier will be included in ACOs' expenditure calculations for benchmarking and performance year expenditures and used in the determination of total cost of care.

As described earlier in this section, we are proposing a differential payment for MOD2 that is meant to provide a meaningful increase in the way we pay for primary care provided by ACO participants, ACO professionals, and ACO providers/suppliers (as each is defined at § 425.20, for the Shared Savings Program), as well as LEAD Participant Providers who often provide additional care coordination to beneficiaries in their care as demonstrated by their participation in an ACO, as described in the examples provided earlier in this section. We are further proposing that the use of this modifier be voluntary; and ACO participants, ACO professionals, ACO providers/suppliers (as each is defined at § 425.20, for the Shared Savings Program), and LEAD Participant Providers would determine if this modifier is necessary based on visit complexity and would append MOD1, MOD2, or no modifier, as appropriate. Additionally, we are proposing that ACO participants, ACO professionals,

[20] *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations#quality.*

[21] *https://www.cms.gov/priorities-innovation-key-concepts-accountable-care-accountable-care-organizations.*

[22] *https://www.cbo.gov/publication/60213.*

[23] Berenson, R.A., Burton, R.A., & McGrath, M. (2016). Do accountable care organizations (ACOs) help or hinder primary care physicians' ability to deliver high-quality care? *Healthcare, 4*(3), 155–159. *https://doi.org/10.1016/j.hjdsi.2016.02.011.*

[24] *https://www.cms.gov/medicare/payment/fee-schedules/physician-fee-schedule/advanced-primary-care-management-services* and *https://www.medicare.gov/coverage/advanced-primary-care-management-services.*

[25] Centers for Medicare & Medicaid Services. Care Transformation Toolkit. CMS Innovation Center; 2021. Available at *https://www.mathematica.org/publications/care-transformation-toolkit.*

[26] *https://www.cms.gov/priorities/innovation/key-concepts/value-based-care.*

[27] *https://www.cms.gov/priorities/innovation/key-concepts/person-centered-care.*

[28] *https://www.cms.gov/priorities/innovation/about/strategic-direction.*

and ACO provider/suppliers (as each is defined at § 425.20, for the Shared Savings Program), as well as LEAD Participant Providers may bill this modifier for all beneficiaries to whom they provide care, regardless of whether that beneficiary is assigned, aligned, or attributed to an ACO, to encourage similar care to be provided to all beneficiaries served by health care providers who participate in ACOs. Given that ACO Primary Care Flex (ACO PC Flex) Model participation is predicated on participation in the Shared Savings Program, we are proposing that ACO PC Flex Model ACOs may also utilize the MOD2 modifier. Finally, we are proposing that LEAD Participant Providers billing under a Participant TIN that is in a LEAD ACO may bill modifier MOD2. Refer to the discussion later in this section for additional information on the use of modifier MOD2 on alignment in the LEAD model.

(A) Impacts on Assignment of Beneficiaries to Shared Savings Program ACOs

HCPCS code G2211 is included in the definition of primary care services used for purposes of assignment under § 425.400(c). Although we are proposing that HCPCS code G2211 be deleted, under this proposal, it would remain in the regulations at § 425.400(c) to be included for purposes of determining the population of OM beneficiaries for whose care the ACO is accountable under 42 CFR subpart F, and for determining whether an ACO has achieved savings under 42 CFR subpart G, and will continue to be used for assigning beneficiaries to an ACO in benchmark years during which HCPCS code G2211 was still an allowable service. If the proposal is finalized, the code will no longer be payable, and there will be no impact on future calculations of allowed charges used for purposes of assignment.

Modifier MOD2 can be appended to O/O or home or residence E/M services exclusively by ACO participants, ACO professionals, ACO providers/suppliers (as each is defined at § 425.20, for the Shared Savings Program), and LEAD Participant Providers who can bill O/O or home or residence E/M service, regardless of specialty. In performing claims-based assignment under the Shared Savings Program, CMS determines whether allowed charges for a beneficiary's primary care services (as identified for ACO professionals, including at Electing Teaching Amendment hospitals and Method II Critical Access Hospitals, and services furnished at an FQHC or RHC) in an ACO are greater than allowed charges for the beneficiary's primary care services in any other ACO, or other individual health care providers, or groups of health care providers identified by Medicare-enrolled billing TINs or CMS Certification Numbers that are not participating in the Shared Savings Program. In making this determination, we determine where the beneficiary received the plurality of his or her primary care services.

The allowed charges associated with O/O or home or residence E/M services billed with or without modifiers MOD1 or MOD2 will be used in determining beneficiary assignment. Since the CPT codes identified as O/O or home or residence E/M services are included in the definition of primary care services used for purposes of assignment as defined in 42 CFR 425.400(c), we do not believe that changes to the regulatory text are required. Certain operational changes will need to be implemented which will be communicated via Change Request,[29] Medicare Learning Network (MLN) Matters® article,[30] or other sub-regulatory guidance.

(B) Impacts on Assignment of Beneficiaries to LEAD ACOs

In LEAD, if this proposal is finalized, we will handle the deletion of HCPCS code G2211 and the transition to the modifiers similarly to the Shared Savings Program. As indicated in Appendix C of the LEAD Request for Applications, the HCPCS code G2211 code is one of the Primary Care Qualified Evaluation and Management (PQEM) services that CMS uses to align beneficiaries to LEAD ACOs via claims-based alignment. We will continue to use HCPCS code G2211 allowable charges to conduct claims-based alignment in LEAD when HCPCS code G2211 was an allowable service in the requisite claims look back period. For example, when conducting initial claims-based alignment in Performance Year (PY) 2027, we will reference claims from October 1, 2025 to September 30, 2026. HCPCS code G2211 allowable charges will be included in the claims-based alignment run since it is an allowable service during this period.

When aligning beneficiaries to LEAD ACOs, CMS looks first for an existing primary care relationship within the claims lookback period. If 10 percent or more of a beneficiary's PQEM allowable charges (measured by dollar amount) were billed by physicians or non-physician health care providers with a primary-care specialty (family medicine, internal medicine, geriatrics, general practice, nurse practitioner, physician assistant, and clinical nurse specialist), alignment is based solely on these primary care providers. If less than 10 percent of a beneficiary's PQEM allowable charges were billed by primary-care specialties, alignment considers certain non-primary care providers that manage chronic or complex conditions (for example, cardiology, nephrology, endocrinology, psychiatry, etc.). The beneficiary is aligned to a LEAD ACO if the Participant TIN that furnished the largest share of allowable charges incurred for PQEM services during the lookback period is participating in a LEAD ACO.

Once the claims-based alignment look back period rolls forward to include 2027 (and future years) the LEAD alignment methodology will include the allowed charges associated with modifier MOD1 and MOD2 when conducting claims-based alignment (the underlying O/O or home or residence E/M service that will be modified by MOD1 and MOD2 are already LEAD PQEM services). LEAD ACOs will be accountable for expenditures incurred by using either modifier MOD1 or MOD2. Expenditures associated with modifier MOD1 and MOD2 will be included in total Medicare Parts A and B expenditures when CMS conducts financial settlement for LEAD ACOs. More information on the impact to claims processing, capitated payments, and LEAD benchmarks will be shared with ACOs that were selected for participation in LEAD in PY 2027.

(iv) MOD1 and MOD2 Billed With Modifier –25

When we finalized the HCPCS code G2211 policy in the CY 2021 PFS final rule (85 FR 84572), we did not limit the use of HCPCS code G2211 with O/O E/M visits in which CPT Modifier –25 was appended. CPT Modifier –25 denotes a significant, separately identifiable O/O E/M visit by the same physician or other qualified health care professional on the same day as a procedure or other service. We finalized HCPCS code G2211 as payable in the CY 2024 PFS final rule (88 FR 78974), and in the CY 2025 PFS final rule (89 FR 97856 through 97858), we finalized that we would allow payment of HCPCS code G2211 with –Modifier 25 when the O/O E/M base code is reported by the same practitioner on the same day as an annual wellness visit (AWV), vaccine administration, or any Medicare Part B preventative service when furnished in

[29] Available at *https://www.cms.gov/medicare/regulations-guidance/transmittals.*

[30] Available at *https://www.cms.gov/training-education/medicare-learning-networkr-mln/resources-training/mln-matters-articles.*

the office or outpatient setting. For CY 2027, we are proposing to maintain the same limitations we established for HCPCS code G2211 in the CY 2025 PFS final rule (89 FR 97856 through 97858) for MOD1 and MOD2 when billed with Modifier –25.

Later in this section, we are making additional proposals related to changes for payment when modifier –25 is appended. Given these changes, we are seeking comment on whether we should consider changes to this policy, such as allowing MOD1 or MOD2 to be billed with modifier –25 when an O/O E/M is performed on the same day as a 0-, 10-, or 90- day global procedure?

(54) Shared Medical Appointment (HCPCS Code GSMAS)

In accordance with President Trump's Executive Order, ''Establishing the President's Make America Healthy Again Commission,'' [31] the Administration is directing agency focus towards understanding and drastically lowering chronic disease rates. As part of this commitment, we remain focused on the prevention and management of chronic disease, including through approaches that address underlying behavioral and lifestyle drivers of health.

In CY 2026, we solicited feedback on how CMS could further support the prevention and management of chronic diseases. In response to our request for information on chronic disease prevention and management, commenters indicated that many services that help prevent and manage chronic disease, such as lifestyle modification support, health education, and peer support, require time, coordination and multidisciplinary engagement that is not adequately supported under the current PFS. Additionally, many commenters indicated that social isolation and loneliness is a persistent barrier to effective care for Medicare beneficiaries. The commenters indicated that although health care providers are already implementing interventions to identify and address social isolation, these efforts are resource intensive and not adequately supported under the current PFS.

Based on this feedback, we recognize the importance of health care delivery approaches that enable multidisciplinary support, foster beneficiary engagement, and encourage sustainable lifestyle and behavioral changes. Shared medical appointments (SMAs) are one such approach to offer a group-based environment in which beneficiaries can receive clinical guidance while also engaging with peers facing similar health challenges. SMAs may also help address social isolation and loneliness for some beneficiaries.

SMAs, also known as shared medical visits or group visits, are voluntary group-based sessions where multiple patients with a common chronic condition, such as type 2 diabetes mellitus, receive medical care together. In general, SMAs involve more than one healthcare provider, such as a person trained or skilled in delivering patient education or facilitating patient interaction and a prescribing practitioner to make and initiate a comprehensive care plan. SMAs generally last from 60 to 120 minutes and incorporate time for social integration, interactive education, and adjustments to the patient's care plan.[32] Compared with group education alone, SMAs allow patients to participate in clinical care activities that are tailored to the needs of both the group and the individual participants.[33] During the SMA session, a practitioner may meet with a patient individually in a private or semi-private manner or conduct the visit in a group setting where other patients are able to listen and, in some cases, contribute to the discussion.[34]

Reported advantages of shared medical appointments include providing patients more time with their health care provider, creating opportunities for patients to learn from and share self-management strategies with one another, improving access to care, incorporating nonpharmacologic treatment approaches, enhancing the overall quality of care, and helping reduce emergency department visits.[35]

Currently there is no CPT or HCPCS code specifically designated for SMAs. However, practitioners typically bill SMAs using existing Evaluation and Management (E/M) codes, CPT codes 99212–99215, based on medical decision-making criteria; and if another billable clinician such as a registered dietician assists with the SMA, the registered dietician may also bill for their portion of the SMA separately (for example, CPT code 97804 (*Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes)*). Therefore, we propose to create coding and valuation specifically for SMAs.

We propose that SMAs be limited to beneficiaries who have received a professional service from the billing physician or other qualified health professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice within the previous 12 months. We believe this requirement is necessary to ensure beneficiaries have an existing clinical relationship with the practitioner before the beneficiary is integrated into a group-based medical care setting.

We propose requiring beneficiaries to consent to SMA participation, since they may elect to receive individual medical appointments instead. Additionally, we propose that beneficiaries must consent to confidentiality terms because personal health information would be discussed in the group setting.

SMA sessions generally last 60 to 120 minutes and may include up to 25 patients, however SMAs most commonly consist of 6 to 10 patients.[36] We propose establishing SMAs as 60-minute sessions with a maximum of 10 beneficiaries per session.

The expansion of telehealth services has increased opportunities for SMAs to improve access for individuals in geographically remote areas, and those with transportation challenges. We propose that SMA sessions can be held either in-person or via telehealth, and we are proposing to add the SMA service to the Medicare Telehealth list accordingly.

We propose that each shared SMA session be documented in each participating beneficiary's medical record. Each beneficiary receives individualized clinical care, and the medical record must reflect the specific services that the individual beneficiary received during the SMA session. The need for individualized care may depend on the intervention and surrounding evidence. Therefore, if a beneficiary requires a level of individualized care that extends beyond what can appropriately be provided

[31] *https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/.*

[32] *https://www.ncbi.nlm.nih.gov/books/NBK99776/#.*

[33] Kirsh, Susan R., Aron, David C., Johnson, Kimberly D., Santurri, Laura E., Stevenson, Lauren D., Jones, Katherine R., and Jagosh, Justin. ''A realist review of shared medical appointments: How, for whom, and under what circumstances do they work?'' Available from *https://pmc.ncbi.nlm.nih.gov/articles/PMC5291948/pdf/12913_2017_Article_2064.pdf.*

[34] Thompson-Lastad, Ariana. ''Group Medical Visits as Participatory Care in Community Health Centers.'' Available from *https://pmc.ncbi.nlm.nih.gov/articles/PMC6500445/pdf/nihms-1015904.pdf.*

[35] Lacagnina, Salvatore, Tips, Jean, Pauly, Kaitlyn, Cara, Kelly, and Karlsen, Micaela. ''Lifestyle Medicine Shared Medical Appointments.'' Available from *https://pmc.ncbi.nlm.nih.gov/articles/PMC7781059/.*

[36] *https://www.hsrd.research.va.gov/publications/esp/shared-med-appt.pdf.*

within the group-based session of a SMA, that individualized care should be provided in a separate individual medical appointment. The services provided to the group as a whole at each session would also need to be captured in the medical record. We seek comments on additional guardrails to consider in preventing fraud, waste and abuse when billing SMAs, such as following an evidence-based protocol for delivery of the intervention, conducting fidelity checks to ensure it is being delivered as intended, identifying key outcomes and goals that are established in shared decision making, and ensuring that the interventionist is trained in the intervention as appropriate.

SMAs are an approach in managing chronic conditions, especially among motivated patients.[37] SMAs are an appropriate healthcare delivery approach for conditions that are modifiable with lifestyle change, including diabetes mellitus, obesity, hypertension, and hyperlipidemia, such that behavioral changes including diet, physical activity, and self-management-can influence health outcomes. Therefore, we propose to establish coding and payment for SMAs provided for medical conditions that are modifiable with lifestyle change. We seek comment on how to determine when SMAs would be appropriate, including identifying which medical conditions would be considered modifiable with lifestyle change, and suggest we would typically consider those conditions with medical guidelines that include lifestyle change as part of prevention and treatment of the condition in this category, such as evidence-based interventions that support lifestyle change.[38] For example, the 2026 Standards of Care in Diabetes published by the American Diabetic Association (ADA) include lifestyle changes including improving nutrient composition and reducing caloric intake, establishing physical activity regimens to support weight loss, and highlighting the role of Medical Nutrition Therapy (MNT) as part of nutrition education.[39] While the exact content the SMA and desired behavioral change would vary (for example, improving diet and exercise as part of both prevention and management of Type 2 Diabetes) we would not consider medication adherence or titrating medications for Type 2 Diabetes to be appropriate for an SMA, but we would consider SMAs focused on improving nutrient composition to be an appropriate SMA activity, for example. CMS acknowledges the substantial changes in patients' lives associated with coping with chronic illness, the behavioral modifications inherent in managing serious and unexpected illnesses, however we would reserve SMA provision for just those conditions which may be treated or prevented with lifestyle changes.

SMAs typically involve multiple healthcare providers, usually two to four. The sessions are generally led by a physician, physician assistant (PA), or an advanced practice registered nurse (APRN), and may have ancillary staff help when the provider is meeting with patients individually.[40] We propose that a SMA session is billed and led by a physician or qualified nonphysician practitioner and may include other qualified healthcare professionals, clinical staff, or auxiliary personnel. We propose that HCPCS code GSMAS would be billed once per patient, per session and would accept any documentation to demonstrate the care was rendered so long as the physician or qualified nonphysician practitioner co-signature is included. In instances where another qualified healthcare professional, such as a registered dietitian, provides a service during the SMA session, such as CPT code 97804 (*Medical nutrition therapy; group (2 or more individual(s)), each 30 minutes),* that service is considered part of the SMA and should not be billed separately, in addition to the physician or qualified nonphysician practitioner billing for the SMA.

We propose requiring each SMA session to include the following components:

- Evaluation and Management (E/M) elements, consistent with the complexity of the beneficiary's condition. Individualized clinical care with medical documentation in the medical record that reflects the specific services that the individual beneficiary received during the SMA session.
- Education, based upon evidence-based content, and discussions related to self-care, wellness, and disease management.
- Discussion of positive lifestyle changes, focusing on behavior modification. Medication management, as clinically appropriate and applicable.

In the event it is medically necessary for a beneficiary to receive an E/M visit on the same day as a SMA by the same physician or other qualified health professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice, we propose that any time and effort cannot be counted more than once. We propose not to consider and treat this as two E/M same-day visits and seek public comment on this proposal. Additionally, we seek comments on what components must be required for each SMA session.

We propose the following descriptor for SMAs:

HCPCS code GSMAS: *Voluntary, group-based medical session involving multiple patients with common medical condition(s), receiving medical care in a group setting; billed and led by a physician or qualified nonphysician practitioner and may include services provided by other qualified healthcare professionals, clinical staff, or auxiliary personnel under the direction of the supervising physician or other practitioner. Session integrates group education, counseling, and peer support with individualized patient clinical assessment and care, 2–10 patients, billed once per patient, per session.*

Because SMA sessions would integrate group education, counseling, and peer support with individualized patient clinical assessment and care, in developing the valuation for the SMA HCPCS code, we propose to use a building block methodology that sums up the values associated with two reference codes. For the overall E/M elements of the SMA service, we are incorporating the work RVUs, work time and direct PE inputs associated with a level 3 O/O visit for an established patient, CPT code 99213 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and low level of medical decision making. When using total time on the date of the encounter for code selection, 20 minutes must be met or exceeded.),* which has a work RVU of 1.30, and a total work time of 30 minutes, which is based on a pre-service evaluation time of 5 minutes, an intraservice time of 20 minutes, and a post service time of 5 minutes. E/M visit level selection does not need to be based on time; practitioners may select the

[37] *https://pmc.ncbi.nlm.nih.gov/articles/PMC2464960/pdf/349.pdf.*

[38] Centers for Disease Control and Prevention. ''Evidence-Based Intervention Planning Guides.'' *CDC: Cancer,* National Center for Chronic Disease Prevention and Health Promotion, 21 May 2024, *https://www.cdc.gov/cancer/php/ebi-planning-guides/index.html.* Accessed 7 July 2026

[39] American Diabetes Association Professional Practice Committee for Diabetes. ''5. Facilitating Positive Health Behaviors and Well-Being to Improve Health Outcomes: Standards of Care in Diabetes—2026.'' *Diabetes Care,* vol. 49, suppl. 1, 2026, pp. S89–S131, *https://doi.org/10.2337/dc26-S005.*

[40] *https://pmc.ncbi.nlm.nih.gov/articles/PMC7781059/pdf/10.1177_1559827620943819.pdf.*

visit level based on the level of medical decision making (MDM). Additionally, as we discussed earlier in this section, we propose that SMAs be limited to beneficiaries who have received a professional service from the billing physician or other qualified health professional or another physician or other qualified health care professional of the exact same specialty and subspecialty who belongs to the same group practice within the previous 12 months. Given this pre-existing clinical relationship and the anticipated clinical profile of beneficiaries that would participate in an SMA, we believe that the level 3 O/O visit for an established patient represents the most typical level of service for the individualized patient clinical assessment component of the SMA.

For the group education, counseling, and peer support elements of the SMA service, we are incorporating CPT code 96202 (*Multiple-family group behavior management/modification training for parent(s)/guardian(s)/caregiver(s) of patients with a mental or physical health diagnosis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of parent(s)/guardian(s)/caregiver(s); initial 60 minutes*), which has a work RVU of 0.43 and a total work time of 15 minutes, which is based on a pre-service evaluation time of 2 minutes, an intraservice time of 10 minutes, and a post service time of 3 minutes.

While a SMA may include up to 10 beneficiaries in a 60-minute session, the individualized care for a participating beneficiary may vary, such that some beneficiaries may receive more or less individualized care than others; nonetheless, documentation in the medical record must reflect the specific services that the individual beneficiary received during the SMA session. As we price services under the PFS based on a typical case, the proposed valuation for HCPCS code GSMAS reflects a typical SMA session and is not intended to represent the exact time distribution for every beneficiary in every SMA. We note that the total work time proposed is for the purposes of valuation and not meant as a requirement for billing. We believe this reflects a typical amount of time for both the individualized patient clinical assessment and the beneficiary's proportionate share of group education, counseling, and peer support that occurs concurrently across all participating beneficiaries during a SMA session.

Considering the aforementioned building block methodology for SMA valuation, we are proposing a work RVU of 1.73 and a total work time of 45 minutes, which is based on a pre-service evaluation time of 7 minutes, an intraservice time of 30 minutes, and a post service time of 8 minutes.

In addition to seeking comments on establishing the proposed HCPCS code GSMAS, we also seek comment on the proposed work RVUs, work times, and direct PE inputs.

(55) Vaccine Adverse Effects Management (HCPCS Code GADV1)

Vaccines prevent serious illnesses and even death in persons who receive them and serve a public health benefit. Vaccines are intended to produce active immunity to specific antigens. An adverse reaction is an undesirable side effect that occurs after a vaccination. Vaccine adverse reactions are classified as (1) local; (2) systemic; or (3) allergic. Local reactions (for example, redness) are usually the least severe and most frequent. Systemic reactions (for example, fever) occur less frequently than local reactions, and severe allergic reactions (for example, anaphylaxis) are the least frequent reactions.[41] Modern vaccines are safe and effective; however, adverse events have been reported after administration of each type of available vaccine.[42] Vaccine providers should be familiar with identifying immediate-type allergic reactions, including anaphylaxis, and be competent in treating these events at the time of vaccine administration. Providers, including practitioners, should also have a plan in place to contact emergency medical services immediately in the event of a severe acute vaccine reaction.[43]

Before a vaccine is licensed, the Food and Drug Administration (FDA) takes steps to make sure the vaccine is safe. FDA requires that a vaccine goes through extensive safety testing. Even though careful studies are done before a vaccine is licensed, rare adverse effects may not be found until a vaccine is given to millions of people with different backgrounds and medical histories.[44] According to clinical trial data, most vaccine-associated adverse events are mild; however, severe adverse reactions such as anaphylaxis, myocarditis, thrombotic events, and pneumonitis have been reported.[45] After a vaccine is licensed, the Vaccine Adverse Event Reporting System (VAERS) is one of the mechanisms used to monitor for any problems, or ''adverse events,'' that happen after vaccination.[46]

We believe that the CPT evaluation and management code set may capture the work and clinical decision making involved in the evaluation and management of most vaccine adverse reactions. However, we believe that physician and nonphysician practitioners' work may not be accurately reflected under the CPT medical decision-making framework relating to the evaluation and management of rare and severe vaccine adverse reactions. E/M visits, like other services under the PFS, are valued based on an assumption of a typical case. We believe that these are additional resource costs that don't fit under a typical E/M. Therefore, we are proposing an add-on code and payment for diagnosis and management of a suspected vaccine adverse reaction for services going above and beyond those captured in an evaluation and management (E/M) visit. These services entail listening to patient concerns, answering questions, and building trust; selecting diagnosis strategies and conveying information in a manner specific to each patient's concerns, cultural and religious beliefs, and literacy level; providing patients with appropriate resources; and planning with patients the treatment of symptoms of vaccine adverse effects. We propose that this add-on code, HCPCS code GADV1 (*Office or other outpatient evaluation and management service(s) for the diagnosis and treatment of vaccine adverse effects, new or established patient; each 15 minutes personally performed by the physician or qualified healthcare professional (list separately in addition to CPT codes 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350)*), would be payable when a physician or nonphysician practitioner (NPP): (1) establishes and documents a temporal relationship to vaccination, and (2) performs a medically appropriate assessment to rule out alternative causes.

For the purposes of valuation, we are proposing a direct crosswalk for HCPCS code GADV1 to HCPCS code G2212 (*Prolonged office or other outpatient*

[41] *https://www.cdc.gov/vaccines/hcp/imz-best-practices/preventing-managing-adverse-reactions.html#cdc_report_pub_study_section_3-preventing-adverse-reactions*, accessed 5/1/2026.

[42] Ibid.

[43] Ibid.

[44] *https://vaers.hhs.gov/docs/VAERS_Brochure_for_Parents_and_Caregivers_EN_508_2026.pdf.*

[45] Suzuki T, Furuta H, Naganawa M, Hayashi K, Kiyotoshi H, Ohta C, Ninomiya S. COVID–19 Vaccine-Induced Severe Pneumonitis. Respirol Case Rep. 2025 Aug 21;13(8):e70274. doi: 10.1002/rcr2.70274. PMID: 40860748; PMCID: PMC12371123.

[46] Ibid.

evaluation and management service(s) beyond the maximum required time of the primary procedure which has been selected using total time on the date of the primary service; each additional 15 minutes by the physician or qualified healthcare professional, with or without direct patient contact (List separately in addition to CPT codes 99205, 99215, 99483 for office or other outpatient evaluation and management services) (do not report G2212 on the same date of service as 99358, 99359, 99415, 99416) (do not report G2212 for any time unit less than 15 minutes)) for 0.61 work RVUs and for direct PE inputs.

We welcome comments on whether a second HCPCS code for 15 minutes of physician or NPP work time should be finalized and structured as a stand-alone code to more accurately capture the work entailed in cases where a patient is being evaluated for only a vaccine related complaint, outside the context of an E/M visit being furnished for a separate complaint. We also welcome comments on whether in finalizing such a stand-alone HCPCS code we should crosswalk its work RVU and PE inputs to HCPCS code G2212.

Finally, we propose adding HCPCS code GADV1 to the Medicare Telehealth List.

(56) Health Coaching (CPT Codes 0591T, 0592T, and 0593T)

Per the Trump Administration's Executive Order, ''Establishing the President's Make America Healthy Again Commission,'' [47] the Administration is directing agency focus towards understanding and drastically lowering chronic disease rates, through thinking on nutrition, physical activity, healthy lifestyles, over-reliance on medication and treatments, the effects of new technological habits, environmental impacts, and food and drug quality and safety. Furthermore, the Executive Order directs that agencies shall ensure the availability of expanded treatment options and the flexibility for health insurance coverage to provide benefits to support beneficial lifestyle changes and disease prevention.

As such, in the CY 2026 PFS proposed rule, we sought comment on a wide range of possible rulemaking topics to promote prevention and management of chronic disease, and in particular, asked more detailed questions surrounding health coaching and motivational interviewing. More specifically, we asked whether we should consider coding and payment for health coaching and motivational interviewing beyond the current contractor-priced CPT codes describing health coaching, as an incident-to service performed under general supervision of a billing practitioner, what an appropriate description would be, what types of clinical staff perform motivational interviewing, how long a session lasts, the overlap between motivational interviewing and health coaching, training requirements for motivational interviewing and health coaches, the types of clinical circumstances where motivational interviewing and health coaching are performed, relevance for audiovisual or audio-only telecommunication, the experience of payers and providers using the CPT Category III CPT codes, and relevance for Evidence-Based Programs that effectively manage or prevent chronic disease. Commenters responded, stating that health coaching could support CMS' goal of preventing or managing chronic disease. Many health coaches wrote about their personal experience working with patients with chronic diseases, assisting them in making behavioral and lifestyle changes to self-manage their conditions, and noted that health coaching is a low-cost and highly effective strategy that empowers patients to manage their health. Many commenters requested paying separately for health coaching via the creation of HCPCS G-codes or another payment mechanism that would allow providers to reliably schedule and bill for health coaching services. Commenters also emphasized the importance of requiring that these services be provided by health coaches with appropriate training and certification.

To ensure we adequately capture the time and resources for health coaching, we are proposing conditions of payment and valuation for 0591T (*Health and well-being coaching face-to-face; individual, initial assessment, 60–90 minutes*), 0592T (*Individual, follow-up session, at least 30 minutes),* and 0593T (*Health and well-being coaching, group [2 or more individuals], at least 30 minutes*). CPT code 0593T would be billed once per beneficiary in the group.

We are also proposing to adopt the CPT prefatory language for 0591T, 0592T, and 0593T: ''Health and well-being coaching is a patient-centered approach wherein patients determine their goals, use self-discovery or active learning processes together with content education to work toward their goals, and self-monitor behaviors to increase accountability, all within the context of an interpersonal relationship with a coach. The health and well-being coach is qualified to perform health and well-being coaching by education, training, national examination and, when applicable, licensure/regulation, and has completed a training program in health and well-being coaching whose content meets standards established by an applicable national credentialing organization. The training includes behavioral change theory, motivational strategies, communication techniques, health education and promotion theories, which are used to assist patients to develop intrinsic motivation and obtain skills to create sustainable change for improved health and well-being.''

We are proposing that CPT codes 0591T, 0592T, and 0593T may be performed under direct supervision of the billing practitioner, as defined by § 410.26(a)(3). We also propose that when the service is performed under direct supervision by auxiliary personnel, the auxiliary personnel must have received appropriate certification to perform the services, which includes, but is not limited to, fulfilling the National Board for Health and Wellness Coaching National Standards, the National Commission for Health Education Credentialing eligibility for Certified Health Education Specialists, or the American Holistic Nurses Credentialing national standards for Certified Nurse Coaches. In response to the Request for Information (RFI) in the CY 2026 PFS proposed rule (90 FR 49479 through 49480), we received comments from interested parties pointing us towards these standards. We also propose that appropriate certification for auxiliary personnel to perform the services can also be fulfilled by receiving training from the evidence-based health promotion and disease prevention programs funded under the Older Americans Act and overseen by the Administration for Community Living (ACL). These programs undergo review, meet significant evidence thresholds, and have training requirements built into the program requirements. We solicit comment on these certification standards for auxiliary personnel performing these services.

Furthermore, we understand that occasionally, community-based organizations (CBOs) are the entities that employ health coaches. As noted in the CY 2023 PFS final rule (87 FR 69790) and explained in the CY 2023 PFS proposed rule (87 FR 46102), when we refer to CBOs, we mean public or private not-for-profit entities that provide specific services to the community or targeted populations in

[47] *https://www.whitehouse.gov/presidential-actions/2025/02/establishing-the-presidents-make-america-healthy-again-commission/.*

the community to address the health needs of those populations. They may include community care hubs, community-action agencies, housing agencies, area agencies on aging, centers for independent living, aging and disability resource centers or other non-profits that apply for grants or contract with healthcare entities to perform social services. They may receive grants from other agencies in the U.S. Department of Health and Human Services, including Federal grants administered by the Administration for Children and Families (ACF), Administration for Community Living (ACL), the Centers for Disease Control and Prevention (CDC), the Health Resources and Services Administration (HRSA), the Substance Abuse and Mental Health Services Administration (SAMHSA), or State-funded grants to provide social services. Generally, we believe such organizations know the populations and communities they serve and may have the infrastructure or systems in place to assist practitioners to provide these services. We note that individuals employed by CBOs may operate under general supervision of the billing practitioner, as long as the training and certification guidelines outlined earlier in this section are met.

Finally, we are proposing national payment for CPT codes 0591T, 0592T, and 0593T. We are proposing to crosswalk work and direct PE inputs for 0591T and 0592T to CPT codes 99490 (Chronic care management) and 99439 (Chronic care management, each additional 20 minutes), respectively, since, like Chronic Care Management (CCM), these visit-based services are performed under general supervision. For 0593T, since it is a group visit billed in 30-minute increments, we are proposing to crosswalk the work and PE inputs to CPT code G0109 (Group diabetes self-management training). Therefore, we are proposing a work RVU of 1.00 for CPT code 0591T, 0.70 for CPT code 0592T, and 0.23 for CPT code 0593T. Since multiple sessions in the same calendar month may be needed, we are not proposing frequency limitations for these codes, as long as they are reasonable and necessary. We will monitor utilization and may re-evaluate these policies in future rulemaking. These services were added to the Medicare Telehealth Services List in the CY 2024 PFS Final Rule (88 FR 78859 through 78860).

We solicit comments on the valuation of these services and the conditions of payment. We are also soliciting comment on whether should consider creating HCPCS G-codes to describe these services for CY 2027, rather than actively pricing these Category III CPT codes that describe health coaching services, including what the potential benefits of G-codes would be compared to using the existing codes.

(57) Vascular Embolization or Occlusion Procedure With Use of a Pressure-Generating Catheter (HCPCS Code G0577)

HCPCS code C9797 (*Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction*) was created for the April, 2025 Quarterly Release for the OPPS and Ambulatory Surgical System (ASC) to describe use of a pressure-generating catheter inclusive of imaging guidance for vascular embolization. Subsequently, we also created HCPCS code C8004 (*Simulation angiogram with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural road mapping, and imaging guidance necessary to complete the angiogram, for subsequent therapeutic radioembolization of tumors*) to describe the simulation angiogram associated with the use of the pressure-generating catheter described by HCPCS code C9797 for the April, 2025 OPPS Quarterly Release. For CY 2026, HCPCS code C9797 is assigned to APC 5194 with a payment rate of around $18,729 while HCPCS code C8004 is assigned to APC 5193 with a payment rate of around $11,874. Currently both HCPCS codes C9797 and C8004 are only payable in the OPPS and ASC settings, as there is currently no coding for the physician office setting describing use of this technology. Under the PFS, vascular embolization procedures are reported using CPT code 37243 (*Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction*) regardless of the technology used to perform the service.

Interested parties have indicated that use of this technology has expanded beyond the OPPS and ASC settings and into the physician office setting; however, the resource costs associated with CPT code 37243 do not accurately account for the use of innovative catheter technology. While this technology may not yet be typical and as such is appropriately absent from the valuation of CPT code 37342, we are concerned that the lack of appropriate coding and payment for the use of innovative catheter technology may negatively impact access in the non-facility setting.

Beginning July 1, 2026, we began making separate payment for vascular embolization or occlusion procedure with the use of a pressure-generating catheter through the contractor priced HCPCS code G0577 (*Vascular embolization or occlusion procedure with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction performed in the non-facility setting*) and are proposing to nationally price this service for CY 2027. We are seeking comment on whether there is a need for creation of a HCPCS G-code to mirror HCPCS code C8004 as currently there are no claims for this service in the HOPD setting.

In the CY 2026 PFS final rule, we finalized use of the relationship between the OPPS APC relative weights for APCs describing radiation treatment delivery services to inform the PE RVUs for those services under the PFS. We believe a similar policy is necessary here to establish the initial valuation for vascular embolization using a pressure generating catheter given the lack of pricing information in the non-facility setting. Therefore we are proposing to use the relative relationship between the approximate APC payment amounts between CPT code 37243 and HCPCS code C9797 to value the PE portion of HCPCS code G0577 and a direct crosswalk to the work and MP RVUs associated with CPT code 37243 as well as the physician time. We are seeking comments on these values. We would also note that this valuation is preliminary and we will consider updates for future rulemaking if use of this technology becomes more widespread in the non-facility setting.

(58) Accounting for E/M Resource Overlap Between Stand-Alone Visits and Global Periods

(a) Background

Surgical procedures with a global surgery period include all the necessary services normally provided by the practitioner before, during, and after a procedure. The global surgery payment includes things like pre-operative visits,

typical intra-operative services for that procedure, post-operative follow-up visits, supplies, and other services such as dressing changes, and removal of items used during or after surgery like sutures, staples, splints, or casts.[48] The payment and coding structure of global surgery periods includes the same foundational pieces as other codes in the PFS: work RVUs, practice expense RVUs, and malpractice RVUs. The work RVUs include time crosswalked from E/M codes to reflect the valuation of things such as pre-operative and post-operative visits. Given that global surgical packages already account for the resource costs associated with visits, standalone E/M codes are not billable on the same day as a procedure code unless they are significant and separately identifiable from the procedure. These visits are identified through appending of modifier–25 to the claim. This proposal is meant to address the likely overlap and duplication of payment between the E/M services already paid for during the global surgical package, and any additional E/M services billed for through the use of modifier–25 as significant and separately identifiable.

The PFS has other existing policies where we reduce payments if multiple procedures are furnished on the same day for the same patient, the multiple procedure payment reduction (MPPR) policies. MPPR is a longstanding Medicare policy to reduce payment by 50 percent for the second and subsequent surgical procedures furnished on the same day to the same patient, largely based on the efficiencies in PE and pre- and post-surgical physician work. Since the implementation of the PFS, MPPR policies were also established on nuclear medicine diagnostic procedures, the professional and technical component of diagnostic imaging, the technical component of diagnostic cardiovascular and ophthalmology procedures, and always-therapy services. In the 2019 PFS proposed rule (83 FR 35840 through 35841), as part of a suite of proposals designed to modify the payment structure of E/M visits, we proposed to reduce payment by 50 percent for the least expensive 0-day global procedure or visit that the same physician (or a physician in the same group practice) furnishes on the same day as a separately identifiable E/M visit, currently identified on the claim by an appended modifier–25.

In the 2019 PFS final rule (83 FR 59638 through 59640), many commenters opposed this proposal, stating that current billing rules allow these services to be billed only when modifier–25 is used, which makes it clear that the visits are significant and separately identifiable. Other commenters described that the RUC review process includes adjustments to account for any costs that the RUC considers duplicative, which means that CMS is making an unnecessary second adjustment. Commenters also stated that CMS provided insufficient rationale for a 50 percent payment reduction instead of other potential adjustments. Some physician organizations and patient advocacy groups also stated concerns that physicians might respond to financial incentives to bring patients back for necessary visits on a different day to avoid triggering the payment reduction. MedPAC, among others, were supportive of the proposal, stating that when a standalone E/M visit occurs on the same day as a procedure, there are efficiencies such as pre-service and post-service clinician work and practice expense, that are not currently accounted for in the system. Other commenters suggested alternative reductions, such as a 5 percent or 25 percent reduction.

In our response to commenters in the CY 2019 final rule (83 FR 59638 through 59640), we stated that we continued to have concerns about 0- and 10-day global periods on the same day as E/M visits. We appreciated the efforts of the RUC to address overlaps when they recognize that a code is often reported with a same day E/M visit, but we also noted that the RUC tends to recommend only minor adjustments to physician time and direct PE inputs to account for overlap. We also discussed that there are several thousand codes with global periods, and while we routinely prioritize review of high-volume services, we believe code-level reviews are not a practical solution to ensuring the accuracy of accounting for these types of efficiencies. We also stated that if practitioners begin deliberately scheduling visits on separate days to avoid the payment adjustment, this could create undue burden and create potential medical risk for beneficiaries.

We did not finalize this proposal in CY 2019 for a few reasons. First, we had concerns related to balancing the appropriate valuation of these codes with potential disruption to patient care. We reiterated that we find the possible practice of scheduling medical services to maximize payment highly problematic, and we invited interested party feedback regarding how to address these challenges. Second, we did not finalize any of the suite of proposals related to the valuation of the E/M code set in CY 2019, as the AMA and the CPT Editorial Panel stated plans to revisit coding for O/O E/M, and we delayed further action to allow that process to play out (83 FR 59638).

(b) Proposed Changes to Payments Using Modifier–25

As we stated in the CY 2019 final rule (83 FR 59638 through 59640), we continue to believe that there are efficiencies when the same physician (or a physician in the same group practice) provides an E/M service for the same patient in conjunction with a procedure with a global period, and that we are likely duplicating payment under the current payment methodology. We are proposing to reduce payment, as described later in this section, when a separately identifiable O/O E/M visit is furnished by the same physician (or a physician in the same group practice) on the same day as a 0-, 10-, and 90-day global procedure. Under this proposal, the most expensive service (either surgical or E/M visit) would be paid at 100 percent, and all other surgical procedure(s) or E/M visit(s) would be paid at 50 percent. For example, a patient receives an O/O E/M visit using CPT code 99212 (*Office or other outpatient visit for the evaluation and management of an established patient, which requires a medically appropriate history and/or examination and straightforward medical decision making. When using total time on the date of the encounter for code section, 10 minutes must be met or exceeded.*) at a dermatologist's office, and then has two skin lesions removed, one using CPT code 11300 (*Shaving of epidermal or dermal lesion, single lesion, trunk, arms, or legs; lesion diameter 0.5cm or less*) and one using CPT code 11301 (*Shaving of epidermal or dermal lesion, single lesion, trunk, arms or legs; lesion diameter 0.6 to 1.0 cm*). Using 2026 RVU values, the total non-facility (NF) RVU of CPT code 99212 is 1.78, the total NF RVU of CPT code 11300 is 2.89, and the total NF RVU of CPT code 11301 is 3.48. Since CPT code 11301 is the highest paid service, CPT code 11301 will be paid at 100 percent (total RVU of 3.48), and CPT code 11300 and the payment for CPT code 99212 will both be reduced by 50 percent, CPT code 11300 down to 1.445 RVUs and CPT code 99212 down to 0.89 RVUs.

The 50 percent value aligns with our previous proposal from CY 2019 PFS proposed rule (83 FR 35840 through 35841) and matches the longstanding surgical MPPR discussed previously in this section. We welcome comments on

[48] *https://www.cms.gov/files/document/mln907166-global-surgery-booklet.pdf.*

the value of this adjustment, including whether it would be more appropriate to match a different MPPR value, such as 25 percent.

While we are proposing to apply this policy only to O/O E/M visits, we are seeking comments on whether it should also apply to other E/M visits, such as inpatient E/M visits.

We reiterate that we do not find it appropriate to schedule medical services for patients to maximize payment, which would create undue burden and potential medical risk for beneficiaries. We have a number of data analysis tools to monitor for potentially problematic utilization patterns which may be useful in future, if necessary, for monitoring for this practice, including distinct claims editing to identify problematic utilization patterns, comparative billing reports to identify to providers their outlier status, and medical review capabilities to determine if the patterns are problematic and indicative of waste or abuse. We are also seeking comment on whether or not it is necessary to revise the conditions of payment to mitigate such payment abuses.

(c) Intravitreal Eye Injections

We are also seeking comment on how this policy might apply to an E/M visit reported on the same day as intravitreal eye injection, such as CPT code 67028, a high volume 000-day global code. In recent years, since new injected medications were developed to treat retinal diseases, there has been new focus from auditors (such as the OIG), MACs, professional eye associations and the AMA, to better understand the standard of care for patients receiving these treatments, in terms of when same-day eye examinations are clinically indicated and separately identifiable from the injection procedure, for the injected eye or the fellow eye. We have heard that patients with retinal diseases require examination every one to three months based on their treatment response, and importantly, both eyes are examined at each visit because of the high incidence of bilateral (though often asynchronous) involvement. The associations have written to CMS outside of the rulemaking process, indicating that around 50 percent of the time, a separately reported E/M visit on the same day to examine the eye(s) may be prompted or required by the symptom or condition for which the injection is being provided. The fellow eye could require examination if the patient reports symptoms in that eye when they present for an injection, and same-day exams determine if the type of medication is appropriate and the length of time between injections can be extended. To help us ensure accurate payment, we are seeking to better understand the clinical circumstances involved, and any overlap with resources already accounted for in valuation of the global procedure, such as for (1) established patients without symptoms in the fellow eye; (2) established patients with symptoms in the fellow eye, whether prior or newly reported upon presenting for their injection; (3) new patients; (4) does it vary according to diagnosis and exam findings; (5) are injections in the fellow eye always deferred to another day; and (6) how CMS might be able to confirm or ensure that the visit being reported is significant and separately identifiable absent medical record review, for example, should we expect to see a new or different diagnosis code on the claim.

We are also seeking to better understand whether the E/M work associated with new patients is typically included in valuation of the minor procedures, or whether there is extra work for new patients that is significant and separately identifiable enough to always warrant separate payment.

(59) Revisions To Teaching Physician Policy Related to the Primary Care Exception

(a) Background

As a general matter, E/M visit codes under the PFS can only be reported when the care is personally provided by a qualified practitioner. Currently, under the primary care exception described at § 415.174, in the case of certain visit codes of lower and mid-level complexity, Medicare contractors may be able to make PFS payment for a service provided by a resident without the presence of a teaching physician, but in specific outpatient primary care centers and when certain conditions must be met. For example, the teaching physician must direct the care from such proximity as to constitute immediate availability (that is, to effectively provide direct supervision).

During the Public Health Emergency (PHE) for the 2019 Novel Coronavirus (COVID–19) pandemic, CMS allowed through an interim final rule (85 FR 19230 through 19292) that all levels of an O/O E/M service provided in specified primary care centers may be provided under supervision of the teaching physician by interactive telecommunications technology (85 FR 19259). At the conclusion of the PHE this flexibility expired, such that only lower and mid-level complexity visits (as specified by CMS in program instructions) could be provided without the presence of a teaching physician under the terms specified in § 415.174.

Additionally, in the CY 2020 PFS final rule (84 FR 62851 through 62854), E/M visits were revised to allow visits to be based on time and medical decision making. According to our claims data, we note that the most commonly billed O/O E/M visit level is now a moderate level visit (level 4), whereas in the past, a mid-level (level 3) visit was most common.

(b) Revisions to Current Policy

We have received multiple requests from interested parties requesting us to allow residents to perform moderate and high (level 4 and 5) E/M visits under the supervision of the teaching physician and to defer to the clinical judgment of that graduate medical education (GME) program as to whether or not these high level visits may be performed without the presence of the teaching physician.

After consideration and evaluation of interested parties' requests, we are proposing that all levels of an O/O E/M service provided in primary care centers, and meeting the requirements in § 415.174, may be provided under direct supervision of the teaching physician in such cases where the teaching physician believes such care is clinically appropriate and without the presence of a teaching physician. Specifically, we are proposing modifications to the requirements at § 415.174 Exception: Evaluation and management services furnished in certain centers, to expand coverage of services for teaching physicians as part of a graduate medical education (GME) program. We are proposing to modify the requirements for certain E/M codes to allow physician fee schedule payment for a service furnished by a resident provided under direct supervision. We are proposing to modify paragraph (a) to state that certain evaluation and management codes (as specified by CMS in program instructions), may be paid by the physician fee schedule and are thus proposing to remove the language ''of lower and mid-level complexity'' to potentially allow for certain moderate and higher-level evaluation and management codes to be billed if the visit meets all the criteria in § 415.174. We are proposing § 415.174 (a) to read as follows: ''In the case of certain evaluation and management codes (as specified by CMS in program instructions), Medicare Administrative Contractors (MACs) may make physician fee schedule payment for a service furnished by a resident without the presence of a teaching physician.

For the exception to apply, all of the following conditions must be met.''

We believe this proposal would provide some autonomy to residents as well as the teaching physician if the specific GME program would support it. We considered that some visits may take more time in the beginning since residents are still learning and we will continue to monitor the visit levels over time. We welcome comments on this proposal.

(60) Bundled Payments Under the PFS for Substance Use Disorders (HCPCS Codes G2086, G2087, and G2088)

In the CY 2020 PFS final rule (84 FR 62673), we finalized the creation of new coding and payment describing a bundled episode of care for the treatment of Opioid Use Disorder (OUD). Then, in the CY 2021 PFS final rule, we finalized a revision to the code descriptors for HCPCS codes G2086, G2087, and G2088 by replacing ''opioid use disorder'' with ''a substance use disorder'' in response to requests to expand these bundled payments to be inclusive of other substance use disorders (SUDs), not just OUD, stating we agreed that doing so could expand access to needed care.

The codes are:

- *HCPCS code G2086: Office-based treatment for a substance use disorder, including development of the treatment plan, care coordination, individual therapy and group therapy and counseling; at least 70 minutes in the first calendar month.*
- *HCPCS code G2087: Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; at least 60 minutes in a subsequent calendar month.*
- *HCPCS code G2088: Office-based treatment for a substance use disorder, including care coordination, individual therapy and group therapy and counseling; each additional 30 minutes beyond the first 120 minutes (List separately in addition to code for primary procedure).*

Interested parties have pointed out disparities in payment for HCPCS codes G2086 through G2088 compared to payment for similar services under the Medicare Opioid Treatment Program (OTP) benefit. They state that both OTPs and non-OTP outpatient addiction treatment settings can provide American Society of Addiction Medicine ASAM Level 1.7's suite of services that include medically managed outpatient treatment services, including evaluation and management of intoxication, withdrawal, biomedical concerns, and common low complexity psychiatric concerns. They state that the only clinical difference between these places of service at ASAM Level 1.7 is that OTPs can provide methadone for the treatment of OUD, and the other cannot due to Federal regulations. OTPs are also governed by extensive Federal and State regulations, unlike office-based practices which are not federally regulated settings but may be subject to extensive State regulations. They note that since the time these codes were created, there is now a new Level 1.0 that describes remission monitoring services or services to patients in stable remission, similar to services described by outpatient E/M codes. The new Level 1.5 provides outpatient counseling and psychotherapeutic services, appropriate for patients with mild SUDs and those in early remission, and a new Level 1.7 that describes medically-managed outpatient treatment, including withdrawal management. They state that the services described by HCPCS codes G2086–G2088 align with Level 1.5, but that there is no existing coding under the PFS to describe level 1.7.

We welcome additional information on this topic, including whether we should consider updates to the rates for HCPCS codes G2086 through G2088, and/or whether additional coding is needed to describe the ASAM 1.7 level of care.

(61) Software as a Medical Service (SaMS) Laboratory Analyses

In recent years, there have been rapid developments in the use of software-based technologies with novel functionalities, including artificial intelligence, to support clinical decision-making in the outpatient and physician office settings. New clinical software, which includes clinical decision support software, clinical risk modeling, and computer aided detection (CAD), is becoming increasingly available to practitioners. These technologies often perform data analysis of diagnostic images from patients, relying on complex algorithms or statistical predictive modeling to aid in the diagnosis or treatment planning of a patient's condition. In previous rulemaking, we have referred to these algorithm-driven services that assist practitioners in making clinical assessments or diagnoses as Software as a Service (SaaS). Some of the software functions that are used in these services are FDA-regulated medical devices. Unlike prescription digital therapeutics (PDTs), for example PDTs that provide cognitive behavioral therapy to treat substance disorders or chronic insomnia, SaaS technologies do not currently treat illnesses or patient injuries. SaaS is also separate from remote patient monitoring (RPM) and remote therapeutic monitoring (RTM), which are digital healthcare tools for tracking patient data outside traditional office settings (90 FR 49394). For CY 2027, we propose a change in terminology. We now understand that in other industries, the existing SaaS terminology is used for general cloud-based computing service models outside of a health care context, which may cause confusion as we are using it to describe specific services that provide a medical function for purposes of PFS Medicare payment policy. To dispel any ambiguity and clarify that distinction, we propose to change our terminology from SaaS to Software as a Medical Service (SaMS) to refer to software-based technologies that support clinical decision making through algorithmic analysis, including those that provide clinical or diagnostic functionality. We welcome public comments on the proposed change in terminology. For further discussion of this terminology and other OPPS SaMS proposals, please see the CY 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Proposed Rule (91 FR 41918).

In recent years, we have seen an increase in laboratory tests that combine laboratory analyses, such as genomic sequencing or immunoassays, with computer algorithms to produce a clinical test result. The AMA CPT Editorial Panel created a category called Multi-Analyte Assays with Algorithmic Analysis, to categorize test codes that combined laboratory analyses with computer algorithms to generate clinical information. More recently, however, we are seeing the development of distinct algorithmic analyses alone.

For example, when the genomic sequencing of an individual is performed, this sequencing will likely only need to be performed once. However, once the genomic sequence has been generated, the subsequent algorithmic analyses of that sequence data can be performed an infinite number of times to produce a wide range of results and/or diagnostic or risk-related information. These secondary analyses of original genomic sequences can be proprietary and unique to a single laboratory but could also be conducted at a range of settings. For purposes of this proposal, we are referring to subsequent stand-alone algorithmic analyses that are separate from a CLIA certified laboratory's examination of human material, as defined by 42 CFR 493.2, as ''SaMS laboratory analyses performed on laboratory tests''.

Currently, certain SaMS analyses performed on laboratory tests are treated as clinical diagnostic laboratory tests (CDLTs) and paid under the Clinical Laboratory Fee Schedule (CLFS). Section 1861(s) of the Act specifies items and services included as ''medical and other health services'' under Part B, including diagnostic X-ray tests, diagnostic laboratory tests, and other diagnostic tests as described in section 1861(s)(3) of the Act. Section 1861(s)(17) of the Act states that no diagnostic tests performed in any laboratory shall be included within paragraph (3) unless such laboratory meets CLIA certification requirements under section 353 of the Public Health Service Act, among other requirements. Sections 1833(h) and 1834A of the Act and the implementing regulations at 42 CFR part 414, subpart G, set forth the CLFS ratesetting methodologies for CDLTs. We do not believe it is appropriate to consider these secondary algorithmic analyses to be CDLTs or establish CLFS payment rates for these analyses because these secondary algorithmic analyses do not require laboratory services or entities, regulated by CLIA, to perform them. Referring to the example above, while an individual's genomic sequence must be performed by a CLIA certified laboratory entity to allow for Medicare payment under the CLFS, the subsequent algorithmic analyses of the sequence data as part of the SaMS analyses performed on laboratory tests can be performed by any non-regulated entity with the computer software needed to perform the analyses.

Our position is that the secondary analyses are ''other diagnostic tests'' under section 1861(s)(3) of the Act as opposed to ''diagnostic laboratory tests.'' As noted previously, Medicare will not pay for CDLTs on the CLFS unless they are furnished by laboratories that meet applicable CLIA certification requirements.

Tests that examine materials derived from the human body are assigned to and paid under the CLFS only when furnished by such certified laboratories, in accordance with 42 CFR 410.32(d). Because SaMS analyses performed on laboratory tests are downstream evaluations of the data generated by a prior laboratory test, an entity that performs only algorithmic analyses of previously sequenced data may not qualify as a CLFS laboratory under 42 CFR 493.2 or require CLIA certification. We believe SaMS that evaluate data generated by a prior laboratory test should not be treated as CDLTs for Medicare payment purposes.

We are also concerned that paying for these analyses based on existing CLFS payment methodologies may create significant vulnerabilities for the Medicare program, due to the lack of data transparency and CDLTs not being subject to beneficiary cost-sharing or budget neutrality. Section 414.508 outlines the ratesetting methodologies CMS uses to set payment rates for new tests on the CLFS. Under § 414.508(b), CMS determines the payment amount based on either crosswalking or gapfilling methodologies until applicable information is available to establish a payment amount under the methodology described in § 414.507(b). Crosswalking is used if it is determined that a new CDLT is comparable to an existing test, multiple existing test codes, or a portion of an existing test code. Gapfilling is used when no comparable existing CDLT is available. Public consultation for payment for new clinical diagnostic laboratory tests is required in determining payment amounts, receiving public comments and recommendations (and data on which the recommendations are based) as well as recommendations from the Advisory Panel on CDLTs per 42 CFR 414.506.

A significant challenge to the ratesetting process for CMS is the lack of transparent data received from laboratories outlining resource costs of a test, particularly for the algorithmic portions of tests that are combined with other analytes. In the past, laboratories have explained to CMS that the algorithmic components of laboratory tests are highly proprietary and details cannot be shared. Thus, we have worked with the limited information available on the details of methods or resources for the algorithmic portions of tests or analyses and has thus far relied on the other laboratory methods provided in the CPT descriptor (*i.e.,* NGS sequencing, RT–PCR, or DNA methylation analysis). As we have gathered more information on SaMS analyses performed on laboratory tests, we now believe that since these analyses are entirely computer-based, comparison based on laboratory methodologies is not appropriate. Additionally, in contrast to the PFS, the CLFS generally does not include beneficiary cost-sharing or budget neutrality adjustments, which limits transparency regarding pricing and creates challenges for ensuring appropriate valuation of these services.

Finally, CMS has an interest in ensuring that services that are fundamentally similar are paid for and treated in the same way, regardless of the setting of care in which the service is furnished. Since SaMS analyses performed on laboratory tests do not require performance by a CLIA-certified laboratory and perform algorithmic analyses on previously generated data, we believe SaMS analyses performed on laboratory tests are substantively similar to other SaMS technologies that are currently paid under the PFS. Accordingly, we believe that whether the SaMS performs algorithmic analyses of an imaging test (*e.g.,* CT scan) or whether it performs an algorithmic analysis on data generated from a laboratory test, all algorithmic analyses should be treated consistently with other comparable SaMS analyses and belong within the broader proposed framework for SaMS. We believe that this approach for SaMS technologies would promote stability and predictability in payment for similar services.

Therefore, for CY 2027, we are proposing to contractor price ten HCPCS codes describing various SaMS analysis performed on laboratory tests under the PFS. Table A–D8 shows the list of currently payable SaMS analysis performed on laboratory tests under the CLFS that we are proposing to contractor price under the PFS. These ten HCPCS codes were identified by the CPT descriptor for the code. If there were no laboratory methods included in the code descriptor, and only a computer analysis was described, we identified the code as a SaMS analysis performed on laboratory tests. We refer to the 2027 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Proposed Rule (91 FR 41918) for discussion of payment for these services under the OPPS, where we are proposing to assign the same SaMS analysis performed on laboratory tests to new technology APCs.

We would appreciate public comment on any other SaMS analysis performed on laboratory tests that should be removed from the CLFS and contractor priced under the PFS. We are seeking comment more broadly on other approaches to payment for these services, including, but not limited to, a direct crosswalk to the proposed OPPS new technology APC dollar amounts for all proposed analyses, a subset of these analyses, or specific analyses as opposed to contractor pricing.

In addition, for CY 2027 and subsequent years, we propose to assign any new codes that describe SaMS analysis performed on laboratory testto contractor pricing for payment under the PFS. We request public comment on these proposals, including the list of ten HCPCS codes that we identified as

SaMS analysis performed on laboratory tests, as well as any additional HCPCS codes that we should designate as SaMS analysis performed on laboratory tests and pay under the PFS rather than as CDLTS paid on the CLFS. We may finalize a policy that includes such payment for additional HCPCS codes in the PFS final rule based on public comment.

TABLE A-D8 : PROPOSED SAMS ANALYSES PERFORMED ON LABORATORY TESTS FOR CY 2027

HCPCS Code	Long Descriptor
0510U	Oncology (pancreatic cancer), augmentative algorithmic analysis of 16 genes from previously sequenced rna whole transcriptome data, reported as probability of predicted molecular subtype
0511U	Oncology (solid tumor), tumor cell culture in 3d microenvironment, 36 or more drug panel, reported as tumor-response prediction for each drug
0512U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) status, formalin-fixed paraffin embedded (ffpe) tissue, reported as increased or decreased probability of msi-high (msi-h)
0513U	Oncology (prostate), augmentative algorithmic analysis of digitized whole-slide imaging of histologic features for microsatellite instability (msi) and homologous recombination deficiency (hrd) status, formalin fixed paraffin-embedded (ffpe) tissue, reported as increased or decreased probability of each biomarker
0208U	Oncology (medullary thyroid carcinoma), mrna, gene expression analysis of 108 genes, utilizing fine needle aspirate, algorithm reported as positive or negative for medullary thyroid carcinoma
0414U	Oncology (lung), augmentative algorithmic analysis of digitized whole slide imaging for 8 genes (alk, braf, egfr, erbb2, met, ntrk1-3, ret, ros1), and kras g12c and pd-l1, if performed, formalin-fixed paraffin-embedded (ffpe) tissue, reported as positive or negative for each biomarker
0418U	Oncology (breast), augmentative algorithmic analysis of digitized whole slide imaging of 8 histologic and immunohistochemical features, reported as a recurrence score
0220U	Oncology (breast cancer), image analysis with artificial intelligence assessment of 12 histologic and immunohistochemical features, reported as a recurrence score
0376U	Oncology (prostate cancer), image analysis of at least 128 histologic features and clinical factors, prognostic algorithm determining the risk of distant metastases, and prostate cancer-specific mortality, includes predictive algorithm to androgen deprivation-therapy response, if appropriate
81416	Exome (eg, unexplained constitutional or heritable disorder or syndrome); sequence analysis, each comparator exome (eg, parents, siblings) (list separately in addition to code for primary procedure)

(62) Caregiver Training Services (CTS)

In the CY 2025 PFS final rule (89 FR 97817 through 97821), we finalized new G-codes and payment for direct care CTS: HCPCS codes G0541 *(Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; initial 30 minutes),* G0542 *(Caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face; each additional 15 minutes (list separately in addition to code for primary service) (use g0542 in conjunction with g0541)),* and G0543 *(Group caregiver training in direct care strategies and techniques to support care for patients with an ongoing condition or illness and to reduce complications (including, but not limited to, techniques to prevent decubitus ulcer formation, wound care, and infection control) (without the patient present), face-to-face with multiple sets of caregivers).*

We are seeking comment on whether the resource costs associated with these services are best reflected through this existing coding or whether these resources costs are reflected in the valuation of other codes paid under the PFS, such as E/M visits.

(63) Comment Solicitation on Payment for Physician-Patient Clinical Trial Discussions

Despite the U.S. investing over $50 billion annually in biomedical research, fewer than 7 percent of adult cancer patients enroll in clinical trials.[49] A central and modifiable reason is that physicians rarely initiate conversations about clinical trials with their patients. For example, national survey data show that 70 percent of oncologists discuss trials with less than a quarter of their patients,[50] yet more than 50 percent of eligible patients enroll when actively offered a clinical trial.[51]

Time and administrative burden are documented as the top barrier to conversations between physician and

[49] Unger JM, Shulman LN, Facktor MA, Helson H, Fleury ME. National estimates of the participation of patients with cancer in clinical research studies based on commission on cancer accreditation data. J Clin Oncol. 2024;42:2139–2148.

[50] Lee SJC, Murphy CC, Gerber DE, et al. Reimbursement matters: overcoming barriers to clinical trial accrual. Med Care. 2021;59(5):461–466. PMC8026490.

[51] Unger JM, Vaidya R, Hershman DL, Minasian LM, Fleury ME. Systematic review and meta-analysis of the magnitude of structural, clinical, and physician and patient barriers to cancer clinical trial participation. J Natl Cancer Inst. 2019;111(3):245–255.

patients about participation in clinical trials in virtually every survey.[52] The current valuation of existing visit codes does not account for the additional time and resource costs associated with the structured physician counseling regarding clinical trial eligibility, options, risks and benefits associated with counseling a beneficiary on whether to enroll in a clinical trial.

We are therefore seeking comment on whether we should effectuate payment for these resource costs through the creation of a HCPCS G-code describing a minimum of 20 minutes of physician or other QHP time spent on clinical trial counseling. We are seeking comment on accurate valuation for this service, including inputs for work and practice expense, and whether the service should be available as a Medicare telehealth service. Interested parties suggested a work RVU value between 1.00 and 1.50 RVUs would accurately account for the physician work associated with this service. We are also seeking comment on what documentation requirements we might consider for such a service, such as the trial(s) discussed and the patient's decision.

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TABLE A-D9: CY 2027 WORK RVUs FOR NEW, REVISED, AND POTENTIALLY MISVALUED CODES

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
0591T	Health and well-being coaching face-to-face; individual, initial assessment	C	C	1.00	Yes
0592T	Health and well-being coaching face-to-face; individual, follow-up session, at least 30 minutes	C	C	0.70	Yes
0593T	Health and well-being coaching face-to-face; group (2 or more individuals), at least 30 minutes	C	C	0.23	Yes
10005	Fine needle aspiration biopsy, including ultrasound guidance; first lesion	1.42	1.35	1.35	No
10006	Fine needle aspiration biopsy, including ultrasound guidance; each additional lesion	0.98	1.00	1.00	No
15X19	Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; first 100 sq cm or less, or 1% of body area of infants and children	NEW	10.97	10.97	No
15X20	Skin cell suspension autograft (SCSA), trunk, arms, and/or legs; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	NEW	0.59	0.59	No
15X21	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; first 100 sq cm or less, or 1% of body area of infants and children	NEW	11.28	11.28	No
15X22	Skin cell suspension autograft (SCSA), face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits; each additional 100 sq cm, or each additional 1% of body area of infants and children, or part thereof	NEW	0.98	0.98	No
20985	Computer-assisted surgical navigational procedure for musculoskeletal procedures	2.44	2.44	2.44	No
209X1	Placement of localization marker(s) (eg, fiducial marker[s]), intraosseous, percutaneous, including imaging guidance, when performed; first target site	NEW	3.00	3.00	No
209X2	Placement of localization marker(s) (eg, fiducial marker[s]), intraosseous, percutaneous, including imaging guidance, when performed; each additional target site	NEW	1.76	1.76	No
209XX	Ablation therapy for reduction or eradication of bone tumor, including adjacent soft tissue when involved by tumor extension, cryoablation, open	NEW	2.70	2.70	No
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	24.75	24.75	23.12	No
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	20.47	23.20	21.72	No
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	20.49	21.72	19.53	No
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment	5.88	3.00	3.00	No
23470	Arthroplasty, glenohumeral joint; hemiarthroplasty	17.44	15.60	13.81	No
23472	Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (eg, total shoulder))	21.58	19.35	17.49	No
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft	19.11	16.70	15.37	No
27278	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive, including imaging guidance, unilateral; placement of intra-articular structural bone graft, metal and/or synthetic device(s) without cortical piercing, including use of osteopromotive material and/or obtaining bone graft, when performed	7.66	7.66	7.66	No
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive, including imaging guidance, unilateral; placement of transarticular and/or intra-articular device(s) (that engage bone with intrinsic fixation (eg, screw[s], flange[s], blade[s]) piercing the lateral cortex of the sacrum and the medial cortex of the ilium (with or without piercing the lateral cortex of the ilium), including use of osteopromotive material and/or obtaining bone graft, when performed	11.83	11.00	11.00	No
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)	19.11	16.70	15.94	No
27X05	Implantation of medial knee extra-articular shock absorber, including fluoroscopic guidance	NEW	13.16	13.16	No
27XX8	Acellular scaffold(s) (eg, aragonite) implant(s), for osteochondral lesion(s), knee, open	NEW	9.53	9.53	No
33340	Percutaneous transcatheter closure of the left atrial appendage with endocardial implant, including fluoroscopy, transseptal puncture, catheter placement(s), left atrial angiography, left atrial appendage angiography, when performed, and radiological supervision and interpretation	9.99	9.99	9.00	No
33X01	Insertion of permanent cardiac contractility modulation (CCM) system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; pulse generator and transvenous electrodes	NEW	8.83	8.83	No
33X02	Insertion of permanent cardiac contractility modulation (CCM) system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; pulse generator only	NEW	5.66	5.66	No
33X03	Insertion of permanent cardiac contractility modulation (CCM) system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; transvenous electrode, single	NEW	6.00	6.00	No

[52] Kumar A, Bhatt DL, Fonarow GC, et al. Barriers for cancer clinical trial enrollment: a qualitative study of the perspectives of healthcare providers. Contemp Clin Trials Commun. 2022;28:100939. PMC9189774.

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
33X04	Insertion of permanent cardiac contractility modulation (CCM) system, including fluoroscopic guidance and programming of sensing and therapeutic parameters, with evaluation when performed; transvenous electrode, dual	NEW	6.23	6.23	No
33X05	Removal of permanent cardiac contractility modulation (CCM) system; pulse generator and transvenous electrodes	NEW	9.90	9.90	No
33X06	Removal of permanent cardiac contractility modulation (CCM) system; pulse generator only	NEW	4.79	4.79	No
33X07	Removal of permanent cardiac contractility modulation (CCM) system; transvenous electrode, single	NEW	7.30	7.30	No
33X08	Removal of permanent cardiac contractility modulation (CCM) system; transvenous electrode, dual	NEW	8.39	8.39	No
33X09	Removal and replacement of permanent cardiac contractility modulation (CCM) system, pulse generator only	NEW	6.00	6.00	No
33X10	Repositioning of previously implanted cardiac contractility modulation (CCM) transvenous electrode(s), including fluoroscopic guidance and programming of sensing and therapeutic parameters	NEW	5.00	5.00	No
33X11	Relocation or revision of skin pocket for implanted cardiac contractility modulation (CCM) pulse generator	NEW	5.12	5.12	No
33X12	Insertion of left heart ventricular assist device (VAD), including radiological supervision and interpretation, open; aorta exposure with creation of conduit by transthoracic (eg, median sternotomy, thoracotomy) incision	NEW	17.52	17.52	No
33X13	Removal of left heart ventricular assist device (VAD) with resection and stapling of graft conduit and skin closure (eg, infraclavicular, supraclavicular)	NEW	6.58	6.58	No
33X15	Insertion of left heart ventricular assist device (VAD), including radiological supervision and interpretation, open; axillary, subclavian, or innominate artery exposure with creation of conduit by infraclavicular or supraclavicular incision, unilateral	NEW	13.65	13.65	No
33X50	Transcatheter tricuspid valve replacement (TTVR) with prosthetic valve, percutaneous approach, including right heart catheterization, temporary pacemaker insertion, and selective right ventricular or right atrial angiography, when performed	NEW	24.38	17.52	Yes
33X51	Transcatheter tricuspid valve edge-to-edge repair (T-TEER), percutaneous approach; initial clip	NEW	23.92	17.06	Yes
33X52	Transcatheter tricuspid valve edge-to-edge repair (T-TEER), percutaneous approach; each additional clip during same session	NEW	8.00	6.34	No
36465	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; single incompetent extremity truncal vein (eg, great saphenous vein, accessory saphenous vein)	2.29	2.29	2.29	No
36466	Injection of non-compounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate, inclusive of all imaging guidance and monitoring; multiple incompetent truncal veins (eg, great saphenous vein, accessory saphenous vein), same leg	2.93	2.93	2.62	No
36470	Injection of sclerosant; single incompetent vein (other than telangiectasia)	0.73	0.73	0.73	No
36471	Injection of sclerosant; multiple incompetent veins (other than telangiectasia), same leg	1.46	1.18	1.18	No
36473	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; first vein treated	3.41	3.41	3.41	No
36474	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical; subsequent vein(s) treated in a single extremity, each through separate access sites	1.71	1.71	1.71	No
38X03	Microvascular anastomosis between a single vein opening and any number of lymphatic vessels, per limb; initial anastomosis	NEW	16.00	14.00	No
38X04	Microvascular anastomosis between a single vein opening and any number of lymphatic vessels, per limb; each additional anastomosis	NEW	6.00	6.00	No
39540	Repair, diaphragmatic hernia (other than neonatal), via laparotomy; traumatic, acute	14.21	24.00	24.00	No
39541	Repair, diaphragmatic hernia (other than neonatal), via laparotomy; traumatic, chronic	15.36	26.00	26.00	No
39545	Plication of diaphragm for eventration or paralysis, via thoracotomy	14.30	18.45	18.45	No
395X2	Thoracoscopy, surgical, with plication of diaphragm for eventration or paralysis	NEW	20.00	20.00	No
39X11	Thoracoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, chronic	NEW	25.44	25.44	No
39X12	Thoracoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); nontraumatic (ie, Bochdalek, Morgagni)	NEW	25.94	25.94	No
39X13	Implantation of mesh or other prosthesis with open, laparoscopic, or thoracoscopic diaphragmatic hernia repair	NEW	3.00	3.00	No
39XX1	Division of median arcuate ligament and release of celiac trunk, with ganglionectomy, when performed	NEW	26.41	26.41	No
39XX2	Laparoscopy, surgical, with division of median arcuate ligament and release of celiac trunk, with ganglionectomy, when performed	NEW	25.94	25.94	No
39XX3	Repair, diaphragmatic hernia (other than neonatal), via laparotomy; nontraumatic (ie, Bochdalek, Morgagni)	NEW	25.75	25.75	No
39XX4	Repair, diaphragmatic hernia (other than neonatal), via thoracotomy; traumatic, chronic	NEW	26.41	26.41	No
39XX5	Repair, diaphragmatic hernia (other than neonatal), via thoracotomy; nontraumatic (ie, Bochdalek, Morgagni)	NEW	25.94	25.94	No
39XX7	Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, acute	NEW	22.04	22.04	No
39XX8	Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); traumatic, chronic	NEW	26.60	26.60	No
39XX9	Laparoscopy, surgical, with repair of diaphragmatic hernia (other than neonatal); nontraumatic (ie, Bochdalek, Morgagni)	NEW	27.00	27.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
42808	Excision or destruction of lesion of pharynx, without magnification, any method	2.29	2.29	2.29	No
42XX1	Transoral removal of oropharyngeal and/or pharyngeal neoplasm under magnification (eg, microscope or telescope), includes robotic assistance, when performed; tongue base	NEW	20.00	20.00	No
42XX2	Transoral removal of oropharyngeal and/or pharyngeal neoplasm under magnification (eg, microscope or telescope), includes robotic assistance, when performed; lateral pharyngeal wall, including tonsil	NEW	20.05	20.05	No
44XX1	Duodenoduodenostomy or duodenojejunostomy for congenital duodenal obstruction	NEW	50.00	50.00	No
44XX2	Laparoscopy, surgical; duodenoduodenostomy or duodenojejunostomy for congenital duodenal obstruction	NEW	52.60	52.60	No
48XXX	Ablation, irreversible electroporation of tumor(s) of the pancreas, open, including imaging guidance	NEW	25.19	25.19	No
4XX01	Endoscopic submucosal dissection (ESD) of upper gastrointestinal tract, including mucosal closure, when performed	NEW	15.00	15.00	No
4XX02	Endoscopic submucosal dissection (ESD) of lower gastrointestinal tract, including mucosal closure, when performed	NEW	16.38	16.38	No
51715	Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck	3.64	-	3.64	No
55705	Biopsy, prostate, any approach, nonimaging-guided	1.88	1.88	1.88	No
55707	Biopsy, prostate, transrectal, including imaging guidance, regional	2.63	2.63	2.63	No
55708	Biopsy, prostate, transrectal, including imaging guidance, regional and fusion-targeted lesion(s)	3.39	3.39	3.39	No
55709	Biopsy, prostate, transperineal, including imaging guidance, regional	3.23	3.23	3.23	No
55710	Biopsy, prostate, transperineal, including imaging guidance, regional and fusion-targeted lesion(s)	3.81	3.81	3.81	No
55711	Biopsy, prostate, transrectal or transperineal, including imaging guidance, fusion-targeted lesion(s) without regional; first targeted lesion	2.61	2.37	2.37	No
55714	Biopsy, prostate, including imaging guidance, in-bore CT- or MRI-guided; first targeted lesion	3.62	3.62	3.62	No
55715	Biopsy, prostate, including imaging guidance, in-bore CT- or MRI-guided; each additional targeted lesion	1.05	1.80	1.80	No
59030	Fetal scalp blood sampling	1.94	0.90	0.90	No
59051	Fetal monitoring during labor by consulting physician (ie, non-attending physician) or other qualified health care professional, with interpretation and report	0.72	0.93	0.93	No
59160	Curettage, postpartum	2.69	2.93	2.93	No
59300	Repair of first or second-degree episiotomy or laceration, by other than attending physician or other qualified health care professional performing vaginal delivery care (separate procedure)	2.35	1.76	1.76	No
59320	Cerclage of cervix, during pregnancy; vaginal	2.42	3.02	3.02	No
59325	Cerclage of cervix, during pregnancy; abdominal	3.96	6.34	6.34	No
59412	External cephalic version	1.71	2.63	2.63	No
59414	Delivery of placenta only (separate procedure)	1.61	1.61	1.61	No
59871	Removal of cerclage suture under anesthesia (other than local)	2.08	2.15	2.15	No
59X10	Uterine tamponade (eg, balloon, catheter, vacuum, packing material)	NEW	2.15	2.15	No
59X11	Repair of episiotomy or laceration; third-degree laceration	NEW	2.47	2.47	No
59X12	Repair of episiotomy or laceration; fourth-degree laceration	NEW	4.14	4.14	No
59XX1	Initial day labor management; straightforward, per day	NEW	3.50	4.03	No
59XX2	Initial day labor management; complex, per day	NEW	4.50	5.18	No
59XX3	Subsequent day labor management; straightforward, per day	NEW	3.00	3.45	No
59XX4	Subsequent day labor management; complex, per day	NEW	4.20	4.83	No
59XX5	Vaginal delivery, with or without episiotomy;	NEW	8.00	9.20	No
59XX6	Vaginal delivery, with or without episiotomy; after previous cesarean delivery	NEW	9.00	10.35	No
59XX7	Cesarean delivery; primary	NEW	12.00	13.80	No
59XX8	Cesarean delivery; repeat	NEW	14.66	16.86	No
59XX9	Subtotal or total hysterectomy after cesarean delivery	NEW	15.56	15.56	No
5XX14	Biopsy, prostate, transrectal or transperineal, including imaging guidance, fusion-targeted lesion(s) without regional; each additional targeted lesion (List separately in addition to code for primary procedure)	NEW	0.80	0.68	No
61781	Stereotactic computer-assisted (navigational) procedure; cranial, intradural	3.66	3.66	3.66	No
61782	Stereotactic computer-assisted (navigational) procedure; cranial, extradural	3.10	2.06	2.06	No
61783	Stereotactic computer-assisted (navigational) procedure; spinal	3.66	3.66	3.66	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
62287	Decompression, percutaneous, of nucleus pulposus of intervertebral disc, any method utilizing needle-based technique to remove disc material under fluoroscopic imaging or other form of indirect visualization, with discography and/or epidural injection(s) at the treated level(s), when performed, single or multiple levels, lumbar	9.03	7.06	6.23	No
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical	17.50	17.25	17.25	No
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; thoracic	16.82	16.71	16.71	No
63047	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; lumbar	14.99	14.99	14.99	No
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional vertebral segment, cervical, thoracic, or lumbar	3.38	3.38	3.38	No
64400	Injection(s), anesthetic agent(s) and/or steroid; trigeminal nerve, each branch (ie, ophthalmic, maxillary, mandibular)	0.73	0.73	0.73	No
64405	Injection(s), anesthetic agent(s) and/or steroid; greater occipital nerve	0.92	0.84	0.84	No
70544	Magnetic resonance angiography, head, including image postprocessing; without contrast material(s)	1.17	1.17	1.17	No
70545	Magnetic resonance angiography, head, including image postprocessing; with contrast material(s)	1.17	1.17	1.17	No
70546	Magnetic resonance angiography, head, including image postprocessing; without contrast material(s), followed by contrast material(s) and further sequences	1.44	1.44	1.44	No
70547	Magnetic resonance angiography, neck, including image postprocessing; without contrast material(s)	1.17	1.17	1.17	No
70548	Magnetic resonance angiography, neck, including image postprocessing; with contrast material(s)	1.46	1.46	1.46	No
70549	Magnetic resonance angiography, neck, including image postprocessing; without contrast material(s), followed by contrast material(s) and further sequences	1.76	1.76	1.76	No
70XX4	Magnetic resonance angiography, head and neck, including image postprocessing; without contrast material(s)	NEW	1.77	1.77	No
70XX5	Magnetic resonance angiography, head and neck, including image postprocessing; with contrast material(s)	NEW	2.10	2.10	No
70XX6	Magnetic resonance angiography, head and neck, without contrast material(s) in 1 or both body regions, followed by contrast material(s) and further sequences in 1 or both body regions, including image postprocessing	NEW	2.23	2.23	No
73200	Computed tomography, upper extremity; without contrast material	0.98	1.00	1.00	No
73201	Computed tomography, upper extremity; with contrast material(s)	1.13	1.16	1.16	No
73202	Computed tomography, upper extremity; without contrast material, followed by contrast material(s) and further sections	1.19	1.24	1.24	No
77402	Radiation treatment delivery; Level 1 (eg, single-electron field, multiple-electron fields, or 2D photons), including imaging guidance, when performed	0.00	-	0.00	No
77407	Radiation treatment delivery; Level 2, single-isocenter (eg, 3D or IMRT), photons, including imaging guidance, when performed	0.00	-	0.00	No
77412	Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (eg, 2D, 3D, or IMRT) or a single-isocenter photon therapy (eg, 3D or IMRT) with active motion management, or total skin electrons, or mixed-electron/photon field(s), including imaging guidance, when performed	0.00	-	0.00	No
77520	Proton treatment delivery; simple, without compensation	C	-	0.00	No
77522	Proton treatment delivery; simple, with compensation	C	-	0.00	No
77523	Proton treatment delivery; intermediate	C	-	0.00	No
77525	Proton treatment delivery; complex	C	-	0.00	No
90832	Psychotherapy, 30 minutes with patient	1.94	-	2.02	No
90833	Psychotherapy, 30 minutes with patient when performed with an evaluation and management service	1.71	-	1.79	No
90834	Psychotherapy, 45 minutes with patient	2.56	-	2.67	No
90836	Psychotherapy, 45 minutes with patient when performed with an evaluation and management service	2.17	-	2.26	No
90837	Psychotherapy, 60 minutes with patient	3.78	-	3.94	No
90838	Psychotherapy, 60 minutes with patient when performed with an evaluation and management service	2.86	-	2.98	No
90839	Psychotherapy for crisis; first 60 minutes	3.58	-	3.73	No
90840	Psychotherapy for crisis; each additional 30 minutes	1.71	-	1.79	No
90845	Psychoanalysis	2.40	-	2.50	No
90846	Family psychotherapy (without the patient present), 50 minutes	2.74	-	2.86	No
90847	Family psychotherapy (conjoint psychotherapy) (with patient present), 50 minutes	2.86	-	2.98	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
90849	Multiple-family group psychotherapy	0.67	-	0.70	No
90853	Group psychotherapy (other than of a multiple-family group)	0.67	-	0.70	No
90901	Biofeedback training by any modality (eg, EMG, EEG, ECG); initial 15 minutes of direct patient contact by physician or other qualified health care professional	0.41	0.61	0.61	No
90912	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient	0.90	0.90	0.90	No
90913	Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient	0.50	0.50	0.50	No
90X03	Biofeedback training by any modality (eg, EMG, EEG, ECG); each additional 15 minutes of direct patient contact by physician or other qualified health care professional	NEW	0.48	0.48	No
92508	Treatment of speech, language, voice, communication, and/or auditory processing disorder, group, 2 or more individuals	0.33	0.28	0.28	No
92978	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; initial vessel	1.76	1.76	1.40	No
92979	Endoluminal imaging of coronary vessel or graft using intravascular ultrasound (IVUS) or optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention including imaging supervision, interpretation and report; each additional vessel	1.40	1.40	1.04	No
92X0X	Treatment of fluency disorder (eg, stuttering and cluttering), direct (one-on-one) patient contact; initial 30 minutes	NEW	0.92	0.92	No
92X10	Video head impulse testing (vHIT), with recording, interpretation, and report; of lateral semicircular canal function	NEW	0.53	0.53	No
92X11	Video head impulse testing (vHIT), with recording, interpretation, and report; of lateral and vertical semicircular canal function	NEW	0.84	0.84	No
92X1X	Treatment of fluency disorder (eg, stuttering and cluttering), direct (one-on-one) patient contact; each additional 15 minutes	NEW	0.44	0.44	No
92X2X	Treatment of speech sound production disorder (eg, articulation, phonological process, apraxia, dysarthria), direct (one-on-one) patient contact; initial 30 minutes	NEW	0.90	0.90	No
92X3X	Treatment of speech sound production disorder (eg, articulation, phonological process, apraxia, dysarthria), direct (one-on-one) patient contact; each additional 15 minutes	NEW	0.44	0.44	No
92X4X	Treatment of language comprehension and expression disorder (eg, receptive and expressive language), direct (one-on-one) patient contact; initial 30 minutes	NEW	1.00	1.00	No
92X5X	Treatment of language comprehension and expression disorder (eg, receptive and expressive language), direct (one-on-one) patient contact; each additional 15 minutes	NEW	0.48	0.48	No
92X6X	Treatment of speech sound production disorder (eg, articulation, phonological process, apraxia, dysarthria) and language comprehension and expression disorder (eg, receptive and expressive language), direct (one-on-one) patient contact; initial 30 minutes	NEW	1.00	1.00	No
92X7X	Treatment of speech sound production disorder (eg, articulation, phonological process, apraxia, dysarthria) and language comprehension and expression disorder (eg, receptive and expressive language), direct (one-on-one) patient contact; each additional 15 minutes	NEW	0.50	0.50	No
92X8X	Treatment of voice, upper airway dysfunction, and/or resonance disorders, direct (one-on-one) patient contact; initial 30 minutes	NEW	0.98	0.98	No
92X9X	Treatment of voice, upper airway dysfunction, and/or resonance disorders, direct (one-on-one) patient contact; each additional 15 minutes	NEW	0.48	0.48	No
92XX5	Rotational vestibular assessment by sinusoidal harmonic acceleration (SHA) testing with calibrated, computer-controlled chair, with interpretation and report;	NEW	0.92	0.92	No
92XX6	Rotational vestibular assessment by sinusoidal harmonic acceleration (SHA) testing with calibrated, computer-controlled chair, with interpretation and report; with velocity step testing (VST)	NEW	0.48	0.35	No
93X01	Programming of the cardiac contractility modulation (CCM) system (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, including review and report by a physician or other qualified health care professional	NEW	0.90	0.90	No
93X02	Interrogation device evaluation (in person) with analysis, review, and report by a physician or other qualified healthcare professional, including connection, recording, and disconnection, per patient encounter, implantable cardiac contractility modulation (CCM) system	NEW	0.80	0.80	No
93X03	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation (CCM) system, with interim analysis, review, and report(s) by a physician or other qualified health care professional	NEW	0.59	0.59	No
93X04	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation (CCM) system, remote data acquisition(s),	NEW	0.00	0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	receipt of transmissions, technician review, technical support, and distribution of results				
95921	Testing of autonomic nervous system function, with interpretation and report; cardiovagal innervation (parasympathetic function), including 2 or more of the following: heart rate response to deep breathing with recorded R-R interval, Valsalva ratio, and 30:15 ratio	0.88	0.88	0.74	No
95922	Testing of autonomic nervous system function, with interpretation and report; vasomotor adrenergic innervation (sympathetic adrenergic function), including beat-to-beat blood pressure and R-R interval changes during Valsalva maneuver and at least 5 minutes of passive tilt (ie, tilt table)	0.96	0.96	0.96	No
95923	Testing of autonomic nervous system function, with interpretation and report; sudomotor, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint	0.88	0.88	0.88	No
95924	Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic and sympathetic adrenergic function testing with at least 5 minutes of passive tilt (ie, tilt table)	1.73	1.50	1.50	No
95X18	Unattended sleep study, set-up, data acquisition and technical analysis; low complexity of 3-4 channels that generate at least 3-5 parameter categories	NEW	0.00	0.00	No
95X19	Unattended sleep study, set-up, data acquisition and technical analysis; moderate complexity of 5-10 channels that generate at least 6-8 parameter categories	NEW	0.00	0.00	No
95X20	Unattended sleep study, set-up, data acquisition and technical analysis; high complexity of 11 or more channels that generate at least 9 parameter categories	NEW	0.00	0.00	No
95X21	Unattended sleep study, interpretation and report by a physician or other qualified health care professional; low complexity of 3-4 channels that generate at least 3-5 parameter categories	NEW	0.81	0.81	No
95X22	Unattended sleep study, interpretation and report by a physician or other qualified health care professional; moderate complexity of 5-10 channels that generate at least 6-8 parameter categories	NEW	1.05	1.05	No
95X23	Unattended sleep study, interpretation and report by a physician or other qualified health care professional; high complexity of 11 or more channels that generate at least 9 parameter categories	NEW	1.60	1.42	No
95XX4	Testing of autonomic nervous system function, with interpretation and report; use of tilt table	NEW	0.34	0.34	No
95XX5	Testing of autonomic nervous system function, with interpretation and report; sudomotor, thermoregulatory sweat test	NEW	1.00	1.00	No
95XX6	Testing of autonomic nervous system function, with interpretation and report; sudomotor, assessing the sympathetic skin response (SSR) potential	NEW	0.50	0.50	No
95XX7	Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint	NEW	1.17	1.17	No
95XX8	Testing of autonomic nervous system function, with interpretation and report; combined sympathetic adrenergic with at least 5 minutes of passive tilt (ie, tilt table) and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint	NEW	1.75	1.56	No
95XX9	Testing of autonomic nervous system function, with interpretation and report; combined parasympathetic, sympathetic adrenergic function with at least 5 minutes of passive tilt (ie, tilt table), and sudomotor testing, quantitative sudomotor axon reflex test (QSART) or silastic sweat imprint	NEW	1.91	1.77	No
96156	Health behavior assessment, or re-assessment (ie, health-focused clinical interview, behavioral observations, clinical decision making)	2.40	-	2.50	No
96158	Health behavior intervention, individual, face-to-face; initial 30 minutes	1.66	-	1.73	No
96159	Health behavior intervention, individual, face-to-face; each additional 15 minutes	0.57	-	0.60	No
96164	Health behavior intervention, group (2 or more patients), face-to-face; initial 30 minutes	0.24	-	0.25	No
96165	Health behavior intervention, group (2 or more patients), face-to-face; each additional 15 minutes	0.11	-	0.12	No
96167	Health behavior intervention, family (with the patient present), face-to-face; initial 30 minutes	1.77	-	1.85	No
96168	Health behavior intervention, family (with the patient present), face-to-face; each additional 15 minutes	0.63	-	0.66	No
96920	Laser treatment, 308-312 nanometer wavelengths, for inflammatory or autoimmune skin diseases (eg, psoriasis); total area less than 250 sq cm	0.81	1.00	1.00	No
96921	Laser treatment, 308-312 nanometer wavelengths, for inflammatory or autoimmune skin diseases (eg, psoriasis); 250 sq cm to 500 sq cm	0.88	1.24	1.24	No
96922	Laser treatment, 308-312 nanometer wavelengths, for inflammatory or autoimmune skin diseases (eg, psoriasis); over 500 sq cm	1.12	1.50	1.50	No
97151	Behavior identification assessment, administered by a physician or other qualified health care professional (QHP), each 15 minutes of the physician's or other QHP's time face-to-face with patient and/or caregiver(s) administering assessments and discussing	C	C	C	No

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	findings and recommendations, and non-face-to-face analyzing past data, scoring and/or interpreting the assessment, and preparing the report and/or treatment plan				
97152	Behavior identification–supporting assessment, administered by technician, face-to-face with the patient, each 15 minutes	C	C	C	No
97153	Adaptive behavior treatment by protocol, administered by technician, face-to-face with 1 patient, each 15 minutes	C	C	C	No
97154	Group adaptive behavior treatment by protocol, administered by technician, face-to-face with 2 or more patients, each 15 minutes	C	C	C	No
97155	Adaptive behavior direction of technician and analysis by physician or other qualified health care professional, face-to-face with a patient, each 15 minutes	C	C	C	No
97156	Family adaptive behavior treatment guidance with analysis, administered by physician or other qualified health care professional (with or without the patient present), including discussing protocols and treatment targets and/or training the caregiver(s) to implement assessment or treatment protocols with the patient, face-to-face with caregiver(s) for 1 patient, each 15 minutes	C	C	C	No
97157	Multiple-family group adaptive behavior treatment guidance with analysis, administered by physician or other qualified health care professional (without the patient present), face-to-face with multiple sets of caregivers for multiple patients, each 15 minutes	C	C	C	No
97158	Group adaptive behavior treatment with analysis, administered by physician or other qualified health care professional, face-to-face with multiple patients, each 15 minutes	C	C	C	No
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day	0.39	-	0.39	No
976XX	Real-time fluorescence wound imaging with clinical darkness to identify presence, location, load of bacteria, and measure wound size, per day	NEW	C	0.80	Yes
978X1	Lactation care directed by a physician or other qualified health care professional, including history, assessment, training, and report; each additional 15 minutes	NEW	0.00	0.00	No
978XX	Lactation care directed by a physician or other qualified health care professional, including history, assessment, training, and report; first 30 minutes	NEW	0.18	0.18	No
97X1X	Behavior identification–supporting assessment of harmful behavior; each 15 minutes of technician time face-to-face with a patient, requiring the following components: • delivered by 2 technicians, • for a patient who exhibits harmful behavior, • conducted in an environment that is customized to the patient's behavior.	NEW	C	C	No
97X2X	Behavior identification–supporting assessment of harmful behavior; additional technicians present, each 15 minutes	NEW	C	C	No
97X3X	Adaptive behavior non-face-to-face services, personally performed by a physician or other qualified health care professional, each 15 minutes, with any of the following elements, when performed: • review and analysis of data and session notes on patient treatment targets, • clinical decision-making regarding the need to modify treatment targets, goals, or protocols and/or making those modifications, • clinical decision-making regarding the need for additional assessment and developing or modifying assessment protocols, • developing discharge or transition plan, • training on or reviewing treatment targets and/or revised assessment or treatment protocols with technician(s).	NEW	C	C	No
97X4X	Adaptive behavior treatment of harmful behavior; each 15 minutes of technician time with a patient, requiring the following components: • delivered by 2 technicians, • for a patient who exhibits harmful behavior, • conducted in an environment that is customized to the patient's behavior.	NEW	C	C	No
97X5X	Adaptive behavior treatment of harmful behavior; each additional technician present, each 15 minutes	NEW	C	C	No
97X6X	Adaptive behavior treatment with analysis, administered by physician or other qualified health care professional, face-to-face with 1 patient, each 15 minutes	NEW	C	C	No
98975	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); initial set-up and patient education on use of equipment	0.00	0.00	0.00	No
98976	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 16-30 days in a 30-day period	0.00	0.00	0.00	No
98977	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 16-30 days in a 30-day period	0.00	0.00	0.00	No
98978	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data	C	C	0.00	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	access or data transmissions to support monitoring of cognitive behavioral therapy, 16-30 days in a 30-day period				
98979	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 10 minutes	0.31	0.31	0.31	No
98980	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; first 20 minutes	0.62	0.62	0.62	No
98981	Remote therapeutic monitoring treatment management services, physician or other qualified health care professional time in a calendar month requiring at least 1 real-time interactive communication with the patient or caregiver during the calendar month; each additional 20 minutes	0.61	0.61	0.61	No
98984	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of respiratory system, 2-15 days in a 30-day period	0.00	0.00	0.00	No
98985	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of musculoskeletal system, 2-15 days in a 30-day period	0.00	0.00	0.00	No
98986	Remote therapeutic monitoring (eg, therapy adherence, therapy response, digital therapeutic intervention); device(s) supply for data access or data transmissions to support monitoring of cognitive behavioral therapy, 2-15 days in a 30-day period	C	C	0.00	No
99091	Collection and interpretation of physiologic data (eg, ECG, blood pressure, glucose monitoring) digitally stored and/or transmitted by the patient and/or caregiver to the physician or other qualified health care professional, qualified by education, training, licensure/regulation (when applicable) requiring a minimum of 30 minutes of time, each 30 days	1.10	1.10	1.10	No
99406	Smoking and tobacco use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes	0.24	-	0.29	No
99407	Smoking and tobacco use cessation counseling visit; intensive, greater than 10 minutes	0.50	-	0.60	No
99445	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate); device(s) supply with daily recording(s) or programmed alert(s) transmission, 2-15 days in a 30-day period	0.00	0.00	0.00	No
99453	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate); initial set-up and patient education on use of equipment	0.00	0.00	0.00	No
99454	Remote monitoring of physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate); device(s) supply with daily recording(s) or programmed alert(s) transmission, 16-30 days in a 30-day period	0.00	0.00	0.00	No
99457	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 20 minutes	0.61	0.61	0.61	No
99458	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; each additional 20 minutes	0.61	0.61	0.61	No
99470	Remote physiologic monitoring treatment management services, clinical staff/physician/other qualified health care professional time in a calendar month requiring 1 real-time interactive communication with the patient/caregiver during the calendar month; first 10 minutes	0.31	0.31	0.31	No
99473	Self-measured blood pressure using a device validated for clinical accuracy; patient education/training and device calibration	0.00	0.00	0.00	No
99474	Self-measured blood pressure using a device validated for clinical accuracy; separate self-measurements of two readings one minute apart, twice daily over a 30-day period (minimum of 12 readings), collection of data reported by the patient and/or caregiver to the physician or other qualified health care professional, with report of average systolic and diastolic pressures and subsequent communication of a treatment plan to the patient	0.18	0.18	0.18	No
99492	Initial psychiatric collaborative care management, first 70 minutes in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies.	1.88	1.88	2.75	No
99493	Subsequent psychiatric collaborative care management, first 60 minutes in a subsequent month of behavioral health care manager	2.05	2.05	2.26	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment.				
99494	Initial or subsequent psychiatric collaborative care management, each additional 30 minutes in a calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional	0.82	0.82	1.13	No
9XX04	Percutaneous transcatheter therapeutic drug-delivery by intracoronary drug-delivery balloon (eg, drug-coated, drug-eluting), including mechanical dilation by nondrug-delivery balloon angioplasty, single major coronary artery and/or its branch(es)	NEW	10.00	8.05	No
9XX07	Percutaneous transcatheter therapeutic drug-delivery by intracoronary drug-delivery balloon (eg, drug-coated, drug-eluting), single major artery and/or its branches	NEW	4.38	4.38	No
G0396	Alcohol and/or substance (other than tobacco) misuse structured assessment (eg, audit, dast), and brief intervention 15 to 30 minutes	0.65	-	0.77	No
G0397	Alcohol and/or substance (other than tobacco) misuse structured assessment (eg, audit, dast), and intervention, greater than 30 minutes	1.30	-	1.55	No
G0561	Tympanostomy with local or topical anesthesia and insertion of a ventilating tube when performed with tympanostomy tube delivery device, unilateral	C	0.00	0.00	No
G0568	Initial psychiatric collaborative care management, in the first calendar month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: outreach to and engagement in treatment of a patient directed by the treating physician or other qualified health care professional, initial assessment of the patient, including administration of validated rating scales, with the development of an individualized treatment plan, review by the psychiatric consultant with modifications of the plan if recommended, entering patient in a registry and tracking patient follow-up and progress using the registry, with appropriate documentation, and participation in weekly caseload consultation with the psychiatric consultant, and provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies	1.88	1.88	2.75	No
G0569	Subsequent psychiatric collaborative care management, in a subsequent month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional, with the following required elements: tracking patient follow-up and progress using the registry, with appropriate documentation, participation in weekly caseload consultation with the psychiatric consultant, ongoing collaboration with and coordination of the patient's mental health care with the treating physician or other qualified health care professional and any other treating mental health providers, additional review of progress and recommendations for changes in treatment, as indicated, including medications, based on recommendations provided by the psychiatric consultant, provision of brief interventions using evidence-based techniques such as behavioral activation, motivational interviewing, and other focused treatment strategies, monitoring of patient outcomes using validated rating scales, and relapse prevention planning with patients as they achieve remission of symptoms and/or other treatment goals and are prepared for discharge from active treatment	2.05	2.05	2.26	No
G2011	Alcohol and/or substance (other than tobacco) misuse structured assessment (eg, audit, dast), and brief intervention, 5-14 minutes	0.33	-	0.39	No
G2214	Initial or subsequent psychiatric collaborative care management, first 30 minutes in a month of behavioral health care manager activities, in consultation with a psychiatric consultant, and directed by the treating physician or other qualified health care professional	0.77	0.77	1.13	No
GACP1	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), first 20 minutes of clinical staff time with the patient, family member(s), directed by a treating physician or other treating qualified health care professional	NEW	-	1.00	No
GACP2	Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), each additional 20 minutes with the patient, family member(s), directed by a treating physician or other treating qualified health care professional)	NEW	-	0.70	No
GADV1	Office or other outpatient evaluation and management service(s) for the diagnosis and treatment of vaccine adverse effects, new or	NEW	-	0.61	No

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
	established patient; each 15 minutes personally performed by the physician or qualified healthcare professional				
GSLPP	Treatment of speech, language, voice, communication, and/or auditory processing disorder; individual: for the pediatric population up to age 18 or 21	NEW	-	1.30	No
GSMAS	Voluntary, group-based medical session involving multiple patients with common medical condition(s), receiving medical care in a group setting; billed and led by a physician or qualified nonphysician practitioner and may include services provided by other qualified healthcare professionals, clinical staff, or auxiliary personnel under the direction of the supervising physician or other practitioner. Session integrates group education, counseling, and peer support with individualized patient clinical assessment and care, 2-10 patients, billed once per patient, per session.	NEW	-	1.73	No
G0577	Vascular embolization or occlusion procedure with use of a pressure-generating catheter (eg, one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for tumors, organ ischemia, or infarction performed in the non-facility setting	NEW	-	11.45	No

TABLE A-D10: CY 2026 DIRECT PE REFINEMENTS

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change in Dollars
10005	Fna bx w/us gdn 1st les	EQ250	ultrasound unit, portable	NF		37	0	G1: See preamble text	-5.97
10005	Fna bx w/us gdn 1st les	ER130	Fine Needle Aspiration portable ultrasound	NF		0	37	G1: See preamble text	11.74
10006	Fna bx w/us gdn ea addl	EQ250	ultrasound unit, portable	NF		17	0	G1: See preamble text	-2.74
10006	Fna bx w/us gdn ea addl	ER130	Fine Needle Aspiration portable ultrasound	NF		0	17	G1: See preamble text	5.39
976XX	R-t fluor wound imaging pr d	EF015	mayo stand	NF		0	30	G1: See preamble text	0.03
976XX	R-t fluor wound imaging pr d	EF031	table, power	NF		0	30	G1: See preamble text	0.47
976XX	R-t fluor wound imaging pr d	EQ137	instrument pack, basic ($500-$1499)	NF		0	36	G1: See preamble text	0.08
976XX	R-t fluor wound imaging pr d	EQ168	light, exam	NF		0	30	G1: See preamble text	0.10
976XX	R-t fluor wound imaging pr d	ER131	MolecuLight DX System	NF		0	30	G1: See preamble text	2.56
976XX	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available	0	3	G1: See preamble text	1.62
976XX	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Obtain vital signs	0	3	G1: See preamble text	1.62
976XX	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Provide education/obtain consent	0	1	G1: See preamble text	0.54

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change in Dollars
976XX	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Prepare room, equipment and supplies	0	2	G1: See preamble text	1.08
976XX	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Prepare, set-up and start IV, initial positioning and monitoring of patient	0	2	G1: See preamble text	1.08
976XX	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Assist physician or other qualified healthcare professional---directly related to physician work time (100% of physician intra-service time)	0	15	G1: See preamble text	8.10
976XX	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Clean room/equipment by clinical staff	0	3	G1: See preamble text	1.62
976XX	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Clean surgical instrument package	0	10	G1: See preamble text	5.40
976XX	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Check dressings, catheters, wounds	0	1	G1: See preamble text	0.54
976XX	R-t fluor wound imaging pr d	L037D	RN/LPN/MTA	NF	Review home care instructions, coordinate visits/prescriptions	0	2	G1: See preamble text	1.08
976XX	R-t fluor wound imaging pr d	SA043	pack, cleaning, surgical instruments	NF		0	1	G1: See preamble text	11.09
976XX	R-t fluor wound imaging pr d	SB007	drape, sterile barrier 16in x 29in	NF		0	1	G1: See preamble text	0.51
976XX	R-t fluor wound imaging pr d	SB019	drape-towel, sterile 18in x 26in	NF		0	1	G1: See preamble text	0.47
976XX	R-t fluor wound imaging pr d	SB022	gloves, non-sterile	NF		0	2	G1: See preamble text	0.60
976XX	R-t fluor wound imaging pr d	SB028	gown, surgical, sterile	NF		0	1	G1: See preamble text	5.13
976XX	R-t fluor wound imaging pr d	SB044	underpad 2ft x 3ft (Chux)	NF		0	1	G1: See preamble text	0.32
976XX	R-t fluor wound imaging pr d	SB061	MolecuLight DX Eco Dark Drape	NF		0	1	G1: See preamble text	6.25
976XX	R-t fluor wound imaging pr d	SC056	syringe 50-60ml	NF		0	1	G1: See preamble text	1.13

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change in Dollars
976XX	R-t fluor wound imaging pr d	SF007	blade, surgical (Bard-Parker)	NF		0	1	G1: See preamble text	0.68
976XX	R-t fluor wound imaging pr d	SG018	bandage, Kling, non-sterile 3in	NF		0	1	G1: See preamble text	0.34
976XX	R-t fluor wound imaging pr d	SG035	dressing, 3in x 4in (Telfa, Release)	NF		0	2	G1: See preamble text	0.10
976XX	R-t fluor wound imaging pr d	SG051	gauze, non-sterile 4in x 4in	NF		0	8	G1: See preamble text	0.24
976XX	R-t fluor wound imaging pr d	SG052	gauze, self-adherent roll 0.5in to 2in (Fabco, Gauztex)	NF		0	72	G1: See preamble text	5.76
976XX	R-t fluor wound imaging pr d	SG079	tape, surgical paper 1in (Micropore)	NF		0	12	G1: See preamble text	0.12
976XX	R-t fluor wound imaging pr d	SH069	sodium chloride 0.9% irrigation (500-1000ml uou)	NF		0	1	G1: See preamble text	3.34
976XX	R-t fluor wound imaging pr d	SJ046	silver nitrate applicator	NF		0	2	G1: See preamble text	0.38

TABLE A-D11: CY 2026 NEW INVOICES FOR DIRECT PE INPUTS

CPT/HCPCS codes	Item Name	CMS code	Average price	No. of Invoices	NF Allowed Services
10005, 10006	Fine Needle Aspiration portable ultrasound	ER130	83750	1	66,742
27279	Dorsal SI joint articular fixation device	SD390	14,451.00	1	41
51715	urethral bulking agent	SD396	1175	18	1,926
61782	Single Use Instrumentation Wire	SD391	48.40	1	3,565
61782	Patient Tracker	SD392	130.00	2	3,565
61782	Adhesive Pad	SD393	9.50	1	3,565
61782	Cube 4D Navigation system (monitor, 2 mounts, cart, pointer)	ER129	93,850.00	1	3,565
90901	disposable paper shorts	SB060	0.82	1	51,307
92X10, 92X11	Face cushion	SD394	1.475	1	2,349
92X10, 92X11	Monocular Video Frenzel base unit with vestibular software	EQ420	3424.5	1	2,349
92X10, 92X11	Lateral VHIT module	EQ421	7589.7	1	2,349
92X11	Larp/Ralp module	EQ422	6138.9	1	1,565
92XX5, 92XX6	VNG Open Chair System	EF051	113,900.00	1	36,179
95921, 95922, 95924, 95XX7, 95XX8, 95XX9	Filtered Mouthpiece	SD387	1.72	1	152,213
95923, 95XX7, 95XX8, 95XX9	Gel Trode 2x2 Return Electrode	SD388	4.95	1	88,241
95923, 95XX7, 95XX8, 95XX9	Meridian Electrode w/Expanding Foam	SD389	13.25	1	88,241
95X18	Apnea Link Air	EQ418	1,500.00	1	58,431
95X19	Apnea Trak Legacy	EQ419	5,623.00	1	222,669
95X20	Nox A1 Sensor Kit adult	SA143	22.46	1	6,192
95X20	Nox A1s System with SpO2, US	EQ417	14,000.00	1	6,192
976XX	MolecuLight DX Eco Dark Drape	SB061	6.25	1	175,391
976XX	MolecuLight DX System	ER131	21500	1	175,391
978XX, 978X1	scale, infant, digital, fine gradation	EF052	1,409.31	5	-
G0561	Automated PE tube delivery device	SD395	497.5	2	3

TABLE A-D12: CY 2026 INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS

CPT/HCPCS codes	Item Name	CMS code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
27278	Dorsal SI Joint Arthrodesis Implant	SD356	$11,500.00	$12,500.00	9%	1	512
36465, 36466	Varithena admin pack	SA125	$40.00	$55.00	38%	1	119,660
36465, 36466	Varithena (foam)	SD324	$3,195.00	$3,495.00	9%	1	119,660
36516	liposorber system	EQ174	$7,800.00	$56,000.00	618%	1	535
88364, 88365, 88367, 88368, 88369, 88373	Universal Detection Kit	SA117	$6.05	$6.38	5%	1	66,767
93241, 93243, 93245, 93247	extended external ECG patch, medical magnetic tape recorder	SD339	$315.00	$365.00	16%	31	675,748
97113	aquatic therapy pool	EQ050	$36,000.00	$192,171.88	434%	3	1,562,410
97610	kit, low frequency ultrasound wound therapy (MIST)	SA119	$320.18	$100.00	-69%	1	179,021
99151, 99152, G0500	pack, moderate sedation	SA044	$19.20	$15.69	-18%	1	158,962
G2082	Esketamine (56 mg vial)	SH109	$834.20	$895.10	7%	1	4,386
G2083	Esketamine (84 mg vial)	SH110	$1,251.31	$1,324.66	6%	1	32,576
111 codes	pack, basic injection	SA041	$12.73	$15.00	18%	-	-
306 codes	pack, cleaning and disinfecting, endoscope	SA042	$25.3600	$28.3250	12%	-	-
4568 codes	pack, minimum multi-specialty visit	SA048	$4.01	$2.99	-25%	-	-
168 codes	pack, ophthalmology visit (no dilation)	SA050	$2.263	$1.807	-20%	-	-
239 codes	pack, pelvic exam	SA051	$14.38	$8.59	-40%	-	-
1079 codes	pack, post-op incision care (staple)	SA052	$6.50	$8.20	26%	-	-
469 codes	pack, post-op incision care (suture & staple)	SA053	$7.49	$9.52	27%	-	-
1708 codes	pack, post-op incision care (suture)	SA054	$6.53	$8.43	29%	-	-
12 codes	pack, post-op incision care, craniotomy	SA055	$10.93	$14.55	33%	-	-
24 codes	pack, post-op incision care, neurosurgical	SA056	$9.48	$12.77	35%	-	-
38 codes	pack, urology cystoscopy visit	SA058	$75.67	$56.65	-25%	-	-
120 codes	pack, drapes, ortho, large	SA080	$33.33	$29.35	-12%	-	-
145 codes	pack, ophthalmology visit (w-dilation)	SA082	$3.12	$2.73	-13%	-	-
119 codes	pack, protective, ortho, large	SA083	$12.16	$13.45	11%	-	-
27 codes	pack, protective, ortho, small	SA084	$6.71	$7.43	11%	-	-
100 codes	guidewire, hydrophilic	SD089	$27.42	$34.29	25%	-	-

TABLE A-D13: CY 2026 NO PE REFINEMENTS

HCPCS	Description
15X19	Scsa t/a/l 1st 100 sq cm/<
15X20	Scsa t/a/l ea addl 100 sq cm
15X21	Scsa f-dgt 1st 100 sq cm/<
15X22	Scsa f-dgt ea addl 100 sq cm
20985	Cptr-asst navig px muscsk px
209X1	Plmt loclzj mrk ntross prq 1
209X2	Plmt loclz mrk ntross prq ea
209XX	Abltj ther rdctj/erad b1 tum
22210	Incis 1 vertebral seg cerv
22212	Incis 1 vertebral seg thorac
22214	Incis 1 vertebral seg lumbar
22216	Incis addl spine segment
23470	Reconstruct shoulder joint
23472	Reconstruct shoulder joint
27130	Total hip arthroplasty
27278	Arthrd si jt i-artic b1 grf
27279	Arthrd si jt tartclr&/iartic
27447	Total knee arthroplasty
27X05	Impl med kne xartic shck abs
27XX8	Aclr scaf impl ostchndrl les
33340	Perq clsr tcat l atr apndge
33X01	Ins perm ccm pg&trnsvn eltrd
33X02	Ins perm ccm pulse gen only
33X03	Ins perm ccm trnsvns eltrd 1
33X04	Ins perm ccm trnsvn eltrd dl
33X05	Rmv perm ccm pg&trnsvn eltrd
33X06	Rmv perm ccm pulse gen only
33X07	Rmv perm ccm trnsvns eltrd 1
33X08	Rmv perm ccm trnsvn eltrd dl
33X09	Rmvl&rplcmt perm ccm pg only
33X10	Repos prv ccm transvns eltrd
33X11	Rlc/rev skn pckt impl ccm pg
33X12	Insj l heart vad aorta expos
33X13	Rmvl l hrt vad rescj&staplg
33X15	Insj l hrt vad ax subcl/inom
33X50	Ttvr w/prosth valve perq
33X51	T-teer perq initial clip
33X52	T-teer perq each addl clip

HCPCS	Description
36465	Njx noncmpnd sclrsnt 1 vein
36466	Njx noncmpnd sclrsnt mlt vn
36470	Njx sclrsnt 1 incmptnt vein
36471	Njx sclrsnt mlt incmptnt vn
36473	Endovenous mchnchem 1st vein
36474	Endovenous mchnchem add-on
38X03	Mvasc anast 1vn&lymph vsl 1
38X04	Mvasc anast 1vn&lymph vsl ea
39540	Rpr diphrg hrna lapt tr aqt
39541	Rpr diphrg hrna lapt tr chrn
39545	Plctj diaphragm evntrn/palys
395X2	Thrsc plctj dphrm evnt/palys
39X11	Thrsc diphrg hrna traum chr
39X12	Thrsc rpr diphrg hrna ntraum
39X13	Impl mesh diphrg hrna rpr
39XX1	Div med arc lig&rls cel trnk
39XX2	Laps surg div median arc lig
39XX3	Rpr diphrg hrna lapt ntraumt
39XX4	Rpr diphrg hrna thrc tr chrn
39XX5	Rpr diphrg hrna thrcm ntraum
39XX7	Lap rpr dphrg hrna traum aqt
39XX8	Lap rpr dphrg hrna traum chr
39XX9	Laps rpr dphrg hrna nontraum
42808	Exc/dstr les pharynx wo magn
42XX1	Trnsorl rmvl neo tongue base
42XX2	Trnsorl rmv neo lat phrn wal
44XX1	Dd/dj cgen duol obstrcj
44XX2	Laps surg dd/dj cgen duo obs
48XXX	Abltj ire tum pancreas open
4XX01	Esd upper gi tract
4XX02	Esd lower gi tract
55705	Bx prst8 any approach nonimg
55707	Bx prst8 trct regional
55708	Bx prst8 trct reg&fus trgt
55709	Bx prst8 tprnl regional
55710	Bx prst8 tprnl reg&fus trgt
55711	Bx prst8 trct/tprn fus trgt1
55714	Bx prst8 in-bore ct/mri 1
55715	Bx prst8 in-bore ct/mr ea
59030	Fetal scalp blood sampling
59051	Fetal mntr drg labor w/i&r
59160	D & c after delivery
59300	Rpr 1st/2nd episiotomy/lac
59320	Revision of cervix
59325	Revision of cervix
59412	External cephalic version
59414	Delivery of placenta only
59871	Remove cerclage suture
59X10	Uterine tamponade
59X11	Rpr episio/lac 3rd degree
59X12	Rpr episio/lac 4th degree

HCPCS	Description
59XX1	Initial day labor mgmt sf
59XX2	Initial day labor mgmt cplx
59XX3	Sbsq day labor mgmt sf
59XX4	Sbsq day labor mgmt complex
59XX5	Vag dlvr w/w/o episiotomy
59XX6	Vag dlvr after prev cesarean
59XX7	Cesarean delivery primary
59XX8	Cesarean delivery repeat
59XX9	Stot/tot hyst after cesarean
5XX14	Bx prst8 trc/tprn fus trg ea
61781	Scan proc cranial intra
61782	Scan proc cranial extra
61783	Scan proc spinal
62287	Dcmprn pq nuc pul 1/mlt lmbr
63045	Lam facetec & foramot crv
63046	Lam facetec & foramot thrc
63047	Lam facetec & foramot lumbar
63048	Lam facetec &foramot ea addl
64400	Njx aa&/strd trigeminal nrv
64405	Njx aa&/strd gr ocpl nrv
70544	Mra head w/post-pxessing c-
70545	Mra head w/post-pxessing c+
70546	Mra head w/pst-pxessg c-/c+
70547	Mra neck w/post-pxessing c-
70548	Mra neck w/post-pxessing c+
70549	Mra neck w/pst-pxessg c-/c+
70XX4	Mra h&n w/pst-pxessg c-
70XX5	Mra h&n w/pst-pxessg c+
70XX6	Mra h&n w/pst-pxessg c-/c+
73200	Ct upper extremity w/o dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o&w/dye
90901	Biofeedback train any 1st 15
90912	Bfb training 1st 15 min
90913	Bfb training ea addl 15 min
90X03	Biofeedback train any ea add
92508	Tx sp lang voice comm group
92X0X	Tx fluency do 1st 30 min
92X10	Vhit lat smcrclr canal funcj
92X11	Vhit lat&ver smcrcl cnl func
92X1X	Tx fluency do ea addl 15 min
92X2X	Tx sp sound production do 1
92X3X	Tx sp sound production do ea
92X4X	Tx lang cmpre&xprsn do 1st
92X5X	Tx lang cmpre&xprsn do ea
92X6X	Tx sp sound&lang cmpre do 1
92X7X	Tx sp sound&lang cmpre do ea
92X8X	Tx voic uairw dysf&/res do 1
92X9X	Tx voic uairw dys&/res do ea
92XX5	Rotl vstblr assmt sha tstg
92XX6	Rotl vstblr assmt sha w/vst

HCPCS	Description
93X01	Prgrmg ccm sys phys/qhp ip
93X02	Interrog ccm sys phys/qhp ip
93X03	Interog ccm sys phys/qhp rem
93X04	Interrog ccm sys tech remote
95921	Tst ans cardiovagal innervaj
95922	Tst ans vsmtr adrnrgc inrvaj
95923	Tst ans sudomotor qsart
95924	Tst ans parasymp&symp w/tilt
95X18	Unatn slp std setup lo 3-4ch
95X19	Unatn slp st setup mod5-10ch
95X20	Unatn slp std setup hi 11+ch
95X21	Unatn slp std i&r low 3-4 ch
95X22	Unatn slp std i&r mod 5-10ch
95X23	Unatn slp std i&r hi 11+ch
95XX4	Tst ans use of tilt table
95XX5	Tst ans sudomotor thermoreg
95XX6	Tst ans sudomotor ssr pot
95XX7	Tst ans parasymp&sdmtr qsart
95XX8	Tst ans symp adrngc w/tilt
95XX9	Tst ans parasymp symp adrngc
96920	Lsr tx inflam/ai skn<250sqcm
96921	Lsr tx inflam/ai 250-500sqcm
96922	Lsr tx inflam/ai skn>500sqcm
978X1	Lactation care ea add 15 min
978XX	Lactation care 1st 30 min
9XX04	Prq tcat ther rx ntrac balo1
9XX07	Prq tcat ther rx dlvr balo 1
G0561	Temp tube delivery, unil

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4. Potentially Misvalued Services Under the PFS

a. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the relative value units (RVUs) established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) of the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes (PMVC) under the PFS, using the same criteria used to identify PMVC, and to make appropriate adjustments.

As outlined in section II.D. of the proposed rule, under Valuation of Specific Codes, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association (AMA)/Specialty Society Relative Value Scale (RVS) Update Committee (referred to as the RUC), MedPAC, and other interested parties. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process as authorized by statute. We may also consider analyses of work time, work RVUs, or direct practice expense (PE) inputs using other data sources, such as the Veterans Health Administration (VHA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Merit-based Incentive Payment System (MIPS) data. In addition to considering the most recent available data, we assessed the results of physician surveys and specialty recommendations submitted to us by the RUC for our review. We also consider information provided by other interested parties such as from the general medical-related community and the public. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available and requires us to take into account the results of consultations with organizations representing physicians who provide the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs.

In its March 2006 Report to the Congress (*https://www.medpac.gov/document/report-to-the-congress-2006-medicare-payment-policy/*), MedPAC discussed the importance of appropriately valuing physicians' services, stating that misvalued services can distort the market for physicians' services, as well as for other health care services that physicians order, such as hospital services. In that same report, MedPAC postulated that physicians' services under the PFS can become misvalued over time. MedPAC stated, ''When a new service is added to the physician fee schedule, it may be assigned a relatively high value because of the time, technical skill, and psychological stress that are often required to furnish that service. Over time, the work required for certain services would be expected to decline as physicians become more familiar with the service and more efficient in furnishing it.'' We believe services can also become overvalued when PE costs decline. This can happen when the costs of equipment and supplies fall, or when equipment is used more frequently than is estimated in the PE methodology, reducing its cost per use. Likewise, services can become undervalued when physician work increases, or PE costs rise.

As MedPAC noted in its March 2009 Report to Congress (*https://www.medpac.gov/docs/default-source/reports/march-2009-report-to-congress-medicare-payment-policy.pdf*), in the intervening years since MedPAC made the initial recommendations, CMS and the RUC have taken several steps to improve the review process. Also, section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in PE.
- Codes that describe new technologies or services within an appropriate time-period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intraservice work per unit of time.
- Codes with high PE RVUs.
- Codes with high-cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using current processes for consideration of coding changes), which may involve consolidating individual services into bundled codes for payment under the PFS.

b. CY 2027 Identification and Review of Potentially Misvalued Services

In the CY 2012 PFS final rule with comment period (76 FR 73058 through 73059), we finalized a process for the public to nominate PMVC. In the CY 2015 PFS final rule with comment period (79 FR 67606 through 67608), we modified this process whereby the public and interested parties may nominate PMVC for review by submitting the code with supporting documentation by February 10th of each year. Supporting documentation for codes nominated for the annual review of PMVC may include the following:

- Documentation in peer reviewed medical literature or other reliable data that demonstrate changes in physician work due to one or more of the following: technique, knowledge and technology, patient population, site-of-service, length of hospital stay and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high-cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, VA, NSQIP, the STS National Database, and the MIPS data).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

We evaluate the supporting documentation submitted with the nominated codes and assess whether the nominated codes appear to be PMVC appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate for each nominated code whether we agree with its inclusion as a PMVC. The public has the opportunity to comment on these and all other proposed PMVC. In each year's final rule, we finalize our list of PMVC.

In each proposed rule, we seek nominations from the public and from interested parties of codes that they believe we should consider as potentially misvalued. We receive public nominations for PMVC by February 10th and we display these nominations on our public website (*https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*), where we include the submitter's name, their associated organization and the submitted studies for full transparency. We sometimes receive submissions for specific PE-related inputs for codes, and discuss these PE-related submissions, as necessary under the Determination of PE RVUs section of the rule. We summarize later in this section this year's submissions under the PMVC initiative. For CY 2027, we received 15 requests concerning various codes as PMVC.

The nominations are as follows:

(1) Nasal Sinus Irrigation (CPT Codes 31000 and 31002)

We received a request from one nominator to review nasal sinus irrigation codes, CPT 31000 *(Lavage by cannulation; maxillary sinus (antrum puncture or natural ostium)),* and CPT 31002 *(Lavage by cannulation; sphenoid sinus),* as potentially misvalued. We reviewed this code family for the CY 2026 PFS final rule and our extensive discussion and rationale for finalizing the current values can be found at 90 FR 49310 through 49311.

We appreciate the information we received from the nominator. However, we note the information was the same as last year's submission. Additionally, the aforementioned CY 2026 PFS final rule specifically mentions for nasal sinus irrigation that interested parties were encouraged to submit relevant

documentation, such as invoices or other evidence that demonstrates the typical resource costs for providing these services (90 FR 49311). However, we did not receive any invoices from the nominator.

In consideration of the information provided in this potentially misvalued nomination request as well as our previous valuation review and decision stated in the CY 2026 PFS final rule, we are seeking comments on the typicality and usage of the nasal sinus irrigation codes, CPT codes 31000 and 31002.

(2) Urethral Bulking Material (CPT Code 51715)

We received a request from a nominator to review CPT code 51715 *(Endoscopic injection of implant material into the submucosal tissues of the urethra and/or bladder neck)* as potentially misvalued. The nominator stated that CPT code 51715 currently does not include a supply for the implant material necessary to properly perform CPT code 51715 in the office setting, which is a clinically desired place of service for this treatment. The nominator requested that CMS create a supply code for a urethral bulking agent sold in 2 mL vials, with a non-facility quantity of 1 priced at an average of $1,175 and incorporate this new supply into CPT code 51715 to appropriately value the service in the non-facility setting.

We appreciate the nominator submitting invoices regarding the pricing of this urethral bulking agent. Given the information provided by the nominator as well as factoring in the amount of time that has passed since CPT code 51715 was last formally reviewed in the 1990s, we are proposing to create a new supply code (SD396) for this urethral bulking agent. The SD396 supply is based on a 2 mL vial which we are proposing to price at the requested $1,175 based on an average of the submitted invoices. We are proposing to add 1 quantity of this supply to CPT code 51715 in the non-facility setting to reflect current clinical practice. Given the cost of this supply and the length of time since last review, we are also seeking comment on whether CPT code 51715 should be referred to the RUC for review.

(3) Complex Cystometrogram (CPT Codes 51728 and 51729)

We received a request from a nominator to review CPT code 51728 *(Complex cystometrogram (i.e., calibrated electronic equipment); with voiding pressure studies (ie, bladder voiding pressure), any technique)* and CPT code 51729 (*Complex cystometrogram (i.e., calibrated electronic equipment); with voiding pressure studies (ie, bladder voiding pressure) and urethral pressure profile studies (ie, urethral closure pressure profile), any technique).* The nominator submitted invoices to request a pricing increase in the supply codes SD017 (catheter balloon), SD027 (catheter pressure), and SD131 (tubing pressure) for CPT codes 51728 and 51729. The invoices submitted from the requestor are dated from January 2025 to October 2025 and the nominator specifically is requesting an increase in the price of the SD017 supply from $35.89 to $74.00, an increase in the price of the SD027 supply from $19.35 to $86.80, and an increase in the price of the SD131 supply from $2.90 to $25.48.

We appreciate the information submitted from the nominator and note we previously reviewed these supply codes in the CY 2026 PFS final rule and stated, ''Given the differences between the names of the items in question, and the significant increases in requested pricing, we proposed not to update the pricing of these three supplies as we cannot verify that the invoices refer to the same supply items.'' (90 FR 49279) Taking into consideration the invoice for the SD017 supply listed a ''Abdominal Sensor Catheter'', the invoice for the SD027 supply listed a ''Single Sensor Catheter'', and the invoice for the SD131 supply listed a ''Tubing, Pump, Infusion Line'' our rationale that we cannot verify the names of items in question remains the same. Therefore, based on a lack of additional information submitted to explain the differences in names of the supply codes in question, we are not proposing to update the pricing of these three supplies as we are still unable to verify that these invoices refer to the same supply items.

(4) Carpal Tunnel Release Procedure (CPT Code 64728)

We received a request from one nominator to review CPT code 64728 (*Decompression; median nerve at the carpal tunnel, percutaneous, with intracarpal tunnel balloon dilation, including ultrasound guidance*) as potentially misvalued. The nominator stated that this code is misvalued due to the following reasons: (1) the anomalous relationship between the valuation for CPT code 64728 and other CPT codes for carpal tunnel release procedures; (2) Incorrect assumptions were made based on the previous valuation of the service, including a misleading survey and flawed crosswalk assumptions; and (3) Analysis of work relative value units (RVUs) from reliable data sources support increased valuation. The nominator requested an increase in work RVUs to appropriately reflect the intensive work associated with this procedure.

This code family was reviewed in the CY 2026 PFS final rule and our extensive discussion for finalizing a work RVU of 2.70 can be found in 90 FR 49374 through 49376. We previously addressed the concerns of the nominator in this preamble and we have received no new data for CY 2027 which would support a higher valuation for CPT code 64728. Based on the lack of new information submitted for CY 2027, we do not believe this code to be potentially misvalued. We are seeking comment on this issue, including the submission of new information to support the request.

(5) Electronic Analysis of Implanted Neurostimulator Pulse Generator/Transmitter (CPT Codes 95970, 95976, 95977)

We received a request from one nominator to review CPT codes 95970 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with brain, cranial nerve, spinal cord, peripheral nerve, or sacral nerve, neurostimulator pulse generator/transmitter, without programming*), 95976 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with simple cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional*), and 95977 (*Electronic analysis of implanted neurostimulator pulse generator/transmitter (e.g., contact group[s], interleaving, amplitude, pulse width, frequency [Hz], on/off cycling, burst, magnet mode, dose lockout, patient selectable parameters, responsive neurostimulation, detection algorithms, closed loop parameters, and passive parameters) by physician or other qualified health care professional; with*

complex cranial nerve neurostimulator pulse generator/transmitter programming by physician or other qualified health care professional).

The nominator stated they believe this code family is potentially misvalued due to differing valuations relative to the recently reviewed CPT codes 93150 (*Therapy activation of implanted phrenic nerve stimulator system, including all interrogation and programming*), 93151 (*Interrogation and programming (minimum one parameter) of implanted phrenic nerve stimulator system*), and 93153 (*Interrogation without programming of implanted phrenic nerve stimulator system*), despite being clinical similar services. The nominator also believed there were discrepancies in equipment used to perform each procedure as opposed to what is included in the current valuation due to inaccurate assumptions about what clinical specialties most commonly furnish these procedures. To support their requests, the nominator shared 2024 utilization data showing an increase in certain clinical specialties furnishing these services. We appreciate the additional information and are seeking comment on the appropriate valuation of this code family as well as any additional information on the typical specialty and resource costs associated with furnishing these procedures.

(6) Scalp Cooling (CPT Code 97007, 97008, 97009)

We received a request from one nominator to review the mechanical scalp cooling family of services described by CPT codes 97007 (*mechanical Scalp cooling, including individual cap supply with head measurement, fitting, and patient education*), 97008 (*mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and pre-cooling period*), and 97009 (*mechanical scalp cooling; each 30 minutes*), as potentially misvalued. We reviewed this code family for the CY 2026 PFS final rule and our extensive discussion and rationale for finalizing the current values can be found at 90 FR 49405 through 49406.

The nominator stated that they believe this code family may be potentially misvalued based on newly available empirical evidence (a Time and Motion Study) that demonstrates incorrect assumptions were made during our prior valuation decision for the CY 2026 PFS final rule. They reference in their nomination that the August 2024 Time and Motion Study demonstrated that the clinical staff and PE inputs required to furnish this service are materially greater than those reflected in the current valuation and were not made available to CMS prior to our valuation review and decision for CY 2026. Specifically, the nominator recommended an increase in PE clinical staff time to 103 minutes for CPT code 97007, 52 minutes for 97008, and 23 minutes for 97009.

We appreciate the information we received from the nominator. However, we disagree with their assertion that CMS did not have the results of the August 2024 Time and Motion Study when making our valuation decision for CY 2026. The aforementioned CY 2026 PFS final rule discussion outlines the information considered for the valuation decision and specifically mentions the August 2024 Time and Motion Study results as well as the public comments received for the CY 2026 PFS proposed rule, which reflect the requested increase in PE clinical staff time. We assure the nominators and readers of this discussion that all the information provided in this potentially misvalued nomination request was considered when making our previous valuation review and decision for CY 2026. Accordingly, we disagree with the assertion that this family is misvalued. However, we are seeking comment, particularly updated information that could support a change in valuation for these services.

(7) Hyperbaric Oxygen Under Pressure (HCPCS Code G0277)

The RUC has requested the deletion of HCPCS code G0277 (*Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval*), and recommended that CPT code 99183 be revised to be time-based as well to appropriately describe the treatment delivery, attendance and supervision. The RUC concluded that maintaining a separate G-code creates unnecessary coding complexity without adding clinical or administrative value and that one clear and consistent coding structure should exist for this service.

In 2015, CMS created HCPCS code G0277 to describe direct practice expense inputs associated with CPT code 99183 (*Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session*). We noted that under the Outpatient Prospective Payment System (OPPS), the treatment used to be reported using separate treatment code C1300 (*Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval.*) Therefore, we created HCPCS code G0277 to report the treatment delivery and to maintain consistency with the OPPS coding and PFS payment systems.

HCPCS code G0277 was identified as a high-volume growth code that has Medicare utilization of 10,000 or more. High utilization of this magnitude reflects that the code has been broadly adopted across multiple care settings and underscores its operational importance within the Medicare program. Deleting or replacing a high-volume code without an equivalent can disrupt billing practices, create reporting gaps, and impose unnecessary administrative burden on providers who have integrated it into their standard practice. As such, we believe there is a reason to continue to maintain the use of the G-code for hyperbaric oxygen therapy since HCPCS code G0277 is utilized in multiple Medicare payment systems to report the time the patient uses the hyperbaric oxygen therapy. Accordingly, we are proposing to maintain HCPCS code G0277.

(8) Image-Guided Robotic Linear Accelerator Stereotactic Radiosurgery (HCPCS Code G0339 and G0340)

Image-guided robotic linear accelerator-based stereotactic radiosurgery services are currently reported by and paid for using HCPCS G-codes established the in CY 2007 PFS final rule HCPCS codes G0339 (*Image-guided robotic linear accelerator-based stereotactic radiosurgery, complete course of therapy in one session or first session of fractionated treatment*) and G0340 (*Image-guided robotic linear accelerator-based stereotactic radiosurgery, delivery including collimator changes and custom plugging, fractionated treatment, all lesions, per session, second through fifth sessions, maximum five sessions per course of treatment*). In April 2025, the RAW identified HCPCS code G0340 with 2023 Medicare utilization over 10,000 and Medicare status of ''C'' contractor priced. The Workgroup requested an action plan for G0340 for September 2025. In September 2025, the Workgroup reviewed the action plan and recommended that the RUC request that CMS delete G0339 and G0340 having identified a CPT code 77373 (*Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance, entire course not to exceed 5 fractions*) that is available to report in lieu of G0339 and G0340.

A review of Medicare claims data shows that HCPCS codes G0339 and G0340 are billed frequently. HCPCS code G0339 was billed approximately 3,000 times and HCPCS code G0340 12,000 times in 2024 respectively. As

such, we believe there is a reason to maintain the G codes for image-guided robotic linear accelerator-based stereotactic radiosurgery services since both sets of codes are billed so frequently, and we do not want to cause disruption in billing practice. Since the RUC plans on reviewing these codes during its September 2026 meeting if the codes are not deleted for CY 2027, we welcome the RUC's additional information regarding appropriate coding and payment for these services.

(9) Request for Revaluation of Physician Work Time Based on Empiric Data (CPT Codes 15734, 19318,19380, 23472, 27130, 27447, 37227, 37229, 43281, 43644, 47120, 88305, 88307)

An interested party nominated 13 CPT codes as potentially misvalued. These codes are listed in Table A–D14.

TABLE A-D14: CPT CODES NOMINATED FOR REVALUATION BASED ON CHANGES IN PHYSICIAN WORK TIME

CPT Codes	Description
Integumentary system (CPT codes 15734, 19318, 19380)	
15734	Muscle, myocutaneous, or fasciocutaneous flap obtained from the trunk
19318	Breast reduction
19380	Revision of reconstructed breast (eg, significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction
Musculoskeletal system (CPT codes 23472, 27130, 27447)	
23472	Arthroplasty, total shoulder (glenoid and proximal humeral replacement (eg, total shoulder)
27130	Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft
27447	Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)
Cardiovascular system (CPT codes 37227 and 37229)	
37227	with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed*
37229	with atherectomy, includes angioplasty within the same vessel, when performed*
Digestive system (CPT codes 43281, 43644, 47120)	
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh
43644	Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)
47120	Hepatectomy, resection of liver; partial lobectomy
Surgical pathology (CPT codes 88305 and 88307)	
88305	Level IV - Surgical pathology, gross and microscopic examination
88307	Level V - Surgical pathology, gross and microscopic examination

*Deleted as of CY 2026.

The nominator provided evidence that current physician work time values in the PFS do not accurately reflect real-world clinical practice for 13 CPT codes across five code families. Their methodology focused on codes involving large discrepancies between empirically derived intraservice estimates and intraservice times assigned in the PFS. The nominator did not assert that their research provided confirmatory evidence for every intraservice time discrepancy, which is why their analysis focused on coding families related to the 13 CPT codes listed previously (Table A–D14). They provided additional details on their findings related to the 13 CPT codes and other codes included in their coding families in this section.

Using the 2023 Maryland All-Payer Claims Database (MD–APCD), the nominator's analysis indicates that some of these codes are likely to be overvalued. In their nomination, their analysis reveals that the 88305 (Level IV Tissue Exam by Pathologist) code had the highest number of provider days with intraservice time exceeding an 8-hour workday, with more than 1,763 days, which was significantly higher than the other 12 CPT codes. There were 587 instances of physicians billing 88305 so many times in a single day that the total intraservice time exceeded 24 hours. For these 1,763 days, when they added up the total time spent on services (including other codes billed in a day, and pre-services times as well), the average time that services were billed for during these days was 2,217 minutes (approximately 37 hours). Additionally, despite the name of the code being ''Tissue Exam by Pathologist,'' they found that gastroenterologists and dermatologists frequently billed this code while exceeding eight hours of work in a single day. According to the nominator, data from a 2016 Urban study [53] indicated that the median intraservice time for 88305 was only 2 minutes, compared to 25 minutes in the PFS, which is a 1,250 percent difference—larger than any of the empiric differences between NSQIP and the PFS intraservice times.

They also reviewed additional codes outside of the Urban study that are in the Level IV tissue exam by pathologist coding family, specifically CPT codes 88302, 88304, 88307, and 88309, to conduct a thorough check. As a result, they found that CPT code 88307 had 40 provider days where the total intraservice time exceeded 8 hours. The nominator suggested that CMS should consider reviewing the physician time for all codes within this family to address the existing PFS intraservice times.

In addition, they stated that several codes from the integumentary systems—CPT codes 15734 (*Muscle, myocutaneous, or fasciocutaneous flap; trunk*), 19318 (*Breast reduction*), and 19380 (*Revision of reconstructed breast (e.g., significant removal of tissue, re-advancement and/or re-inset of flaps in autologous reconstruction or significant capsular revision combined with soft tissue excision in implant-based reconstruction)*)—are likely overvalued as clinicians spend 34, 90 and 14 days, respectively, performing these services, where the intraservice times of these codes themselves were more than 8 hours. Over these days, clinicians spent

[53] *https://www.urban.org/research/publication/collecting-empirical-physician-time-data-piloting-approach-validating-work-relative-value-units.* Stephen Zuckerman, Ph.D., Katie Merrell, BA, Robert A. Berenson, MD, Susan Mitchell, RHIA, Divvy Upadhyay, MD, MPH, Rebecca Lewis, MPH, Collecting Empirical Physician Time Data: Piloting an Approach for Validating Work Relative Value Units. *https://www.urban.org/sites/default/files/publication/87771/2001123-collecting-empirical-physician-time-data-piloting-approach-for-validating-work-rel.ative-value-units_0.pdf.*

an average of 32, 17, and 41 hours when the PFS times for all services they billed on these days were summed (including pre-service times). The RAND study [54] identified that 21 codes in the integumentary system had PFS intraservice times that were likely too long, and 3 codes had PFS intraservice times that were likely too short.

In the musculoskeletal system, they identified specific procedures with extended service times. For CPT codes 23472 (*Arthroplasty, glenohumeral joint; total shoulder (glenoid and proximal humeral replacement (e.g., total shoulder))*), 27130 (*Arthroplasty, acetabular and proximal femoral prosthetic replacement (total hip arthroplasty), with or without autograft or allograft*), and 27447 (*Arthroplasty, knee, condyle and plateau; medial AND lateral compartments with or without patella resurfacing (total knee arthroplasty)*), there were 12, 10, and 26 Provider Days, respectively, that exceeded the 8-hour intraservice thresholds. These instances resulted in average total service times of 19, 19, and 21 hours, respectively. The NSQIP RAND study found that 97 musculoskeletal codes had intraservice times that were likely too long, while 14 had intraservice times that were likely too short.

According to the nominator, CPT codes 43281 (*Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh*), CPT 43644 (*Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less)*), and CPT 47120 (*Hepatectomy, resection of liver; partial lobectomy*) were found to have 15, 14, and 10 practitioner days, respectively, where the intraservice time exceeded 8 hours. On these days, the providers recorded average total service times of 25, 33, and 52 hours, respectively. Additionally, the nominator stated that the 2015 NSQIP RAND study identified 86 digestive system codes that were likely too long and 12 codes that were likely too short.[55]

We appreciate the detailed information provided to us by external interested parties and welcome comments from the public regarding any potential actions for CY 2027 or for future rulemaking. We acknowledge the limitations associated with NSQIP data in terms of its applicability to other settings, as it is representative of the hospital setting, however we believe this empirical data may be a better input than limited survey data. Therefore, we are seeking comment on whether we should make these changes for CY 2027, or for future rulemaking, and whether we should consider making corresponding changes to the work RVUs for these services or if changes to the physician time would be sufficient.

(10) Request for Reassessment of Assigned RVUs for ''Harvard-Valued'' Codes (CPT Codes 24515, 22216, 22210, 64721, 29824, 20610, and 20680)

We received notification from concerned interested parties about the ''Harvard-valued'' codes from 1992 that have not undergone a reassessment of assigned RVUs for over 20 years in some cases (see Table A–D15). We share their concerns about whether the current values for the CPT codes accurately reflect the resource inputs associated with furnishing the services. Because the CPT codes have not been recently reviewed and potentially significant technological changes have occurred during this time, we are proposing these CPT codes as potentially misvalued and requesting that the RUC and other interested parties review these services in terms of appropriate work RVUs, work time assumptions and direct PE inputs.

TABLE A-D15: [UNDER DEVELOPMENT]

CPT Codes	Description
24515	Open treatment of humeral shaft fracture, with or without internal fixation, includes repair of fracture fragments
22216	Spine, posterior or posterolateral technique, 3–6 vertebral segments, cervical or thoracic; includes all decompression and fusion work
22210	Spine, posterior or posterolateral technique, single vertebral segment, cervical or thoracic; includes all decompression and fusion work
64721	Neuroplasty and/or transposition; median nerve at carpal tunnel
29848	Endoscopy, wrist, surgical, with release of transverse carpal ligament
29824	Arthroscopy, shoulder, distal claviculectomy, includes debridement, limited capsular release as needed
20610	Arthrocentesis, large joint(s) (eg, shoulder, elbow, hip, knee, or wrist); with or without injection, including ultrasound guidance if performed
20680	Removal of deep implant, includes incision, dissection, and closure; eg, plates, rods, screws, or nails

(11) Allergy Immunotherapy (CPT Code 95165)

In the CY 2001 PFS final rule (65 FR 65393), we discussed the direct PE inputs for CPT code 95165 *(Professional services for the supervision of preparation and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses).* As in the case of venoms, some non-venom antigens cannot be mixed together, that is, they must be prepared in separate vials. An example of this is mold and pollen. Therefore, some patients will be injected at one time from one vial—containing in one mixture all of the appropriate antigens—while other patients will be injected at one time from more than one vial. We extensively discussed how the practice expense component for mixing a multidose vial of antigens was computed, and how we observed that the most common practice at the time was to prepare a 10 cc vial; we also observed that the most common use was to remove aliquots with a volume of 1 cc. Therefore, a physician's removing 10 1cc aliquot doses captured the entire PE component for the service.

Recently we have received interested parties' communication from relevant specialties on the definition of a dose as

[54] *https://www.rand.org/pubs/research_reports/RRA3470-1.html.*

[55] *https://www.rand.org/content/dam/rand/pubs/research_reports/RR600/RR662/RAND_RR662.pdf.*

it pertains to an allergy immunotherapy. They are concerned that clinical practice is not using this method of dosage to treat patients and the definition that Medicare is using is causing general confusion. They note that Medicare's 1cc aliquot dose is now creating reimbursement-driven changes to medical practice, rather than changes that align with clinical practice and is increasingly adopted by commercial payers and Medicaid plans, thereby negatively impacting the delivery of medically necessary and cost-effective patient care to Medicare beneficiaries. According to the specialty societies, when this Medicare policy was implemented, few Medicare beneficiaries received allergy immunotherapy—most practices report that less than 5 percent of patients receiving treatment at that time were Medicare beneficiaries. Today, specialty societies report, Medicare beneficiaries often comprise more than 20 percent of an individual practice's allergy immunotherapy patients.

We invite comment from the wider medical community, including analyses or studies, regarding CPT code 95165 and the definition of an allergy immunotherapy dose. In particular, we are interested in how these concepts are interpreted and implemented within clinical practice.

Additionally, Medicare utilizes a medically unlikely edit (MUE) of 30 doses per claim to flag potential overutilization. Specialty societies claim a more appropriate policy should use common clinical practice, by having an annual limit on doses of medically necessary treatment. For example, the annual limit of up to 160 doses per year during the first year of therapy would be higher to account for the build-up phase, then reduced to 130 or fewer doses per year thereafter when the beneficiary is receiving maintenance doses.

We welcome comments, including research or opinions from the medical community, on appropriate annual dose limits billed for CPT code 95165 based on clinical practice.

(12) Ultrasonic Wound Assessment (CPT Code 97610)

An interested party nominated CPT code 97610 (*Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day*) as potentially misvalued due to an inflated supply costs direct PE input. The nominator stated that this inflation causes a site of service disparity where CMS pays significantly more for the non-facility practice expense compared to the hospital outpatient (OPPS) payment rate. The CY 2026 non-facility PE RVU of 11.51 for CPT code 97610 results in a payment of $384, compared to an OPPS payment rate of $205, representing a payment differential of $179. The nominator stated that this disparity is primarily driven by the $320 direct PE input, SA119 (kit, low frequency ultrasound wound therapy (MIST)). The nominator provided a hyperlink to the UltraMIST® system manufacturer's Investor Presentation [56] from December 2025 which states that ''consumable costs = ~$100/procedure (list price).'' On slide 13 of the presentation, it states that the single use applicators are $100 and that the pricing reflects manufacturer's suggested retail price (MSRP). The nominator also estimated an implied sales price of $86 per disposable kit on average using publicly available manufacturer disclosures and Medicare claims data. The nominator stated that the manufacturer reported $21.0 million in U.S. consumable and parts net revenue for CY 2024. The nominator was able to estimate the total volume of kits sold by the manufacturer by assuming each of the 745 unique billing NPIs in Medicare claims have approximately one of the ~1,000 UltraMist® systems in the field, such that the 181,851 Medicare claim lines account for 74.5 percent of total volume ($21.0 million/[181,851/{745/1,000}] = $86), noting that actual sales price would vary due to volume-based or other supplier discounts, commercial utilization, and other factors.

We agree with the nominator and are proposing CPT code 97610 as potentially misvalued. Additionally, we are proposing to change the cost of supply code SA119 to $100 in the direct PE database. We seek comment on this proposal and invite interested parties to submit paid invoices for supply code SA119 (kit, low frequency ultrasound wound therapy (MIST)). We also note that physician time may be currently overstated for CPT code 97610, as the December 2025 Investor Presentation asserts that the procedure takes about 3 to 20 minutes, with an average of 6 minutes. The current total physician time is nearly 26 minutes, with a work RVU of 0.39. Because the current intraservice time is over double the time asserted by the supply manufacturer in the Investor Presentation, we are seeking comment on whether the typical physician time to perform this service is closer to the manufacturer's assertion of 6 minutes or the current intraservice time of nearly 15 minutes.

[56] *https://sanuwave.com/investors/presentations.*

(13) Autologous Platelet Rich Plasma (HCPCS Code G0465)

We received a request from a nominator to review HCPCS code G0465 *(Autologous platelet rich plasma (PRP) or other blood-derived product for diabetic chronic wounds/ulcers, using an FDA-cleared device for this indication, (includes as applicable administration, dressings, phlebotomy, centrifugation or mixing, and all other preparatory procedures, per treatment)* as potentially misvalued. The nominator requested that CMS update the work RVUs for HCPCS code G0465 from 1.78 to 5.50 based on the results of an independent survey of physicians and qualified health professionals who have training and experience treating chronic, non-healing diabetic wounds that was performed by a third party in the Fall of 2025. The nominator also requested that CMS update its policy to state that multiple procedure payment adjustments do not apply to HCPCS code G0465. Additionally, in the CY 2025 PFS Final rule, we finalized crosswalking G0465 to CPT code 15275 (*Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area*), however, the nominator believes this is not an appropriate crosswalk for G0465.

We thank the nominator for submitting the information, including the survey conducted by the third party. However, we note the sample size of the survey shows only 34 respondents and so we have concerns as to whether this is a representative sample size of practitioners furnishing this service. Additionally, we continue to believe that the MPPR payment adjustment is applicable to multiple units of this service billed to the same beneficiary on the same day due to overlapping resource costs. Given that no additional information was submitted to support the increase in work RVU, we are not proposing this code as potentially misvalued.

E. Request for Information: Redesigning Primary Care To Make America Healthy Again

1. Introduction

Primary care is an essential component of the HHS Secretarial priority to ''Make America Healthy Again'' commonly known as MAHA.[57]

[57] U.S. Department of Health and Human Services. *Make America Healthy Again (MAHA).* HHS.gov, *https://www.hhs.gov/maha/index.html.* Accessed 29 Apr. 2026.

Relatively and accurately valuing primary care appropriately is essential. It is the cornerstone of a high-functioning health care system, helping enable the shift in U.S. health care toward a focus of preventive rather than reactive medicine—for health care rather than ''sick care.'' [58] Critical to this transition is incentivizing investment in high-value care that reduces health care costs (especially from chronic disease) in the long term. Building off recent HHS rulemaking that established such incentives for commercial health plans,[59] we are interested in how Original Medicare may similarly be able to incorporate more robust incentives to invest in high-value care, which will reduce costs of care in the long-term within the Physician Fee Schedule (PFS). More specifically, the agency is soliciting comment on how we might reconsider primary care service valuation to better support this objective amidst what may be a meaningful shift in how primary care is delivered given more recent technological innovation.

Primary care services delivered in the physician office were the locus for continuous, coordinated, and comprehensive care when the PFS was established in 1992. This definition of primary care as a beneficiary's first point of contact with the health care system [60] has been increasingly challenged by broader access to medical information through digital resources. This may accelerate as the increasing adoption of technology reshapes access to increasingly sophisticated sources of medical information before beneficiaries ever show up in the doctor's office.[61] Advances in technology, including generative and agentic artificial intelligence (AI), are poised to transform both beneficiary experience [62] and the role of the primary care clinicians.[63] These were not anticipated when defining the relative value units and time and intensity of services delivered by physicians, which are essential inputs to the PFS.[64]

To both support broader MAHA priorities and to reconcile with how technology is reshaping primary care delivery for beneficiaries and clinicians, we are seeking comment on how to re-imagine and improve the relative valuation of primary care services. We are focused on understanding how that re-imagination might occur within the current construct of office/outpatient (O/O) evaluation and management (E/M) services as well as via alternatives to fee-for-service payment, including through outcomes-based payment and/or the expansion of prospective primary care payment (PPCP). The latter, in particular, has long been a goal of external policy experts, including as a recommendation from the 2021 National Academy of Science, Engineering, and Medicine report '*Implementing High Quality Primary Care,'* which recommends team-based delivery supported by 'hybrid' payment models that combine prospective monthly and visit-based payments.[65] Over the past decade, the CMS Innovation Center tested PPCP in Medicare using a series of increasingly sophisticated hybrid payment approaches from the Comprehensive Primary Care initiative (CPC) to Primary Care First (PCF). The lessons learned from these Innovation Center model tests led Medicare to establish advanced primary care management (APCM) codes in the CY 2025 PFS final rule as a first step towards PPCP.[66] The potential changes to primary care practice with increasing adoption of technology also raises concerns for increasing opportunity for fraud, waste, and abuse from malicious actors.[67] For these and other reasons, as the agency thinks about the re-imagination of primary care payment in the PFS, we are considering first establishing PPCP permanently in the Medicare Shared Savings Program. We would also like to better understand if there are suggestions on how to implement PPCP within the broader Original Medicare program with appropriate guardrails.[68]

We seek comment on three main topics:

- *Reconsidering relative primary care payment in the Medicare PFS:* We are increasingly concerned about the relative undervaluation of primary care services. We would like feedback on how to reconsider this relative undervaluation in the PFS under the current paradigm of O/O E/M visits, the Annual Wellness Visit (AWV), and care management codes. We seek comment on updating this code set, and how or if CMS should consider a 'two-track' approach to care management services with one track focused on technology enabled care and the other track focused on 'traditional' care management.
- *The payment implications of technology–enablement of primary care:* We are seeking comment on how technology and clinical AI are impacting primary care, both broadly and more narrowly within the care management codes and the AWV. We also would like to better understand how CMS might update its approach to paying for technology-enabled care given the potentially transformative effects on the beneficiary and clinician experience. If we were to approach paying for technology-enabled primary care differently, how should we consider the relative valuation, in terms of time and intensity of services? How else could these services be valued? How should we consider evidence of the impact or outcome of technology-enabled services in primary care?
- *Establishing Prospective Primary Care Payment in the Medicare Shared Savings Program:* Given the series of CMS Innovation Center PPCP model tests, how should CMS approach establishing PPCP in the Shared Savings Program, and more broadly across Original Medicare?

In short, this RFI seeks comment on how we should evaluate which of the payment models discussed previously in this section (FFS payment models, outcomes-based payments, or prospective payment) makes the most

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[58] Kennedy, R.F., Jr. (2025). Remarks on the U.S. ''sick-care system.'' *Fox News interview. https://www.foxnews.com/health/rfk-jr-likely-confirmed-health-secretary-dr-siegel-saysAccessed5/31/26.*

[59] ''Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2027; and Basic Health Program.'' **Federal Register**, vol. 91, 2026, p. 29683. U.S. Government, *https://www.federalregister.gov/d/2026-10050/p-1540.*

[60] O'Connor, S.M. ''Citing Primary Care.'' *British Journal of General Practice,* vol. 61, no. 586, 2011, pp. 361–362. *https://pmc.ncbi.nlm.nih.gov/articles/PMC3133574.*

[61] Rastogi, Namrata. ''Healthcare's New Frontier: The Digital Front Door.'' *BMJ Innovations,* vol. 8, no. 2, 2022, *https://doi.org/10.1136/bmjinnov-2021-000874.*

[62] Yang, Betsy, et al. ''Transforming the Primary Care Journey with Generative AI: A Foundation Model to Boost Efficiency, Quality, and Engagement.'' *Journal of General Internal Medicine,* 2026, *https://doi.org/10.1007/s11606-025-09716-y.*

[63] Sarkar, Urmimala, and David W. Bates. ''Using Artificial Intelligence to Improve Primary Care for Patients and Clinicians.'' *JAMA Internal Medicine,* vol. 184, no. 4, 2024, pp. 343–344. *https://doi.org/10.1001/jamainternmed.2023.7965.*

[64] Berenson, Robert A., and Kevin J. Hayes. ''Could Artificial Intelligence Affect Physician Payment for Nonprocedural Services? Part 1.'' *Health Affairs Forefront,* Health Affairs, 2025, *https://www.healthaffairs.org/content/forefront/could-artificial-intelligence-affect-physician-payment-nonprocedural-services-part-1.*

[65] National Academies of Sciences, Engineering, and Medicine. ''Designing Interprofessional Teams and Preparing the Future Primary Care Workforce.'' *Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care,* National Academies Press, 2021.

[66] Agarwal, Sumit D., et al. ''The Underuse of Medicare's Prevention and Coordination Codes in Primary Care: A Cross-Sectional and Modeling Study.'' *Annals of Internal Medicine,* vol. 175, no. 8, 2022, pp. 1100–1108. *https://doi.org/10.7326/M21-4770.*

[67] Gray, Jacob. ''Strengthening Healthcare Program Integrity with AI.'' *ICF,* 2026, *https://www.icf.com/insights/health/healthcare-fraud-waste-abuse-ai.*

[68] Centers for Medicare & Medicaid Services. *Accountable Care Organization Operational System (ACO–OS).* CMS, *https://security.cms.gov/pia/accountable-care-organization-operational-system.*

sense for primary care given the rapid changes that may arise for recent technological innovation.

2. Reconsidering Relative Primary Care Payment in the Medicare Physician Fee Schedule

a. O/O E/M Visits

Under the PFS, in accordance with section 1848 of the Act, we establish payment amounts for covered physicians' services and update payment policies to address changes, including those in medical practice, coding, or new data on relative value components. Original Medicare's fee-for-service payments for primary care services are overwhelmingly made through traditional O/O E/M visit codes. E/M codes describe a broad range of physician services that occur in an office setting, and do not distinguish between a one-time consultative visit and care that is part of a longitudinal care relationship, which may require additional time, coordination, and resources. We have previously described our concern that the complexity of services required to provide longitudinal care is not fully incorporated as part of the valuation of the work RVUs when the E/M code itself is used as the primary way to report the work of the professional (88 FR 78972). The physician community had previously supported this view when they highlighted that the existing E/M services, such as office visits, do not adequately describe the typical non-face-to-face care management work required by certain categories of beneficiaries most often served by primary care practitioners (78 FR 43337).

As a result, specialties that do not routinely furnish procedural interventions or diagnostic tests and for which E/M visits represent a greater share of total allowed services are paid differently and generally less than their counterparts who routinely furnish procedural interventions and diagnostic tests. Section 1848 of the Act prohibits specialty-specific payment under the PFS, so we cannot vary the conversion factor or the number of relative value units for a physician's service based on the specialty type of the physician. Instead, in CY 2021, we adopted the RUC's recommendations for increased E/M work RVUs, based on their review of physician time for the E/M visit code set (84 FR 62851 through 62854). Next, in the CY 2024 PFS final rule, we took steps to better recognize the inherent complexity of visits associated with primary and longitudinal care of patients by finalizing Healthcare Common Procedure Coding System (HCPCS) code G2211 *(Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care complex condition. (Add-on code, list separately in addition to office/outpatient evaluation and management service, new or established)).* HCPCS code G2211 is used by practitioners furnishing services as the continuing focal point for all the patient's needed health care services, including but not limited to primary care practitioners (88 FR 78969). In the CY 2026 PFS final rule (90 FR 49462 through 49464), we finalized our proposal to allow HCPCS code G2211 to be billed as an add-on code with the home or residence E/M visits, in addition to office/outpatient E/M visits. We are proposing changes to HCPCS code G2211 for CY 2027; see section II.D of this proposed rule for further discussion.

The current O/O E/M code set may still insufficiently reflect differences in the nature and intensity of care provided. As such, we are considering establishing distinct categories of O/O E/M visits in future rulemaking. Potential categories could be longitudinal care, acute care, or consultative visits, with distinctions based on the clinical purpose of the encounter and the associated resource costs of furnishing care. Longitudinal care visits involve care delivered both during and between encounters as part of an ongoing comprehensive care relationship. During these visits, a beneficiary establishes, maintains, or updates that relationship. For example, a beneficiary returns to the clinic 3 months after their AWV for ongoing management of their diabetes, which requires an oral medication titration, and elevated blood pressure and hyperlipidemia, which includes a discussion about lifestyle modification. The practitioner also notices that they are overdue for an immunization, schedules them for a necessary screening test, and updates their plan of care accordingly. We would distinguish this visit (including the valuation of the pre- and post-service time and proximity to prior visits) from the care delivered in an acute care visit. In the future, we may consider valuing these visits as a combination of the E/M service furnished during the encounter and certain between-visit care management activities. In contrast, acute care visits are focused on the evaluation and management of a discrete, episodic problem that is generally resolved after treatment. For example, a beneficiary may seek care for a sore throat and suspected streptococcal pharyngitis, with no expectation of an ongoing care relationship related to that condition once it is resolved. While consultative visits are distinct from longitudinal and acute care visits because they are furnished in response to a referral to address a specific clinical question, consultative services could be considered similar in complexity to acute care, distinguished largely by consultative services typically including an evaluation of the patient and communication of findings or recommendations back to the referring practitioner.

We also note that CPT codes exist and are paid by private payers for consultative services (for example, CPT codes 99242 through 99245), although they are not paid by Medicare. We are seeking comment on whether to consider the complexity of these services to be closer to the acute care services versus the longitudinal care services. As a general matter, we would expect to consider consultative visits to be less complex than longitudinal care visits. We are seeking feedback on further actions we could take around appropriate valuation of primary care services:

- What updates to the HCPCS code G2211 policy (or the proposed modifiers, MOD1 and MOD2) should CMS consider to ensure the clinician billing HCPCS code G2211 (or proposed modifiers, MOD1 and MOD2) is serving as the focal point for beneficiaries, and that the practitioner is also considering preventive care, risk factor reduction, and other services necessary for coordinating the care of beneficiaries who have a complex condition?
- Given the broad range of changes CPT makes annually, we recognize updates to the CPT code set to reflect distinctions among O/O E/M visits by the function of the visit (longitudinal, acute, or consultative) may have significant advantages within the current billing and coding ecosystem. However, absent a change in CPT coding, should we consider the possibility of creating G codes to better recognize distinction between and among these kinds of visits? If so, what categories should we consider? How could we effectively differentiate longitudinal care visits from acute care visits? What number of levels would be needed and for which settings of care? Should we use existing CPT codes as templates? How should we consider valuing these potential G-codes under the PFS, including the basis for the standard inputs: work RVUs, time

values, specialty mix for utilization crosswalks, direct PE inputs, etc.? How would practitioners balance and manage the increasing number and complexity of these codes?

- If CMS were to propose longitudinal or primary care visit types, what should the service period be? Should subsequent care management services be bundled in? If so, for what period of time? Which care management services might be included?
- Are there specific data on the resources used in furnishing longitudinal care, acute care, or consultative services CMS should consider for potential categorization of O/O E/M services?

3. Care Management Code 'Family'

We have for the last 14 years sought to unbundle services previously considered bundled into E/M services through separate coding and payment for care management services. In 2013, the agency implemented a transitional care management code for post-discharge care (77 FR 68978). This was then followed by the creation of a broader family of codes for care management, including for beneficiaries with multiple chronic conditions or chronic care management (CCM) (78 FR 74414), for those requiring complex medical decision-making (for example, complex CCM, 81 FR 80349), and for those with a single or principal condition (principal care management (PCM), 85 FR 84697). In total, the CCM and PCM code families now include five sets of codes which are reported monthly on a timed basis, each set with a base code of 20 to 60 minutes and an add-on code for each additional 30 minutes. In the CY 2025 PFS final rule (89 FR 97859), we finalized three APCM codes (HCPCS codes G0556, G0557, and G0558) to recognize the evolving way primary care practices manage prevention and chronic condition management through interprofessional care teams. See Table A–E1 for more specificity on the purpose of each of the codes.

Despite these important steps to pay separately for care management services, uptake of the care management codes has been limited.[69] Interested parties cite cost-sharing and non-trivial documentation requirements as the primary barriers to broader adoption.[70] In response to these considerations, we removed the CCM requirement to count and document the minutes of care management services provided in the patients' medical record when billing APCM services. Interested parties had stated this was so burdensome it limited their use of the CCM Current Procedural Terminology (CPT) codes. At the same time, the agency was concerned about program integrity and therefore code auditability. In the absence of medical record documentation, we required that if a practitioner billed the APCM codes, they must report the Value in Primary Care MIPS Value Pathway (89 FR 97864). Despite these changes, uptake in the first year was less than anticipated. We seek feedback on whether a different payment structure might be more appropriate as well as what might be done to further simplify the code set and associated requirements.

TABLE A-E1: CARE MANAGEMENT SERVICES PAID UNDER THE PFS

Service	Description
Care Management Services	
Chronic Care Management (CCM) (CPT Codes 99487, 99489, 99490, 99491, 99439, 99437)	Management of all care for patients with two or more serious chronic conditions, timed, per month.
Principal Care Management (PCM) (CPT Codes 99424, 99425, 99426, 99427)	Management of all care for patients with one serious chronic condition, timed, per month.
Transitional Care Management (TCM) (CPT Codes 99495, 99496)	Management of transition from acute care or certain outpatient stays to a community setting, with face-to-face visit (bundled into payment for the code), once per patient within 30 days post-discharge.
Advanced Primary Care Management (APCM) (HCPCS G0556, G0557, and G0558)	Management of all care for patients with or without chronic conditions, not timed, per month.
Communication Technology-Based Services	
Remote Physiologic Monitoring (RPM) and Remote Therapeutic Monitoring (RTM) (CPT codes 99453, 99445, 99454, 99470, 99457, 99458, 99091)	Remote monitoring and assessment of physiologic data or adherence and response to therapeutic treatment, timed, per month.

We are also asking for comment on how to reconfigure the care management code 'family' to better establish effective relative payment options for between visit care management services and how supervision requirements may need to change in technology-enabled care models where patients may initially engage with digital tools or receive care entirely in a digital environment. In addition, given our concerns about fraud, waste, and abuse in the care management code families, we would like to better understand how to ensure care management services are impacting care.

To improve the utilization of care management services where it is clinically appropriate, we seek comment on the following questions:

- What additional requirements should CMS consider to reduce fraud, waste, and abuse in care management services? Specifically on the following:

++ What is the appropriate 'trigger' or initiating visit for care management services? How would this change if it were an initiating visit vs. another event?

++ Should CMS consider changing supervision requirements in care management services to prevent fraudulent billing of care management services? What is the appropriate supervision requirement for care management services?

++ How should data submission to CMS change to verify services are received?

++ What guardrails should CMS consider to prevent inappropriate billing?

++ What proportion of care management services must be delivered

[69] Agarwal SD, Basu S, Landon BE. The Underuse of Medicare's Prevention and Coordination Codes in Primary Care: A Cross-Sectional and Modeling Study. Ann Intern Med. 2022 Aug;175(8):1100–1108. doi: 10.7326/M21–4770. Epub 2022 Jun 28. PMID: 35759760; PMCID: PMC9933078.

[70] Agarwal SD, Barnett ML, Souza J, Landon BE. Adoption of Medicare's Transitional Care Management and Chronic Care Management Codes in Primary Care. *JAMA*. 2018;320(24):2596–2597. doi:10.1001/jama.2018.16116.

by the supervising provider, versus auxiliary personnel?

- Are there specific data on the resources used in furnishing advanced primary care, which incorporates population health management, enhanced communication technology, and longitudinal care management? We welcome submission of any such data.
- To what extent are the current care management codes duplicative? Are there efficiencies to be gained in simplifying the current care management code 'family' into a more efficient code set? To what extent would this improve appropriate utilization of care management services?
- If reducing the number of care management codes would not increase efficiency or utilization of appropriate services, how else can CMS standardize the requirements across the care management codes?
- As care management becomes increasingly technology-enabled, how should CMS consider changing the code family and their relative valuations? How can CMS ensure that automated billing leveraging technology reflects actual care delivered to beneficiaries by care teams or practitioners?
- Should CMS create 'technology-enabled care management' codes or a 'two-track' approach to care management? How should we ensure these codes are appropriately differentiated?

4. Payment Implications of Technology Enablement of Primary Care

a. Changes to Primary Care and Care Management Due to Technology and Clinical AI

Adoption of new technology and AI tools in primary care has the potential to transform clinical care to such a degree that it may challenge how we traditionally think about care delivery. However, as of this request for information, clinician-facing AI tools that are currently in widespread use are more focused on administrative burden reduction and clinical decision-support. For example, tools focused on *reducing clinician documentation burden* (*e.g.* AI scribes), have perhaps been the most widely taken up by clinicians,[71] with an estimated 25% penetration among all US physicians.[72] Early system-level evaluations demonstrate generally increased productivity among adopters along with decreases in perceived documentation burden.[73] The most widely used AI tool in primary care is likely a *clinical decision-support* application, Open Evidence, which more than forty percent of US physicians have self-reported using.[74] This software allows clinicians to ask an AI chat interface a wide variety of clinical questions and receive answers based on a large language model only drawing from well-known peer reviewed journals and guidelines (*i.e.* not the entire internet). *AI-assisted care delivery* agents have been deployed in a number of health systems but have not yet reached widespread use, to the best of CMS' knowledge.[75] In general, we note greater technological adoption may support a shift in care management from reactive, manual processes to proactive, data-driven, and personalized care.

In short, we believe technology is being used in increasingly innovative ways throughout primary care but would like to better understand that usage. Given this changing backdrop, we are seeking comment on how we develop a comprehensive and consistent approach to payment for technology-enabled care given likely lower cost-to-serve but potentially higher quality of care delivered. There are challenges in establishing appropriate valuation methodologies, due to the rapidly evolving nature, accuracy, impact, and scope of these technologies as well as the limited transparency into underlying costs and effect of these tools in primary care and other specialties.

One potential approach may be to link payment more directly to demonstrated clinical outcomes. We are seeking additional information on how to best structure payment for these technologies in a way that aligns with our agency's mission to increase quality, improve health, reduce costs, and strengthen the healthcare system. Clinical technology tools of interest would include those that provide clinical decision-making support that deliver AI-assisted (or augmented, etc.) primary care, or that are otherwise of note. We seek input on the following:

- Our understanding is that clinical documentation and clinical decision-support tools are currently the most commonly used applications of AI in primary care. Does this reflect current practice? In particular, are there additional *clinical* AI tools and new technologies that are frequently being used in primary care settings with high accuracy, demonstrated safety, and clinical outcomes reported? If so, please describe how they impact the clinical workflow and the beneficiary experience.
- If you are a physician furnishing primary care services, how has your practice been impacted or how do you expect it will be impacted by clinical AI tools?
- How has incorporating technology and AI tools impacted the resource costs associated with primary care practice, in terms of the time and intensity of services delivered?
- How has the implementation of clinical AI tools led to improvements in the quality of care, or reduced downstream costs? In general, please cite any evidence available for your comments.
- If these tools are increasing productivity, what are clinicians and other health professionals doing with the additional time/bandwidth created? Are you seeing more patients in visits, engaging more with population-health management or care management, accomplishing administrative tasks, or something else?
- How do you ensure patient data and privacy is adequately protected during use of these tools?
- Please describe areas *where clinical AI tools in primary care are not well captured* in the current coding and payment system and suggest how these may be incorporated to facilitate *high-value,* technology-enabled primary care.

What lessons can CMS learn and adopt from private payors with respect to clinical AI? More specifically, we ask the following:

- What can CMS learn from how private payors have approached payment and coverage of clinical AI in primary care? How are they monitoring for safety, privacy, fraud, waste, and abuse?
- How could private payor coverage of clinical AI in primary care streamline or otherwise facilitate CMS coverage or payment?

[71] Littrell, A. (2026, May 19). *The AI tool physicians actually love: A conversation with Robert Wachter, M.D., chair of UCSF Medicine.* Medical Economics. *https://www.medicaleconomics.com/view/the-ai-tool-physicians-actually-love-a-conversation-with-robert-wachter-m-d-chair-of-ucsf-medicine.*

[72] Doximity. (2026). *State of AI in medicine report 2026. https://www.doximity.com/reports/state-of-ai-medicine-report/2026.*

[73] Holmgren AJ, Fenton CL, Thombley R, et al. Ambient Artificial Intelligence Scribes and Physician Financial Productivity. JAMA Netw Open. 2026;9(1):e2553233. doi:10.1001/jamanetworkopen.2025.53233.

[74] OpenEvidence. (2025, July 15). *OpenEvidence, the fastest-growing application for physicians in history, announces $210 million round at $3.5 billion valuation. https://www.openevidence.com/announcements/openevidence-the-fastest-growing-application-for-physicians-in-history-announces-dollar210-million-round-at-dollar35-billion-valuation.*

[75] Examples include ''Cedars-Sinai Connect'', from *https://www.cedars-sinai.org/csconnect.html* or 'Hartford Healthcare GPT' *https://www.aha.org/aha-center-health-innovation-market-scan/2026-05-19-hartford-healthcare-embraces-ai-patientgpt.* Retrieved May 31, 2026.

• From an outcomes-based perspective, how should CMS evaluate and monitor the impact of technology-enabled care in primary care?

• What outcomes would accurately capture whether these technologies have improved or negatively affected primary care practice for both clinicians and beneficiaries? Are there different outcomes for short-term and long-term impacts?

What type of outcomes data should be shared with CMS? For example, to what extent would submission via Fast Healthcare Interoperability Resources (FHIR)-based APIs of clinical outcomes or activity sets be an appropriate approach by which to tie payment?

• What submission frequency and formats would be most appropriate?

• How can we collect those outcomes in a way that minimizes administrative burden?

• Are there other payment structures, beyond outcomes-based and prospective (which will be discussed in the next section), that would be more suited to the unique nature and impact of these technologies? If so, please describe.

5. Technology and AI-Augmentation in Primary Care via the Medicare AWV

As we at CMS endeavor to shift US health care toward a focus on preventive rather than reactive medicine—for health care rather than 'sick care'—there may be no more obvious starting place for Medicare than the Initial Preventive Physical Exam (IPPE) and Medicare AWVs. The IPPE is a one-time preventive check-up where practitioners review the beneficiary's medical history, make sure they are up to date on important screenings and vaccines, and talk with the beneficiary about their family history and how to stay healthy.[76] Then every year following, beneficiaries have a conversation-focused visit to create a personalized prevention plan, called an Annual Wellness Visit (AWV).[77]

The IPPE and AWV were established under section 4103 of the Affordable Care Act which requires Medicare to cover an AWV in which a personalized prevention plan is created (Pub. L. 111–148). The payment for AWVs has been updated to reflect the resource costs associated with advanced care planning (80 FR 70956), review of opioid use (85 FR 84713), and optionally physical activity and nutrition (90 FR 49483). The current requirements can be found on the CMS website.[78]

Section 1861(hhh)(4)(F) of the Act gives the Secretary the authority to experiment with the use of personalized technology focusing on health behavior change. We are interested in understanding whether advances in technology, including clinical AI, could improve the effectiveness, personalization, and both beneficiary and clinician experience for the AWV. Despite the importance of prevention and early identification of risk factors, evidence regarding the impact of the AWV on outcomes is mixed. Some studies have found that AWV receipt is associated with increased use of preventive services [79] but may not sufficiently close gaps in preventive care.[80] However, other studies have found no substantive association between AWV adoption and improvements in evidence-based screening, acute care utilization, or spending,[81] or potentially increasing downstream low-value services.[82] Given the heterogeneity of these findings, we are interested in whether technology-enabled AWVs can improve not only the proportion of Medicare beneficiaries completing an AWV but also meaningful outcomes.

We are interested in whether clinical adoption of technology including clinical AI tools may facilitate transformation of the AWV from a point-in-time assessment to a more continuous, data-driven, and beneficiary-specific preventive care function. The function of these tools may support AWV completion from pre-visit activities as well as activities during and after the clinical encounter. As examples, clinical AI tools may support pre-visit collection of beneficiary reported information such as in the health risk assessment, adapting questions to a beneficiary's language or health literacy level.[83] For reviewing the medical and family history, AI tools have demonstrated superiority to even human experts in summarizing health information from structured and unstructured fields.[84] During the clinical encounter, AI tools may also support standardized clinical workflows embedded in the electronic health record environment,[85] identify beneficiaries who may warrant additional assessment, and generate suggested follow up steps for clinicians to review.[86] Following the encounter, AI tools may assist with developing post-encounter instructions in the language and health literacy level of the patient.[87]

We believe much of this can occur under current CMS billing guidance, and reiterate that under current policy, the AWV must be performed by a physician or other health professional, or team of medical professionals directly supervised by a physician currently enrolled as a Medicare provider. We are interested in what barriers—if any—these requirements create to innovative AWV delivery models in which an AI technology company develops or operates these clinical AI tools and affiliates with a Medicare enrolled provider or supplier. We seek comment on the following:

• How can CMS improve the effectiveness, efficiency, personalization, and beneficiary experience of the IPPE and Medicare AWV?

• Which, if any, AWV components are being delivered (or could be) more efficiently delivered through technology and clinical AI-enabled tools? Please comment on how technology is being used today within the AWV, how that

[76] ''Welcome to Medicare Preventive Visit.'' *Medicare.gov,* Centers for Medicare & Medicaid Services, *https://www.medicare.gov/coverage/welcome-to-medicare-preventive-visit.* Accessed 16 June 2026.

[77] ''Yearly 'Wellness' Visits.'' *Medicare.gov,* Centers for Medicare & Medicaid Services, *https://www.medicare.gov/coverage/yearly-wellness-visits.* Accessed 16 June 2026.

[78] Centers for Medicare & Medicaid Services. ''Medicare Wellness Visits.'' *Centers for Medicare & Medicaid Services,* U.S. Department of Health and Human Services, *https://www.cms.gov/medicare/coverage/preventive-services/medicare-wellness-visits.* Accessed 7 July 2026.

[79] Beckman AL, et al. The effect of Medicare's Annual Wellness Visit on preventive care for the elderly. *Prev Med.* 2018;116:126–133.

[80] Camacho F, Yao N, Anderson R. The Effectiveness of Medicare Wellness Visits in Accessing Preventive Screening. *Am J Health Promot.* 2017.

[81] Ganguli I, Souza J, McWilliams JM, Mehrotra A, et al. Association of Medicare's Annual Wellness Visit with Cancer Screening, Referrals, Utilization, and Spending. *Health Affairs.* 2019.

[82] Ganguli I, Lupo C, Mainor AJ, et al. Assessment of Prevalence and Cost of Care Cascades After Routine Testing During the Medicare Annual Wellness Visit. *JAMA Netw Open.* 2020;3(12):e2029891. doi:10.1001/jamanetworkopen.2020.29891.

[83] Swisher AR, Wu AW, Liu GC, Lee MK, Carle TR, Tang DM. Enhancing Health Literacy: Evaluating the Readability of Patient Handouts Revised by ChatGPT's Large Language Model. Otolaryngol Head Neck Surg. 2024 Dec;171(6):1751–1757. doi: 10.1002/ohn.927. Epub 2024 Aug 6. PMID: 39105460.

[84] Van Veen D, Van Uden C, Blankemeier L, et al. Adapted large language models can outperform medical experts in clinical text summarization. *Nature Medicine.* 2024;30:1134–1142.

[85] Perkins SW, Muste JC, Alam T, Singh RP. Improving Clinical Documentation with Artificial Intelligence: A Systematic Review. Perspect Health Inf Manag. 2024 Jun 1;21(2):1d. PMID: 40134899; PMCID: PMC11605373.

[86] Yao, X., Rushlow, D.R., Inselman, J.W. *et al.* Artificial intelligence–enabled electrocardiograms for identification of patients with low ejection fraction: a pragmatic, randomized clinical trial. *Nat Med* 27, 815–819 (2021). *https://doi.org/10.1038/s41591-021-01335-4.*

[87] Young, Albert T., et al. ''Patients and Dermatologists Are Largely Satisfied with ChatGPT-Generated After-Visit Summaries: A Pilot Study.'' *JAAD International,* vol. 15, 2024, pp. 33–35. Elsevier, *https://doi.org/10.1016/j.jdin.2023.12.004.*

has changed over the last year, and how the community sees that changing over the next couple of years. Which activities require direct involvement by a physician, qualified non-physician practitioner, or medical professional under physician supervision?

- Could AI-enabled AWVs improve health outcomes that prior studies have found to be inconclusive?
- What evidence should CMS consider regarding whether technology or clinical AI-enabled AWVs improve clinical usefulness of visit and clinical outcomes, beneficiary reported outcomes, or utilization? In particular, research around changes in the use of preventive services, the application of preventive services to individual clinical risk factor assessment or in low-value downstream utilization are of specific interest.
- What existing statutory, regulatory, enrollment, billing, supervision, documentation, data-sharing or other requirements may create barriers to an AI technology company delivering AWV-related services while employing or contracting with appropriately licensed physicians or other medical professionals to perform AWVs? To what extent may program integrity concerns exist with these models?
- In what circumstances should CMS consider payment or policy changes that would allow technology-enabled organizations, including AI technology companies, to participate in AWV delivery models, either directly or through partnerships with Medicare-enrolled providers or suppliers?
- How should CMS evaluate whether AI-enabled AWVs are improving outcomes rather than merely increasing AWV volume, documentation completeness, coding intensity, or low-value care follow 'cascades' of services? Specifically, for which outcomes should CMS hold technology companies accountable?
- How could CMS optimize information sharing from AWV throughout the duration of the primary care relationship? Where could AI-enabled tools facilitate this process?

6. Developing Prospective Payment in the Shared Savings Program

a. Background

We stated at the beginning of this request for information that we are interested in further developing prospective primary care payment (PPCP) in Original Medicare, beginning with the Shared Savings Program. There is growing recognition that the fee-for-service (FFS) payment model has inherent limitations as a primary care payment mechanism, as it is not designed to support the comprehensive, coordinated care that primary care requires. In 2015, the Medicare Payment Advisory Commission (MedPAC) recommended a per beneficiary payment for primary care providers to support additional care coordination activities for Medicare beneficiaries.[88] MedPAC explained that while a per beneficiary payment in itself will not guarantee an increase in care coordination activities or even an increase in compensation for eligible primary care practitioners, it would be a first step in transitioning from FFS to a beneficiary-centered payment approach that encourages care coordination, including the non-face-to-face activities that are a critical component of care coordination.[89]

In a 2021 report on implementing high-quality primary care, the National Academies of Sciences, Engineering, and Medicine (NASEM) recommended that health care payers ''pay for primary care teams to care for people, not doctors to deliver services'' and encouraged payers to adopt a hybrid reimbursement model that combines FFS and capitation over time with an overarching goal to eventually pay for the majority of primary care services through risk-adjusted prospective payment.[90] NASEM recommended that a hybrid reimbursement model—with a mix of FFS and lump-sum or per-person payments—become the default method for paying for primary care teams.[91] NASEM found that with time, hybrid reimbursement models show improvements in care and reductions in use, particularly for people with multiple complex chronic conditions.[92]

Over the past 13 years, the CMS Innovation Center has tested a number of models that have progressively moved away from FFS billing, including: CPC, Comprehensive Primary Care Plus (CPC+), PCF, Next Generation ACO (NGACO), Global and Professional Direct Contracting (GPDC) Model, ACO REACH, and ACO Primary Care (PC) Flex. These models have focused on testing whether Medicare payment for primary care services through hybrid payments (a mix of FFS and capitated payments), population-based payments (PBPs), or total care capitation (TCC) improves quality of care for beneficiaries and reduces Medicare spend. Evidence from these models suggests that primary care capitation (PCC) is most effective when it is embedded in an accountable care framework, such as the Shared Savings Program.[93] Model design and evaluations are available on the model-specific websites that can be found on *https://www.cms.gov/priorities/innovation/models#views=models*.

Previous Innovation Center primary care model tests have yielded lessons that shape current and future work, including the development of codes and payment for APCM services. Participants, namely clinicians, in primary care models have indicated, however, difficulties with investing in and maintaining primary care redesign activities due to a range of challenges. First, additional non-visit-based primary care payments have been generally layered upon base payments that are still predominantly FFS in structure. While payment for APCM services represents a meaningful step toward non-visit-based payments in concept, we do not view APCM as the end goal of primary care payment reform. The payment amounts associated with APCM are predicated on furnishing and billing APCM services. As such, APCM retains the fundamental structure of FFS billing and may not provide sufficient incentives for practices to focus on proactive, population-based non-visit care management activities.

Second, Innovation Center model funding that supports salaries for clinical and administrative staff, who are needed for advanced primary care coordination and population health

[88] Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare Payment Policy,* page 106 Washington, DC: MedPAC. *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-mar2015_entirereport_revised-pdf/*.

[89] Medicare Payment Advisory Commission. 2015. *Report to the Congress: Medicare Payment Policy,* page 106 Washington, DC: MedPAC. *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-mar2015_entirereport_revised-pdf/*.

[90] National Academies of Sciences, Engineering, and Medicine. ''Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care,'' pages 7–8. Washington, DC: The National Academies Press, 2021. *https://doi.org/10.17226/3393 https://www.nationalacademies.org/read/25983/chapter/3#8*.

[91] National Academies of Sciences, Engineering, and Medicine. ''Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care,'' page 8. Washington, DC: The National Academies Press, 2021. *https://doi.org/10.17226/3393 https://www.nationalacademies.org/read/25983/chapter/3#8*.

[92] National Academies of Sciences, Engineering, and Medicine. ''Implementing High-Quality Primary Care: Rebuilding the Foundation of Health Care,'' page 301. Washington, DC: The National Academies Press, 2021. *https://doi.org/10.17226/3393 https://www.nationalacademies.org/read/25983/chapter/3#8*.

[93] *See, for example,* O'Malley A, Singh P, Fu N, et al. Independent Evaluation of the Comprehensive Primary Care Plus (CPC+): Final Report. Mathematica, page xviii. December 2023. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report*.

functions, is contingent on continued participation in these models. Unlike APCM codes,[94] which are billing codes paid under the PFS and can be used to support ongoing primary care workforce investments, once the models end, practices are left without the funding that they received under the models for the clinical and administrative staff that had supported population health functions. Based on a review of internal CMS data related to billing for APCM services, billing for APCM services is higher for Shared Savings Program ACO-assigned beneficiaries compared to Medicare beneficiaries outside of an ACO. This finding suggests that the accountability and care management infrastructure associated with ACOs may support more robust adoption of non-visit based primary care payment mechanisms.

Table A–E3 identifies recent Innovation Center models that tested capitated payment arrangements. As outlined in the table, the payment arrangements tested across these models reflect a progression from hybrid (FFS + capitation) payment structures to PBPs and TCC, with each successive model designed to build upon the experience of previous models. CPC+ and PCF relied on care management fees, performance-based incentive payments, and PBPs that partially replaced traditional FFS billing. While neither model reduced total Medicare expenditures or achieved net savings, the CPC+ evaluation found that independent practices who spent a longer time in the model, and those participating in the Shared Savings Program tended to have more favorable results.[95] This finding underscores the importance of embedding primary care payment reform within an accountable care framework.

Other Innovation Center models that have tested different kinds of cash flow and primary care capitated payments have focused on ACOs in models that build on the foundation of the Shared Savings Program. For example, ACOs in the NGACO model could select from four payment mechanisms: (1) traditional FFS; (2) FFS with a fixed per beneficiary per month (PBPM) infrastructure payment; (3) PBPs that gave ACOs a fixed percentage of expected FFS claims reductions in prospective monthly payments; or (4) all-inclusive PBPs, in which the ACO received expected FFS claim reductions in prospective monthly payments. Three quarters of NGACOs primarily chose FFS-based payment mechanisms such as the FFS or FFS with infrastructure payment (FFS+ISP). NGACOs electing PBP mechanisms had larger spending reductions of 3 percent ($409.1 per beneficiary per year (PBPY), $p<0.01$), compared with 1.3 percent ($172.9 PBPY, $p<0.01$) for NGACOs electing FFS-based payment mechanisms. Additionally, NGACOs, particularly the 35 that remained through PY 6, showed improvements in model reported quality measures over time for prevention and screening and for chronic disease management. Further, 25 of 35 NGACOs had reduced cumulative Medicare spending while maintaining or reducing rates of ambulatory care-sensitive conditions-related hospitalizations or 30-day unplanned readmissions, tended to reduce outpatient spending and Emergency Department visits, and tended to reduce skilled nursing facility spending and utilization. Over the course of the model, NGACOs invested in initiatives to better manage their patient populations, toward the goals of reduced spending and improved quality.[96]

Under the GPDC Model[97] (the successor to the NGACO model) and the ACO REACH model,[98] we offered two capitation options: (1) TCC (a PBPM capitated payment for all Medicare Part A and Part B services) and (2) PCC for primary care services equal to seven percent of the estimated total cost of care and composed of both a base amount and an enhanced amount designed to provide upfront revenue. Direct contracting entities and ACOs that selected PCC could also select an advanced payment option (APO), which provided upfront payments for services beyond primary care.

The ACO PC Flex model extends capitated payment arrangements to ACOs participating in the Shared Savings Program. The model is designed to test how prospective payments and increased funding for primary care in ACOs affects health outcomes, quality, and costs of care within the Shared Savings Program.[99] Model participants are limited to ACOs that participate in the Shared Savings Program and qualify as a ''low revenue ACO'' as defined by § 425.20.[100] ACOs participating in the ACO PC Flex Model receive two payments: a monthly PPCP and a one-time advanced shared savings payment. The PPCP is a PBPM payment for primary care services that replaces FFS payments for eligible primary care services with a monthly prospective payment composed of a county base rate (based on a county's average primary care spending), an ACO enhanced amount, and a population adjustment.[101] ACOs are required to spend at least 90 to 95 percent (depending on the performance year) of the total PPCP payment on the provision of care.[102] The ACO enhanced amount includes three types of payment enhancements: (1) the county enhancement, which is applied at the county level in counties designated as low spending counties relative to standardized spending nationally; (2) the flex enhancement, which is applied at the ACO level to all PC Flex ACOs, regardless of location or utilization, and (3) the enhancement add-on, which is a fixed amount PBPM for a performance year that may be used to increase the

[94] Three APCM codes and payment amounts were established in the CY 2025 Physician Fee Schedule final rule (89 FR 97859 through 97902). In the CY 2026 PFS final rule, CMS established three new G-codes (HCPCS codes G0568, an add-on code based on CPT code 99492, G0569, an add-on code based on CPT code 99493 for CoCM services delivered to patients also receiving APCM services, and G0570, an add-on code for general behavioral health integration services based on CPT code 99484) to be billed as add-on services to APCM base codes: HCPCS codes G0556, G0557, and G0558 (90 FR 49464 through 49471).

[95] O'Malley A, Singh P, Fu N, et al. ''Independent Evaluation of the Comprehensive Primary Care Plus (CPC+): Final Report,'' page 209. Mathematica. December 2023. *https://www.cms.gov/priorities/innovation/data-and-reports/2023/cpc-plus-fifth-annual-eval-report.*

[96] Lowell, K.H., and contributing authors. ''Evaluation of the Next Generation Accountable Care Organization (NGACO) Model, Final Report,'' page 10. Bethesda, MD: NORC at the University of Chicago, 2024. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/nextgenaco-sixthevalrpt.*

[97] Lowell, K.H., and contributing authors. ''Evaluation of the Global and Professional Direct Contracting Model, Annual Report 2.'' Bethesda, MD: NORC at the University of Chicago, 2024. *https://www.cms.gov/priorities/innovation/data-and-reports/2024/gpdc-2nd-ann-report.*

[98] ''ACO REACH Model, PY 2026 Financial Operating Policies: Capitation and Advanced Payment Mechanisms.'' Baltimore, MD: RTI International, 2025. *https://www.cms.gov/priorities/innovation/files/aco-reach-py26-financial-ops-capitation-payment-mechanisms.pdf.*

[99] ACO PC Flex (ACO Primary Care Flex) Model website: *https://www.cms.gov/priorities/innovation/innovation-models/aco-primary-care-flex-model.*

[100] Under § 425.20, a ''low revenue ACO'' is an ACO whose total Medicare Parts A and B fee-for-service revenue of its ACO participants, based on revenue for the most recent calendar year for which 12 months of data are available, is less than 35 percent of the total Medicare Parts A and B fee-for-service expenditures for the ACO's assigned beneficiaries, based on expenditures for the most recent calendar year for which 12 months of data are available.

[101] ACO Primary Care Flex Model Financial Methodology: Rate Book Development, Calculation of Monthly Prospective Primary Care Payment, and Financial Settlement, June 2025, version 2, pages 1–2. *https://www.cms.gov/files/document/aco-pc-flex-fin-meth-ratebook-dev.pdf.*

[102] ACO Primary Care Flex Model Financial Methodology: Rate Book Development, Calculation of Monthly Prospective Primary Care Payment, and Financial Settlement, June 2025, version 2, page 56. *https://www.cms.gov/files/document/aco-pc-flex-fin-meth-ratebook-dev.pdf.*

ACO enhanced amount for underlying changes in the Medicare PFS that are not reflected in the rate book. The enhanced amount will not be subject to recoupment in full by CMS based on the PC Flex ACO's performance in achieving shared savings.[103] Although interest in the ACO PC Flex model was robust, many eligible ACOs that expressed initial interest in the model ultimately did not submit applications, citing challenges associated with the application timeline. Additionally, several interested parties shared that concurrent interest in the Making Care Primary model was a factor in their decision not to participate in ACO PC Flex.

The Innovation Center recently announced the Long-term Enhanced ACO Design (LEAD) model,[104] which is scheduled to begin on January 1, 2027. As currently designed, LEAD's capitated payment architecture builds directly on the framework used in ACO REACH and ACO PC Flex. Similar to ACO REACH and the ACO PC Flex model, participating ACOs will be required to select from either: (1) TCC payment or (2) PCC payment. The LEAD model plans to offer ACOs that elect PCC the option to receive additional payments to extend value-based arrangements beyond primary care. Specifically, ACOs may elect the non-primary care capitation (NPCC) or the APO to support alternative payment arrangements for non-primary care providers. It is anticipated that these options would allow ACOs to incrementally expand capitation beyond primary care without adopting full TCC.

TABLE A-E2: CAPITATED PAYMENT ARRANGEMENTS IN SELECT CMS INNOVATION CENTER MODELS

Model	Type	Capitated Payment Arrangement Options
Comprehensive Primary Care Plus (CPC+) 2017-2021	Hybrid (OM+ capitation)	FFS base + care management fees + performance-based incentive payments. Alternative payments to partially replace FFS billing available to Track 2 practices.
Primary Care First (PCF) 2021-2025	Population-based payments	Quarterly population-based payments that exceed FFS rates + flat visit fees replaced E/M billing + performance-based adjustment (based on performance measures) of -10 percent to 50 percent + payment accuracy adjustment to account for primary care furnished outside participating PCF practices.
Next Generation ACO (NGACO) 2016-2021	OM + Hybrid + Population-based payments	Four options: (1) FFS; (2) FFS + fixed per-beneficiary per-month infrastructure payment; (3) population-based payments as fixed percent of expected FFS claims; (4) all-inclusive population-based payments (prospective monthly payments based on expected FFS claim reductions).
Global and Professional Direct Contracting (GPDC) 2021-2022	Primary care capitation or Total Care Capitation	Two monthly payment options: (1) primary care capitation (PCC) payment or (2) total care capitation (for all Medicare Part A and Part B services). PCC includes a base primary care capitation amount + enhanced primary care capitation amount. Advanced payment option available for ACOs that select PCC.
ACO REACH 2023-2026	Primary care capitation or Total Care Capitation	Two monthly payment options: (1) primary care capitation (PCC) payment or (2) total care capitation. PCC consists of base primary care capitation amount + enhanced primary care capitation amount. Advanced payment option available for ACOs that select PCC.
ACO PC Flex 2025-2029	Primary Care Capitation	Monthly prospective primary care payment (PPCP) to replace FFS for eligible primary care services + one-time $250,000 advance shared savings payment. PPCP consists of: county base rate + ACO enhanced amount + population adjustment. Enhanced amount consists of: county enhancement + flex enhancement.
Long-term Enhanced ACO Design (LEAD) 2027-2036 (planned)	Primary Care Capitation or Total Care Capitation	Two monthly payment options are planned: (1) primary care capitation (PCC) payment or (2) total care capitation. As currently designed, PCC consists of: a base primary care capitation amount + enhanced primary care capitation amount. As currently designed, Advanced payment option and non-primary care capitation payment may be available for ACOs that select PCC.

b. Primary Care Capitated Payment Arrangements Considerations for the Shared Savings Program

The goal of capitated payments is to give health care providers additional flexibility in how they deliver care and to reduce the volume-based incentives of Original Medicare (OM) payment. With capitated payments, health care providers receive steady, predictable cash flow that is not tied to the number of services they provide. This flexibility frees health care providers to deliver care in innovative and flexible ways, such as non-face-to-face care management, telehealth, and electronic messaging, without worrying about foregone OM revenue, tying these services to overall outcomes. We are interested in building on the experience of previous Innovation Center models that tested capitated payment arrangements. Section 1899(i)(2) of the Act authorizes the Secretary to use partial capitation in which an ACO is at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B, provided that the partial capitation payments for a year made under the partial capitation model do not result in additional program expenditures than would otherwise be expended for such ACO for such beneficiaries for such year if the model were not implemented. The Secretary may limit a partial capitation model to ACOs that are highly integrated systems of care and to ACOs capable of bearing risk, as determined to be appropriate by the Secretary. Additionally, section 1899(i)(3) of the Act authorizes the Secretary to use other payment models instead of the one-sided model described in section 1899(d) of the Act as long as the Secretary determines that the other payment model will improve the quality and efficiency of items and services furnished to Medicare beneficiaries without additional program expenditures.

We have previously described how primary care teams are central to the relative success of Shared Savings Program ACOs.[105] [106] In 2024, as in

[103] ACO Primary Care Flex Model Financial Methodology: Rate Book Development, Calculation of Monthly Prospective Primary Care Payment, and Financial Settlement, June 2025, version 2, page 33. *https://www.cms.gov/files/document/aco-pc-flex-fin-meth-ratebook-dev.pdf.*

[104] *https://www.cms.gov/priorities/innovation/innovation-models/lead.*

[105] ''Medicare Shared Savings Program Continues to Deliver Meaningful Savings and High-Quality Health Care'', October 29, 2024, Press Release. *https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-continues-deliver-meaningful-savings-high-quality-health-care.*

[106] ''Medicare Shared Savings Program Saves Medicare More Than $1.8 Billion in 2022 and Continues to Deliver High-quality Care'', August 24, 2023, Press Release. *https://www.cms.gov/newsroom/press-releases/medicare-shared-savings-program-saves-medicare-more-1–8-billion-2022-continues-deliver-high-quality.*

previous years, ACOs comprised of larger proportions of primary care clinicians had significantly higher net per capita savings than ACOs comprised of smaller proportions of primary care clinicians (with $403 vs $224 in net per capita savings).[107] In recent years, we have received significant input from interested parties regarding opportunities to increase participation in ACO initiatives. One such option to increase participation would be to identify ways that the Shared Savings Program can support ACOs' efforts to strengthen primary care, such as by providing prospective monthly primary care capitated payments to primary care practices, to reduce reliance on OM payments and support innovations in care delivery that better meet beneficiary needs.

In the CY 2026 PFS proposed rule (90 FR 32502), we solicited comments on whether CMS should consider new payments to Shared Savings Program ACOs for prospective monthly APCM payments to be delivered to primary care practices that satisfy the APCM billing requirements, with the payments reconciled under the ACO benchmark. Nearly all commenters supported giving ACOs the option to receive prospective APCM payments. Only one commenter opposed prospective APCM payments, arguing that APCM delivery solely through ACOs risks undermining the core principles of CCM.

We are seeking feedback regarding potential primary care capitated payment arrangements in the Shared Savings Program. Specifically, we are requesting input on the following questions:

ACO and ACO Participant Readiness

- To what extent are Shared Savings Program ACOs and ACO participants, and their associated health care providers (referred to herein as ''ACO providers/suppliers''), ready to take on capitated payment arrangements? Please describe ACO and ACO participant level of readiness for each of the following:

++ Hybrid capitation (a combination of capitated and OM payments).

++ Full capitation for primary care services (that could enable ACOs to provide downstream payments to ACO participants).

++ PBPs as a fixed percentage of expected OM claims.

We are interested in understanding what operational changes ACOs would need to undertake to effectively receive, manage, and distribute capitated payments. Please describe any barriers or conditions—legal, financial, or operational—that could affect an organization's readiness to participate in each type of arrangement.

- If an ACO received capitated payments for primary care services furnished by ACO providers/suppliers billing through the TIN of an ACO participant (as defined in § 425.20), what organizational and programmatic goals would the ACO seek to advance with those payments? For example, we are interested in understanding whether ACOs would use capitated payments to expand the scope or capacity of existing care coordination and population health programs, or whether capitated payments would instead enable ACOs to operationalize new care delivery initiatives. Please describe the specific types of initiatives that ACOs would seek to implement, and how ACOs would ensure that these payments went to support primary care practices directly.

Eligibility for Participation

- Should CMS limit access to capitated payment arrangements exclusively to ACOs participating in two-sided risk tracks (BASIC tracks C, D, E or the ENHANCED track), or should all ACOs be eligible to receive some form of capitated payments, regardless of the ACO's participation track? ACOs participating in two-sided risk tracks must establish a repayment mechanism prior to the start of an agreement period, and we are interested in whether similar proof that an ACO could repay losses should be required as a condition for receiving capitated payments, even for ACOs in one-sided risk tracks.
- Should CMS limit capitated payment arrangements to ACOs with prior risk-bearing experience—either through participation in a previous Shared Savings Program agreement period in a two-sided risk track (BASIC tracks C, D, E or the ENHANCED track) or through prior participation in a risk-bearing track in an Innovation Center model, such as ACO REACH—or should risk-bearing ACOs in their first Shared Savings Program agreement period also be eligible to participate in capitated payment arrangements? Why would commenters support one approach over the other? We are interested in whether prior experience with risk-bearing should be an explicit prerequisite for capitated payment eligibility or whether risk-bearing ACOs in their first agreement period should also be eligible to participate in capitated payment arrangements.
- Should CMS permit some, but not all, ACO participants within an ACO to participate in capitated payment arrangements, or should CMS require all ACO participants within an ACO to participate in capitated payment arrangements?
- Should CMS establish a minimum percentage of attributed beneficiaries[108] for whom eligible primary care practices must be furnishing care management services to receive capitated payments, either at the ACO level or at the individual ACO participant level?
- To what extent should the payment design and structure differ based on the level of risk or participation track of an ACO?

Payment Design and Structure

- What percentage of base year OM payments should be replaced by PCC, and what factors should guide this determination? For example, under the ACO REACH model, the PCC payment—including both the base PCC and the enhanced PCC—is set at 7 percent of the REACH ACO's prospective monthly performance year benchmark, a level designed to provide ACOs with a predictable, non-visit-based revenue stream for primary care services.
- What services should be included in primary care capitation (and reciprocally, in a fee reduction) to accurately capture an appropriate scope of primary care services furnished to beneficiaries, balancing the importance of providing up-front flexible payments, with the potential for risk to practices if service utilization grows? For example, under both the ACO REACH and ACO PC Flex models, the set of services eligible for primary care capitated payments is based on a specific list of CPT and HCPCS codes billed by primary care specialists (health care providers with specific specialty codes). In both models, the PCC bundle includes certain E/M office visits along with CCM, behavioral health integration, transitional care management, AWVs, advance care planning, and virtual communication services.
- We are interested in feedback about whether and in what form we should establish an enhanced primary care payment amount—in addition to the base primary care capitated payment amount—as a feature of primary care capitated payment arrangements in the Shared Savings Program. Specifically, we are interested in:

[107] Medicare Shared Savings Program Accountable Care Organizations Updated Performance Year 2024 Financial and Quality Results Fact Sheet, September 29, 2025. *https://www.cms.gov/files/document/fact-sheet-ssp-py24-financial-quality-results.pdf.*

[108] Specific Medicare beneficiaries for whom an ACO is responsible for the care and total cost of care. Generally determined based on care furnished during a specific calendar window and the clinicians that provided the care.

++ *Calculation:* For example, in ACO REACH, the enhanced primary care payment is calculated as a fixed percentage of the ACO's performance year benchmark, while in ACO PC Flex, the Flex Enhancement component of the primary care payment is calculated as a fixed dollar amount ($125) per eligible beneficiary per year, with additional enhancements (*i.e.* the County Enhancement) derived from county-level or regional spending benchmarks.

++ *Reconciliation:* In ACO REACH, enhanced primary care capitation (EPCC) is subject to recoupment at the end of the performance year. In ACO PC Flex the enhanced amount is included in total cost of care, subject to offsets from the prior savings adjustment and/or the regional adjustment.

• We are interested in whether CMS should consider offering an advanced payment option (APO) within the Shared Savings Program, similar to the APO offered by the ACO REACH model, to ACOs that have elected PCC. Specifically, we are interested in:

++ Does the availability of an APO enhance an ACO's ability to align specialist financial incentives with the ACO's total cost of care goals, or do the structural and administrative requirements of implementing an APO within the Shared Savings Program present barriers that outweigh the potential benefits?

++ Do Shared Savings Program ACOs have access to sufficient data—shadow bundles, claims data, public use files, and data from arrangements with other payers—to support the development and ongoing administration of an APO? If not, what data would be necessary?

• The ACO REACH model has offered TCC as a payment option for ACOs assuming the highest level of financial risk. The LEAD model also plans to offer TCC as a payment option for ACOs assuming the highest level of financial risk. We are interested in whether CMS should provide a full capitation option to Shared Savings Programs ACOs. Specifically, we seek feedback on:

++ Should CMS consider offering a full capitation option to Shared Savings Program ACOs that have demonstrated readiness to administer prospective payments, under which all Medicare Part A and Part B services furnished to assigned beneficiaries by ACO providers/suppliers billing through the TIN of ACO participants—but not services furnished to assigned beneficiaries by providers that are not on the ACO's participant list—would be paid through a TCC payment?

++ Should CMS limit full capitation to ACOs in tracks with the highest level of risk—ENHANCED track or BASIC track Level E—on the basis that full capitation should be reserved for ACOs that have already assumed downside financial risk and the organizational readiness to manage prospective payment for Medicare Part A and Part B services?

++ Are there other flexibilities that CMS should give ACOs to make TCC effective?

++ How should CMS calculate the per-beneficiary, per-month payment amount under a full capitation arrangement in the Shared Savings Program? Under ACO REACH, the monthly TCC payment amount paid to the ACO equals 1/12 of the performance year benchmark, adjusted by the TCC withhold.[109]

• Should CMS issue prospective capitated payments on a monthly or quarterly basis? Please describe the potential advantages, disadvantages, and operational implications of each approach.

• Should capitated payments be paid to ACOs and distributed downstream to ACO participants, or should CMS make payments directly to ACO participants that provide primary care services, similar to how CMS makes payments for APCM services, and what are the implications of each approach? Should CMS consider alternative mechanisms for delivering capitated payments directly to ACO Participants that are also primary care practices participating in Shared Savings Program ACOs? If so, what payment design, infrastructure, and policy considerations should guide the development of such alternative payment mechanisms?

• If capitated payments are issued directly to ACOs, should CMS require ACOs to provide a specific percentage of those payments to ACO participants that provide primary care services? How might this be audited? Additionally, should CMS require ACOs to have written capitated payment agreements with ACO participants to specify that a minimum percentage of the capitated payment will flow to ACO participants?

Care Delivery Requirements

• Should CMS require ACOs seeking to participate in capitated payment arrangements to make commitments to specific care delivery goals as a condition for participation? If so, what goals should be required and how should compliance be assessed and enforced? For example, we are interested in whether we should require ACOs to submit a primary care transformation plan—similar to the care delivery requirements under the CPC+ model, which required participating practices to demonstrate progress across five comprehensive primary care functions, including access and continuity, care management, comprehensiveness and coordination, patient and caregiver engagement, and planned care and population health—that specifies measurable targets for care delivery improvements, such as expanding after-hours access, increasing care management for high-risk beneficiaries, or reducing avoidable emergency department utilization.

• How should CMS balance meaningful capitated payment levels with reduced administrative and reporting burdens for participating ACOs, and what primary care delivery requirements should CMS establish as conditions of eligibility for capitated payment arrangements in the Shared Savings Program? Should compliance with any care delivery requirements be monitored on a quarterly or annual basis, with the potential for payment recoupment in cases of noncompliance?

• Should CMS require that ACOs and ACO participants receiving capitated payments demonstrate the use of data-driven risk stratification methods to identify high-risk beneficiaries and target enhanced care management resources toward those beneficiaries? CMS provides Shared Savings Program ACOs with data that could be used for risk stratification, such as claims-based beneficiary data, risk scores, and quality performance reports. We are interested in whether CMS should require ACOs and ACO participants to use these data as a baseline input for their risk stratification methodologies or whether ACOs and ACO participants should be given the flexibility to design their own risk stratification approaches.

• Should care delivery requirements for capitated payment eligibility increase depending on the level/type of capitated payment selected by the ACO or ACO participants? For example, should ACOs that are receiving a higher percentage of capitated payments be subject to more comprehensive care delivery requirements or should a uniform set of care delivery requirements apply to all ACOs, regardless of the percentage of capitated payments they receive?

[109] Because it is expected that a portion of the total cost of care for aligned beneficiaries will be for services provided by providers and suppliers not participating in the TCC arrangement, CMS will withhold a portion of the monthly TCC amount to avoid the need for significant year-end recoupments from the REACH ACOs. *https://www.cms.gov/priorities/innovation/files/aco-reach-py26-financial-ops-capitation-payment-mechanisms.pdf.*

c. Primary Care Capitated Payment Arrangements Considerations Outside of the Shared Savings Program

Though CMS is first exploring the development of PPCP within the guardrails of accountable care discussed in the third section of this RFI, we are also considering extending these efforts in future years to develop a bundled or capitated approach, called a 'global period' in the broader Original Medicare program (OM). In OM, many services, including surgical and maternity care services, are managed as 'global' periods by OM, where reasonable and necessary medical services are delivered throughout an episode. Primary care, once an initiating visit has occurred, could also be reimbursed over an interval of care consistent with the development of a trusting, longitudinal relationship between clinician and patient. We have not previously proposed a primary care 'global' period, in part because of the difficulty to ascertain where a primary care relationship starts, and where it stops, through claims data or other information readily obtained by CMS. We do attribute beneficiaries to organizations participating in alternative payment models, such as ACOs in the Medicare Shared Savings Program, based on a plurality of primary care services delivered and also maintain the possibility for beneficiaries to voluntarily align to a Shared Savings Program ACO through Medicare.gov where beneficiaries select a primary care provider.

To establish a primary care global period would require a number of services to be 'bundled' within the primary care global code family, including the IPPE or AWV, O/O E/M services, and care management services such as advanced primary care management services. Central to the challenge inherent in bundling together previously disparate services is ensuring beneficiaries would maintain access to care. CMS could monitor for any potential denials or limitations in care associated with the transition to a global period. We also would like to seek public input on which and how many of the services should be bundled, if they should be bundled entirely or through a 'hybrid' capitation with reduced FFS model, and how best to establish the payment levels for this global period. We seek input on the following:

- What would be the appropriate services to bundle in such a primary care global period (*e.g.* E/M, care management codes, AWV, etc.)? How should the agency consider the benefits and drawbacks regarding quality of care, patient safety, and evidence regarding care delivery changes in a fully or globally capitated approach with no per-visit payment vs. a hybrid payment approach with reduced per-visit payment and per-member per-month payment?
- For both a fully capitated and hybrid payment approach, CMS has in past considered patient complexity (*e.g.* number of chronic conditions or HCC level) in our alternative payment models for primary care. How should CMS approach defining these levels or stratum for payments in a fully capitated or hybrid payment model for primary care? How many levels should be considered?
- In the absence of an encounter, is there another appropriate 'trigger' or initiation for a primary care global period? How long should it last? Is beneficiary receipt of an AWV in the previous 12 months sufficient?
- What necessary reporting requirements and accountability should CMS require for clinicians receiving primary care capitated payments? For example, should there be explicit minimum visit requirements for a clinician to be eligible to receive primary care capitated payments for their Original Medicare patients? Should we require specific clinical outcomes-based reporting? If so, what clinical outcomes should we measure?
- Broadly, to what extent should the approach Original Medicare takes to primary care payment differ between the Shared Savings Program and the broader program? If yes, how?
- In so much as the agency considers a prospective primary care payment (PPCP) for primary care, to what extent should the IPPE/AWV be the initiating visit for that global period?

F. Comprehensive Outpatient Rehabilitation Facility (CORF) Services and KX Modifier Threshold, and Medical Review Threshold

1. Technical Corrections of CORF Regulations

During rulemaking for CY 2008 (72 FR 66399), we made several regulation text revisions and redesignations at § 410.100 without changing a related regulatory provision of § 410.105 for the requirements for coverage of CORF services. We also created a new subpart M at 42 CFR 414.1105 for payment of CORF items and services that includes references to § 410.100 without making the corresponding revisions to the sections that were amended during CY 2008 PFS rulemaking.

We are proposing to revise § 410.105(b)(3)(ii) for the home environment evaluation to indicate that the home environment evaluation is specified at § 410.100(l) and not § 410.100(m) as it currently reads.

We are proposing to amend the regulation at § 414.1105(c) for CORF supplies and durable medical equipment to indicate that the supplies and durable medical equipment that are CORF services is specified at § 410.100(k) instead of § 410.100(l), as it currently reads. At the same time, we are also proposing to remove from § 414.1105(c) language that relates to CORF drugs and biologicals because the provisions relating to payment for drugs and biologicals that are CORF services are at § 414.1105(d), which was added in the CY 2008 PFS final rule.

We are requesting comments on these proposals.

2. KX Modifier Thresholds

The KX modifier thresholds were established through section 50202 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123, February 9, 2018) (BBA) and were formerly referred to as the therapy cap amounts. These per-beneficiary amounts under section 1833(g) of the Act (as amended by section 4541 of the Balanced Budget Act of 1997) (Pub. L. 105–33, August 5, 1997) are updated each year based on the percentage increase in the Medicare Economic Index (MEI). Specifically, these amounts are calculated by updating the previous year's amount by the percentage increase in the MEI for the upcoming calendar year and rounding to the nearest $10.00. Thus, for CY 2027, we propose to increase the CY 2026 KX modifier threshold amount by the most recent forecast of the 2017-based MEI. For CY 2027, the proposed MEI increase is estimated to be 2.5 percent and is based on the expected historical percentage increase of the 2017-based MEI. Multiplying the CY 2026 KX modifier threshold amount of $2,480 by the proposed CY 2027 percentage increase in the MEI of 2.5 percent ($2,480 x 1.025) and rounding to the nearest $10.00 results in a proposed CY 2027 KX modifier threshold amount of $2,540 for physical therapy and speech-language pathology services combined and $2,540 for occupational therapy services. We also propose to update the MEI increase for CY 2027 based on historical data through the second quarter of 2026, and we propose to use such data, if appropriate, to determine the final MEI percentage increase and the CY 2027 KX modifier threshold amounts in the CY 2027 PFS final rule.

Section 1833(g)(7)(B) of the Act describes the targeted medical review (MR) process for services of physical therapy, speech-language pathology, and occupational therapy services. The threshold for targeted MR is $3,000 through CY 2027. Effective beginning with CY 2028, the MR threshold levels will be annually updated by the percentage increase in the MEI, per section 1833(g)(7)(B) of the Act. Consequently, for CY 2027, the MR threshold is $3,000 for physical therapy and speech-language pathology services combined and $3,000 for occupational therapy services. Section 1833(g)(5)(E) of the Act states that CMS shall identify and conduct targeted medical review using factors that may include the following:

- The therapy provider has had a high claims denial percentage for therapy services under this part or is less compliant with applicable requirements under this title.
- The therapy provider has a billing pattern for therapy services under this part that is aberrant compared to peers or otherwise has questionable billing practices for such services, such as billing medically unlikely units of services in a day.
- The therapy provider is newly enrolled under this title or has not previously furnished therapy services under this part.
- The services are furnished to treat a type of medical condition.
- The therapy provider is part of a group that includes another therapy provider identified using the factors described previously in this section.

We track each beneficiary's incurred expenses for therapy services annually and count them towards the KX modifier and MR thresholds by applying the PFS rate for each service less any applicable multiple procedure payment reduction (MPPR) amount for services of CMS-designated ''always therapy'' services (see the CY 2011 PFS final rule at 75 FR 73236). We also track therapy services furnished by critical access hospitals (CAHs), applying the same PFS-rate accrual process, even though they are not paid for their therapy services under the PFS and may be paid on a cost basis (effective January 1, 2014) (see the CY 2014 PFS final rule at 78 FR 74406 through 74410).

When the beneficiary's incurred expenses for the year for outpatient therapy services exceed one or both of the KX modifier thresholds, therapy suppliers and providers use the KX modifier on claims for subsequent medically necessary services. Using the KX modifier, the therapist and therapy provider attest that the services above the KX modifier thresholds are reasonable and necessary and that documentation of the medical necessity for the services is in the beneficiary's medical record. Claims for outpatient therapy services exceeding the KX modifier thresholds without the KX modifier included are denied.

G. Supporting Beneficiaries Planning for Future Medical Decisions

1. Advance Care Planning (ACP) Services (HCPCS Codes GACP1 and GACP2)

a. Background

Medicare currently pays for ACP services as an optional element of the annual wellness visit (AWV) or a Part B medically necessary service (see 80 FR 70955 and *https://www.cms.gov/files/document/mln-advanced-care-planning.pdf*). While the Social Security Act covered a similar service as a voluntary part of the initial preventive physical exam under section 1861(ww)(3) of the Act since CY 2012, in CY 2016 we adopted new coding developed by the American Medical Association for payment of ACP services as a separate Part B medically necessary service or an optional element of the annual wellness visit (AWV). In this section of our proposed rule, we propose to create additional codes in this family that more explicitly describe and value the contributions of clinical staff in the provision of ACP services. We emphasize that clinicians must not, under any circumstances, attempt to influence their patients' decisions for ACP.

For CY 2015, the CPT Editorial Panel created two new codes describing ACP services by physicians and other qualified healthcare professionals (QHPs): CPT code 99497 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed*), by the physician or other qualified health care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate) and an add-on code, CPT code 99498 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed*), by the physician or other qualified health care professional; *each additional 30 minutes (List separately in addition to code for primary procedure))* (80 FR 70955).

In the CY 2015 PFS final rule with comment period (79 FR 67670), we assigned a PFS interim final status indicator of ''I'' (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services. This code is not subject to a 90-day grace period.) to CPT codes 99497 and 99498. We had received many public comments in response to the CY 2015 proposed rule recommending that we recognize and make separate payment for both CPT codes, in view of the time required to furnish the services and their importance for the quality of care and treatment of the patient. In the CY 2015 PFS final rule with comment period we responded that we would consider paying for CPT codes 99497 and 99498 after we had the opportunity to go through notice and comment rulemaking (80 FR 70955).

The following year, in the CY 2016 PFS final rule, we finalized our proposal to assign CPT codes 99497 and 99498 a PFS status indicator of ''A'' (Active) with RVUs based on the RUC recommended values. We adopted the RUC-recommended work RVU, physician time and direct PE inputs: 1.5 work RVUs and 1.4 work RVUs for CPT codes 99497 and 99498, respectively. We also added ACP as an optional element, at the beneficiary's discretion, of the AWV and made conforming changes to our regulations at § 410.15 that describe the conditions for and limitations on coverage for the AWV (80 FR 70959). In addition to adopting both CPT codes, we adopted CPT provisions regarding the reporting of timed services (80 FR 70956). We have also instructed practitioners that when reporting ACP as part of managing a beneficiary's illness, the condition discussed with the beneficiary is reported on the claim, whether or not an E/M visit is billed the same day (*https://www.cms.gov/files/document/mln-advanced-care-planning.pdf*). When ACP services are part of an AWV and furnished on the same day by the same practitioner as the AWV, an administrative exam or exam diagnosis is reported along with modifier 33 indicating the ACP services are preventive and not subject to cost sharing (*https://www.cms.gov/files/document/mln-advanced-care-planning.pdf*). In the CY 2016 PFS final rule, we also adopted CPT's coding guidance for ACP performed in conjunction with an E/M visit. CPT prefatory language indicates that when using CPT codes 99497 and 99498, no active management of the problem(s) is undertaken during the time period reported, and these codes may be reported separately if performed on the

same day as most E/M visits.[110] We cited a clinical vignette from the RUC recommendations, illustrating when the services described by CPT codes 99497 and 99498 could be reasonable and necessary for the diagnosis or treatment of illness or injury, stating that this could occur in conjunction with the management or treatment of a patient's current condition, such as a 68 year old male with heart failure and diabetes on multiple medications seen by his physician for the E/M of these two diseases, including adjusting medications as appropriate (80 FR 70955). In addition to discussing the patient's short-term treatment options, the patient might express interest in discussing long-term treatment options and planning, such as the possibility of a heart transplant if his congestive heart failure worsens, and advance care planning including the patient's desire for care and treatment if the patient suffers a health event that adversely affects the patient's decision-making capacity (80 FR 70956). In this case the physician would report a standard E/M CPT code for the E/M service and one or both of the CPT codes describing ACP, depending upon the duration of the ACP service (80 FR 70956). Moreover, the ACP service would not necessarily have to occur on the same day as the E/M service (80 FR 70956).

The CPT Codebook published by the American Medical Association contains prefatory language that describes CPT codes 99497 and 99498 as a ''face-to-face service between a physician or other qualified health care professional and a patient, family member, or surrogate in counseling and discussing advance directives, with or without completing relevant legal forms.'' [111] While this code descriptor language indicates that the time being billed is personally spent by the physician/QHP and the codes are valued accordingly, we finalized a provision in the CY 2016 PFS final rule that allowed the time of clinical staff to be counted if the billing physician or other billing practitioner managed, participated and meaningfully contributed to the provision of the services, because public commenters persuaded us that ACP was performed at times by a team of a treating physician or other treating practitioner and their staff. Therefore, in the CY 2016 PFS final rule (80 FR 70957), we stated that we believed the services described by CPT codes 99497 and 99498 could be appropriately provided by physicians or using a team-based approach where ACP would be provided by physicians, non-physician practitioners (NPPs), and other staff under the order and medical management of the beneficiary's treating physician or treating practitioner. To provide clarity on who could report the new codes, we noted that the CPT code descriptors described the services as furnished by physicians or other qualified health professionals, which for Medicare purposes, has been consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore, we finalized that only these practitioners may report CPT codes 99497 and 99498, and ''incident to'' rules in § 410.26 would apply when these services would be provided incident to the services of the billing practitioner under a minimum of direct supervision. We stated that we expected the billing physician or NPP, in addition to providing a minimum of direct supervision, to manage, participate and meaningfully contribute to the provision of the services. Also, we noted that PFS payment rules would apply when ACP is furnished incident to other physicians' services, including where applicable, that State law and scope of practice must be met (80 FR 70959). Accordingly, even though CPT codes 99497 and 99498 describe (and are valued as) services performed only by the billing practitioner, we finalized a policy allowing the time of clinical staff to be included since we did not have G codes at that time that would have provided coding specific to that situation.

b. Proposals for CY 2027

Since 2016, we have heard from interested parties that ACP services may be under-utilized because some practitioners believe that only time they personally spend can count. While growth in ACP services utilization has been increasing, interested parties have communicated to CMS that the increase in utilization is not commensurate with the need for ACP services. Utilization of ACP services has increased since 2016 from about 650,000 services to about 2.5 million per year in 2025. We note that for patients in critical care, advance care planning is bundled into payment for the critical care service codes (CPT codes 99291–2) and is therefore not separately billed, so these patients may receive ACP services that is not identifiable in the claims data. We believe that new coding could more accurately distinguish and value the work of the billing practitioners from time that is spent by their clinical staff in the provision of ACP services. Therefore, we are proposing to create two new HCPCS codes to describe ACP services furnished by clinical staff under the direct supervision of the billing physician or other practitioner (and incidental to their professional services), and proposing that the existing CPT codes 99497 and 99498 would only be used to report time personally spent by the billing practitioner. The proposed new codes would be: HCPCS G-code GACP1 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), first 20 minutes of clinical staff time with the patient, family member(s), surrogate directed by a treating physician or other treating qualified health care professional) and* GACP2 *(Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), each additional 20 minutes with the patient, family member(s),* surrogate *directed by a treating physician or other treating qualified health care professional (List separately in addition to code for primary procedure)).*

We are proposing a work RVU of 1.00 for HCPCS code GACP1, based on a crosswalk to the work time of CPT code 99490 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline, comprehensive care plan established, implemented, revised, or monitored; first 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month*). For direct PE, we are proposing 20 minutes of clinical labor (L037D) in the service period. We are proposing a work RVU of 0.7 for HCPCS code GACP2, based on a crosswalk to the work time of CPT code 99439 (*Chronic care management services with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient, chronic conditions that place the patient at significant risk of death, acute exacerbation/decompensation, or*

[110] Current Procedural Terminology, (CPT®) 2026 (CPT Codebook), Professional Edition, American Medical Association, page 61.

[111] CPT Codebook 2026, AMA, page 61.

functional decline, comprehensive care plan established, implemented, revised, or monitored; each additional 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month (List separately in addition to code for primary procedure)). For direct PE, we are proposing 20 minutes of clinical labor (L037D) in the service period.

Under this proposal, the new G codes and CPT codes 99497 and 99498 could be reported together, if time thresholds by the billing practitioner and clinical staff were each met with these respective code sets. We are seeking public comment on whether it would be better for the new G codes to represent, and be valued for, the combined time of a billing practitioner and their clinical staff within a single code, in case, for example, the billing practitioner and staff did not meet time thresholds for separate reporting of their respective times, but might meet the threshold for a code combining their time. For both the existing codes (describing physician time but allowing use for clinical staff time, as discussed previously) and newly proposed ACP codes (describing clinical staff time) to be paid ''incident to,'' the reporting practitioner must furnish a prior professional service to which the services of the clinical staff are incidental, such as a prior E/M visit or ACP services personally performed by the billing practitioner the same day. Our manual provides that ''[s]uch a service or supply could be considered to be incident to when furnished during a course of treatment where the physician performs an initial service and subsequent services of a frequency which reflect his/her active participation in and management of the course of treatment'' (Medicare Benefit Policy Manual, Chapter 15, Section. 60.1.B, available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf*). We are seeking clarity from interested parties about whether these ''incident to'' criteria (the requirement for the billing practitioner to perform initial and subsequent services reflecting their participation in and management of the course of treatment) are typically met for beneficiaries needing ACP services, by a separately billed E/M visit (whether the same day as the ACP services or prior), or might best be included in a new code inclusive of combined time spent by both a reporting practitioner and their clinical staff. If the billing practitioner is by definition participating and managing by performing part of the ACP code itself, there would not be a need to require a prior initiating visit as we do for care management services provided ''incident to.'' To help us craft new coding in a manner that reflects typical clinical practice as well as ''incident to'' rules governing payment for services by clinical staff, we are seeking public comments that specify or clarify for the alternative new coding, the typical care team structure; how much time is typically spent by the billing practitioner and spent by their staff, and when; and the clinical circumstances of patients, for example, the care settings and whether the patient is typically a well patient or is doing advance care planning in conjunction with a particular illness. This would inform how the coding structure reflects work that is personally performed by the billing practitioner in conjunction with ACP.

Medicare has not made a national coverage determination regarding ACP services; however, we note that in 2021 a Medicare Administrative Contractor made a Local Coverage Determination, revised in 2023. Contractors remain responsible for local coverage decisions in the absence of a national Medicare policy. We also note that direct supervision may be satisfied by audio visual technology. Furthermore, for CY 2027 we are proposing to add both HCPCS codes GACP1 and GACP2 to the Medicare Telehealth list.

Finally, we note that we are aware of additional factors beyond the scope of this rule that could be influencing uptake of the existing codes. Among these are: practitioner training for bringing ACP up for voluntary discussion, how to ensure that care planning that includes delineation of patient goals, preferences and advance directives are available and actionable at the point of care (especially emergency care), enabling interoperable access to ACP information, lowering out-of-pocket costs for ACP services, and new quality measure that best capture meaningful ACP conversations and documented preferences.

2. Request for Information (RFI) on Community-Based Palliative Care

a. Background

In the FY 2027 Hospice proposed rule, CMS solicited comment on the development of community-based palliative services outside of the hospice benefit (90 FR 17360). By community-based palliative care, we are broadly considering where palliative services can be delivered outside of the hospital, in outpatient clinics, in patients' homes, and other non-hospital settings. In this request for information we sought feedback on whether current evaluation and management (E/M) services, care management services, and ACP services reflected current billing and payment practices for physicians and other health professionals delivering palliative services, as well as on whether challenges in meeting documentation requirements, issues with compliance, or enhancements to current services could be considered to better enhance palliative care service delivery. In addition, in the 2027 ESRD proposed rule, concurrently, we are requesting information to advance payment policy and better understand the differences between maintenance dialysis and dialysis delivered in a comfort-focused context. Comments regarding either of these subjects are best delivered to their respective rules.

In coordination with these requests for information, we are additionally seeking comment on the specific requirements we should consider given the prior CMS Innovation Center model tests focused on complex and serious illness care. The evaluation findings from these prior tests are best summarized in the CMS Innovation Center white paper on '*Palliative care projects: Synthesis of Evaluation Results 2012–2021'*.[112] These results indicate that a comprehensive approach to palliative care services, including access to interdisciplinary teams, home visits, and shared-decision-making may improve care for Medicare beneficiaries.

We continue to prioritize reducing fraud, waste, and abuse throughout CMS programs, and have prioritized reducing fraud, waste, and abuse in hospice programs. While hospice care is not palliative care, in related disciplines and sites of care we are very interested in how to better address fraud, waste, and abuse.

Where should CMS focus on potential fraud, waste, and abuse in community-based palliative care? Please support your statements with peer-reviewed evidence or evidence from your institution with sufficient detail for review.

b. Eligibility for Serious Illness Care

Defining which beneficiaries are eligible for serious illness care is a principal challenge in palliative and supportive care. While many Medicare beneficiaries may benefit from additional supportive care to manage pain and symptom burden, understanding which beneficiaries

[112] *https://www.cms.gov/priorities/innovation/data-and-reports/2022/palliative-care-synthesis-2012-2021.*

should be eligible for this service is of central importance to Medicare. For example, complex chronic care management services require two or more chronic conditions placing the beneficiary at high risk for hospitalization, decline, or death, and requires moderate to high complexity medical decision-making. To elect the Medicare Hospice Benefit, two or more physicians must certify a beneficiary is within 6 months to the end of their life (or, if a beneficiary does not have an attending physician, then the hospice physician alone is permitted to provide the certification).

We are requesting feedback on eligibility and care management services, and for all comments please support your statements with peer-reviewed evidence or evidence from your institution (in sufficient detail for review):

- For any future supportive or palliative care service for Medicare beneficiaries, should eligibility be restricted to certification of a likely life expectancy duration?
- If eligibility is restricted to those beneficiaries with a terminal prognosis, is there evidence to suggest a reasonable interval (that is, less than 1 year of life expectancy as in some States' Medicaid programs)?

c. Eligibility for Palliative Services

Defining eligibility for palliative services beyond the potential criterion of a terminal prognosis is likely necessary to better understand who is eligible for serious illness care.[113] While for complex care management services we restrict eligibility to beneficiaries requiring moderate to complex medical decision making as well as a count of chronic conditions, common definitions of serious illness include not just chronic condition counts but also indicators of the impact on a person's daily function or excessive caregiver strain.[114]

We are requesting feedback on the following:

- For any future supportive or palliative care service for Medicare beneficiaries, how could we consider impact on the daily functions of life or activities of daily living as part of who is eligible for the service?
- Would eligibility best be based on impact on daily function, on caregiver strain, or both?
- How can we avoid overly burdensome requirements for defining eligibility for services?

d. The Future of the Care Management Services

In section II.E. of this proposed rule, we are explicitly reconsidering the future of the care management services that form the basis for payment adequacy for important between visit care (in addition to E/M services for outpatient or home visits). Care for the seriously ill involves interdisciplinary care teams and involves even greater coordination and between visit care than primary care services.[115]

We are requesting feedback on the following:

- How should we differentiate the care management requirements for seriously ill beneficiaries from other Medicare beneficiaries?
- What are the essential service elements that must be included? For example(s), continuity with a designated team member, access to timely clinical support, comprehensive symptom and caregiver assessment, electronic care plans, coordination with treating physicians, patient/caregiver education, timely follow up after ED/discharge. What other service elements should be included? Should any not be included?

e. Advanced Primary Care Management

Currently, for Advanced Primary Care Management (APCM) services (HCPCS codes G0556 through G0558), we require physicians to report to the MIPS Value Pathway for primary care as part of our safeguards for high quality primary care. If we elect to develop additional care management services for seriously ill beneficiaries, however we may define serious illness in the future, determining how best to report quality of care safeguards will be essential to ensure high quality care delivery.

We are requesting feedback on the following:

- Should care management services for seriously ill beneficiaries also require reporting to a MIPS Value Pathway? Which quality measures should be reasonably included?
- If no viable MIPS Value Pathway reporting mechanism is found, what are the essential quality elements required for palliative care management? Is sole reporting of ambulatory palliative care patients feeling heard and understood (CBE 3665) sufficient? Should other measures be considered?

3. Request for Information on Intensive Lifestyle Interventions To Slow Progression of Alzheimer's Disease

a. Background

In the CY 2026 Physician Fee Schedule proposed rule, CMS sought comment in a 'Prevention and Management of Chronic Disease' Request for Information (90 FR 32507), addressing management and self-management of chronic disease, services that address root causes of disease, social isolation and loneliness, improving physical activity, intensive lifestyle interventions, enhancing uptake of the annual wellness visit (AWV), supporting partnerships with AAAs and community care hubs, and addressing motivational interviewing and health coaching. For some topics, responses were of adequate depth for CMS to consider further action, addressed elsewhere in this rule, but as is not uncommon when CMS requests information across a broad range of topics, in other areas responses were limited in the depth and granularity necessary for CMS to address the resource costs to establish coding and payment options. Because of the overwhelming priority for CMS to support the aging processes, given that American older adults commonly cite their fear of Alzheimer's as an even greater health related fear than the development of cancer,[116] and the growing evidence base for using lifestyle changes to slow the progression of cognitive decline and the development of Alzheimer's disease and Alzheimer's disease-related dementias (AD/ADRD), CMS is requesting additional information to better understand the resource costs and requirements for developing intensive lifestyle interventions to reduce the risk of AD/ADRD for Medicare beneficiaries. Intensive lifestyle interventions would be in concert with but would not specifically include risk factor reduction in modifiable behaviors such as controlling contributing conditions (for example, hypertension, diabetes), eliminating tobacco use (in any form), and addressing hearing loss.[117] In other

[113] Kelley AS, Covinsky KE, Gorges RJ, McKendrick K, Bollens-Lund E, Morrison RS, Ritchie CS. Identifying Older Adults with Serious Illness: A Critical Step toward Improving the Value of Health Care. Health Serv Res. 2017 Feb;52(1):113–131. doi: 10.1111/1475–6773.12479. Epub 2016 Mar 18. PMID: 26990009; PMCID: PMC5264106.

[114] *https://pmc.ncbi.nlm.nih.gov/articles/PMC5756466/pdf/jpm.2017.0548.pdf.*

[115] *https://www.capc.org/toolkits/building-and-supporting-effective-palliative-care-teams/.*

[116] Ornish, Dean, et al. ''Effects of Intensive Lifestyle Changes on the Progression of Mild Cognitive Impairment or Early Dementia Due to Alzheimer's Disease: A Randomized, Controlled Clinical Trial.'' *Alzheimer's Research & Therapy,* vol. 16, 2024, p. 122. *https://link.springer.com/article/10.1186/s13195-024-01482-z.*

[117] National Institute on Aging. ''*Cognitive Health and Older Adults.*'' National Institutes of Health, *https://www.nia.nih.gov/health/brain-health/cognitive-health-and-older-adults.* Accessed 30 Apr. 2026.

countries, there is randomized controlled trial evidence that multi-domain approaches can slow cognitive decline amongst at-risk older adults,[118] which appear to be superior to individual domain interventions such as physical activity programming or diet changes.[119] In the U.S. there have also been a number of studies demonstrating the potential impact of diet changes on cognition (for example, the MIND trial demonstrated improved cognition for both groups undergoing diet changes, however one diet was not shown to be superior).[12] [13] [14] [120] To support high-value care, the payer assuming financial risk for an individual's health would do so over a long-term to give that payer an incentive to invest in high-value care that reduces health care costs over that long-term. As discussed in the recent HHS Notice of Benefit and Payment Parameters for 2027,[121] creating these incentives for payers throughout the healthcare system is an HHS priority. Outside of these needed incentives exists Medicare fee-for-service, which has historically employed price-setting regimes that are not market-based and are slow to change with improvements and health innovations. As HHS continues to improve incentives for private payers to invest in preventive health care, we are interested in how to ensure fee-for-service Medicare is similarly able to benefit from better incentives to invest in high-value care.

To better understand resource costs associated with intensive, multi-domain interventions:

- Given the discussion of the evidence to date on the effectiveness of intensive lifestyle interventions for CMS to pursue, we are particularly interested in demonstrations of cost-savings associated with these and other interventions. Please cite any evidence available in your discussion.
- Given CMS' concern for addressing fraud, waste, and abuse throughout the Medicare program, please comment on any potential or observed FWA in diagnosis, treatment, or management of AD/ADRD.
- Given the emerging role of biomarker diagnostic testing (for example, p-tau217, et. al) for AD/ADRD leading to early diagnosis, please provide any evidence supporting earlier detection and its role in supporting improving AD/ADRD care and any potential role in identifying eligibility for an intensive lifestyle intervention focused on AD/ADRD.
- What are the essential domains to address in a multi-domain intensive lifestyle intervention to reduce the risk of cognitive decline for older adults at risk for developing AD/ADRD that would be appropriate to include under Medicare?
- Should these interventions be made available as a one-time service (that is, to teach older adults how to make changes in their lifestyle to help reduce AD/ADRD risk) or on a recurring (for example, annual) basis?
- Should the eligibility for these services be restricted to beneficiaries with a diagnosis of mild cognitive impairment (MCI), or early-stage dementia? If so, how should this diagnosis be made or confirmed?

Respondents to the general intensive lifestyle intervention question in the prior RFI focused on the differentiation between intensive lifestyle interventions (ILIs) and intensive behavioral therapy (IBT) where ILIs are more multi-domain, longitudinal, and comprehensive and typically incorporate a multi-disciplinary team and are delivered in a community setting, and noting these are needed flexibilities that current IBT coding does not currently accommodate. To better understand the resource costs and requirements for future AD/ADRD ILI services:

- Given ILI's are multi-domain, and likely include physical activity, nutrition, potentially additional domains such as sleep and stress management, who are the essential interdisciplinary team members that CMS should account for in developing appropriate resource costs for future services?
- How should supervision be determined for AD/ADRD ILI's? Is general supervision sufficient for ensuring clinical safety and oversight? Is direct supervision required?

While there are many variations of ILI's focusing on AD/ADRD that are delivered, the essential 'dose' of intervention or minimum frequency and duration of a future service, as well as the modality (that is, must this intervention be delivered purely in person, can it be delivered virtually) are all important to consider:

- What is the minimum frequency of sessions for an AD/ADRD ILI per week? What is the minimum number of weeks that will be necessary?
- Should CMS require a future AD/ADRD ILI to be delivered in person? Can it be delivered virtually?

Finally, while we are currently accepting applications for a CMS Innovation Center payment model to generate evidence associated with lifestyle interventions (MAHA ELEVATE),[122] including potentially intensive lifestyle interventions focused on reducing risk and/or slowing progression of AD/ADRD, currently CMS has no endorsement process for specific interventions. In development of the CMS Health Technology Ecosystem [123] and the library of applications:

- How should CMS support the development of our Health Technology Ecosystem to support older adults reducing their risk for developing AD/ADRD using intensive lifestyle changes?

Please note, this is a request for information (RFI) only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

H. Current Procedural Terminology (CPT) Request for Information (RFI)

The Current Procedural Terminology (CPT®) coding system is owned and copyrighted by the American Medical Association (AMA) and CMS uses CPT® under a royalty-free licensing agreement with the AMA.[124] The CPT® coding

[118] Ngandu, Tiia, et al. ''*A 2 Year Multidomain Intervention of Diet, Exercise, Cognitive Training, and Vascular Risk Monitoring versus Control to Prevent Cognitive Decline in At-Risk Elderly People (FINGER): A Randomised Controlled Trial.*'' *The Lancet,* vol. 385, no. 9984, 2015, pp. 2255–2263. *https://doi.org/10.1016/S0140-6736(15)60461-5.*

[119] ''2024 Lancet Commission Underscores the Potential for Dementia Risk Reduction, Identifying 14 Modifiable Risk Factors across the Life Course.'' *Alzheimer Europe,* 31 July 2024, *https://www.alzheimer-europe.org/news/2024-lancet-commission-underscores-potential-dementia-risk-reduction-identifying-14-modifiable.*

[120] Barnes, Lisa L., et al. ''*Trial of the MIND Diet for Prevention of Cognitive Decline in Older Persons.*'' *The New England Journal of Medicine,* vol. 389, no. 7, 2023, pp. 602–611. *https://www.nejm.org/doi/10.1056/NEJMoa2302368.*

[121] *https://www.govinfo.gov/content/pkg/FR-2026-05-20/pdf/2026-10050.pdf*

[122] Centers for Medicare & Medicaid Services. ''*MAHA ELEVATE (Make America Healthy Again: Enhancing Lifestyle and Evaluating Value-Based Approaches Through Evidence) Model.*'' *CMS.gov,* 2026, *https://www.cms.gov/priorities/innovation/innovation-models/maha-elevate.*

[123] Centers for Medicare & Medicaid Services. ''*Health Technology Ecosystem.*'' *CMS.gov, https://www.cms.gov/priorities/health-technology-ecosystem/overview.* Accessed 30 Apr. 2026.

[124] Centers for Medicare & Medicaid Services. *AMA Terms and Conditions.* Centers for Medicare

Continued

system was introduced by the AMA in 1966,[125] in part to ''encourage the use of standard terms and descriptors to document procedures in the medical record'' and ''help communicate accurate information on procedures and services to agencies concerned with insurance claims,'' and it ''provided the basis for a computer oriented system to evaluate operative procedures and contributed basic information for actuarial and statistical purposes.'' [126] The CPT® coding system went through a series of early version changes and in 1977 the AMA established the CPT–4 or 4th edition which established the current five-digit numeric structure of the CPT® coding system still used today.[127] The Health Care Financing Administration or HCFA, later renamed CMS,[128] in 1983 required the use of the Healthcare Common Procedure Coding System (HCPCS) for physician services and expanded to non-physician services in 1991.[129] and since this time HCPCS Level I services have been considerd synonymous with CPT, where Level II HCPCS refers to additional products, supplies, and services not included in the CPT® codes.[130]

Following the passage of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) the Department of Health and Human Services (HHS) in subsequent regulation defined the combination of HCPCS, as maintained and distributed by HHS, and CPT–4, as maintained and distributed by the AMA, as the nationally required medical data code sets for physician services, physical and occupational therapy services, radiologic procedures, clinical laboratory tests, other medical diagnostic procedures, hearing and vision services, and transportation services including ambulance services (45 CFR 162.1002(a)(5)). This is commonly understood as a regulatory requirement for CPT–4 codes to be used to define physician services. While this is HHS' current regulatory interpretation of the HIPAA (Pub. L. 104–191), it is important to note that HHS has only specified in regulation that HCPCS and CPT–4 to be used in combination. There is no specification in the HIPAA statute regarding the manner in which these national coding sets may be used or how they may be combined, and only HHS interpretation, not the Act itself, mentions CPT®.

New CPT® codes are introduced by the CPT® Advisory Committee. This committee was established following the initial publication of the CPT® coding system in 1966, which provides advice on procedure coding and appropriate nomenclature as relevant to the committee member's specialty and consists of ''members of national medical specialty societies seated in the AMA House of Delegates.'' [131] When a new CPT® code is defined by the CPT® Advisory Committee, it is then assigned a payment value by the AMA Relative Value Scale Update Committee or RUC.[132]

The AMA RUC was established in 1992, after CMS transitioned to the resource-based relative value scale (RBRVS) to provide recommendations on the valuation of physician services. As established in section 1848 of the Act, CMS began paying for physician services in 1998 on the basis of a product of the relative value of the physician service, incorporating the physician work, the practice expense, and the malpractice component. These elements form the basis for the RBRVS. The components of physician services were originally established by a team of Harvard researchers (William Hsiao, et al.) and CMS has occasionally referenced the 'Harvard' valuations making reference to these original contributions.[133] According to the AMA, the AMA RUC ''*provides medicine a voice in shaping Medicare relative values,*'' and by all published estimates this has been an effective mechanism.[134]

There has also been longstanding concern expressed over the Federal reliance on a private organization with such an obvious conflict of interest as providing information on the time and resource requirements to conduct physician services when this information may influence their own payment. For nearly 20 years, MedPAC has expressed concern over the influence of the AMA RUC to value services, specifically noting that CMS has ''*over-relied on specialty societies with a financial stake in the process*'' and has recommended that CMS establish a separate group of experts to make payment recommendations.[135] Further, we note the historic reliance on the CPT and RUC process as a potential contributor to the development of US health care as a 'sick care' system with limited emphasis on prevention and lifestyle modifications and which may inhibit progress on the Secretarial priority to Make America Healthy Again. Additionally, we note a recent National Academies of Sciences, Engineering, and Medicine (NASEM) report recommending RUC alternatives for establishing primary care payment valuation and recommendations for alternative sources for data collection.[136]

Given these longstanding concerns, we are seeking comment on a number of areas regarding the influence of the CPT® coding system and AMA process on physician payment policy as part of the Secretarial priority to Make America Healthy Again.

(1) What, if any, evidence is there for CMS to consider regarding the harms or

& Medicaid Services, n.d., *https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNEdWebGuide/Downloads/AMA-Terms-Conditions.pdf*.

[125] American Medical Association. *History of CPT® Content.* American Medical Association, 5 Dec. 2025, *https://www.ama-assn.org/practice-management/cpt/history-cpt-content*.

[126] American Medical Association. *The Purpose of the CPT® Coding System & the CPT® Editorial Panel.* American Medical Association, 10 Sept. 2025, *https://www.ama-assn.org/about/cpt-editorial-panel/purpose-cpt-coding-system-cpt-editorial-panel*.

[127] American Medical Association. *The Purpose of the CPT® Coding System & the CPT® Editorial Panel.* American Medical Association, 10 Sept. 2025, *https://www.ama-assn.org/about/cpt-editorial-panel/purpose-cpt-coding-system-cpt-editorial-panel*.

[128] Centers for Medicare & Medicaid Services, Department of Health and Human Services. *Statement of Organization, Functions, and Delegations of Authority*. **Federal Register**, 5 July 2001, *https://www.federalregister.gov/documents/2001/07/05/01-16800/centers-for-medicare-and-medicaid-services-statement-of-organization-functions-and-delegations-of*.

[129] *Medicare Program; Fee Schedule for Physicians' Services; Proposed Rule.* **Federal Register**, vol. 56, no. 108, 5 June 1991, pp. 25792–25978. U.S. Government Publishing Office, *https://www.govinfo.gov/content/pkg/FR-1991-06-05/pdf/FR-1991-06-05.pdf*

[130] Centers for Medicare & Medicaid Services. ''Healthcare Common Procedure Coding System (HCPCS).'' *Centers for Medicare & Medicaid Services,* U.S. Department of Health and Human Services, *https://www.cms.gov/medicare/coding-billing/healthcare-common-procedure-system*. Accessed 7 July 2026.

[131] American Medical Association. *CPT® Nominations & Opportunities.* American Medical Association, 11 Feb. 2025, *https://www.ama-assn.org/about/cpt-editorial-panel/cpt-nominations-opportunities*.

[132] American Medical Association. *RVS Update Committee (RUC).* American Medical Association, 4 Mar. 2026, *https://www.ama-assn.org/about/rvs-update-committee-ruc/rvs-update-committee-ruc*.

[133] Hsiao WC, Braun P, Kelly NL, Becker ER. Results, Potential Effects, and Implementation Issues of the Resource-Based Relative Value Scale. *JAMA.* 1988;260(16):2429–2438. doi:10.1001/jama.1988.03410160105013.

[134] American Medical Association. *RVS Update Committee (RUC).* American Medical Association, 4 Mar. 2026, *https://www.ama-assn.org/about/rvs-update-committee-ruc/rvs-update-committee-ruc*.

[135] Medicare Payment Advisory Commission. *Testimony: Options to Improve Medicare's Payments to Physicians.* 8 May 2007, *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/congressional-testimony/051007_Testimony_MedPAC_physician_payment.pdf*.

[136] National Academies of Sciences, Engineering, and Medicine. *Improving Primary Care Valuation Processes to Inform the Physician Fee Schedule.* National Academies Press, 2025, *https://doi.org/10.17226/29069*.

challenges associated with AMA's monopoly over CPT–4 licenses for health care entities? Please cite potential improvements to patient care diverted or delayed due to AMA'S monopoly over CPT codes, including inhibited innovations and acquisition or maintenance costs of CPT® licensure.

(2) What, if any, evidence is there that the generation of CPT–4 codes follows a process of identification of medical necessity? What opportunities or examples from other populations, sites of care, or international health systems could instruct a process of identification of medical necessity in the CPT–4 code development process?

(3) A combination of CPT–4 and HCPCS codes were formally adopted by HHS as the legal standard for national coding for physician and other services as part of implementing HIPAA (45 CFR 162.1002(a)(5)). If CMS were to revisit this standard in future rulemaking, which if any alternatives exist to CPT–4 for CMS to consider as part of the national coding standard for physician services? Would CMS need to specify a separate legal standard, or could CMS allow for private competition to supplement the existing CPT–4 coding standard?

(4) What objective alternatives exist, or could be developed, to maintain a more objective process to the current AMA CPT and RUC committee processes? How would these alternatives support or inhibit innovation?

(5) What are the benefits and drawbacks of paying for physician procedural services on the basis of the underlying International Classification of Diseases, 10th Revision (ICD–10) procedure code, as an alternative to CPT–4 code? How could the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) services be grouped or bundled into payment categories, similar to Medicare Severity Diagnosis Related Groups (MS–DRGs), or Outpatient Prospective Payment System (OPPS) Ambulatory Payment Classifications (APCs)? What other alternatives exist for bundling or grouping procedural services?

III. Other Provisions of the Proposed Rule

A. Drugs and Biological Products Paid Under Medicare Part B

1. Requiring Manufacturers of Certain Single-Dose Container or Single-Use Package Drugs To Provide Refunds With Respect to Discarded Amounts (§§ 414.902 and 414.940)

a. Background

Section 1847A(h) of the Act requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter referred to as ''refundable drug'') for calendar quarters beginning January 1, 2023.

The calculation of the refund is codified at § 414.940(c). For a new refund quarter (as defined at § 414.902) beginning on or after January 1, 2023, an amount equal to the estimated amount (if any) by which:

- The product of the total number of units of the billing and payment code for such drug that were discarded during such new refund quarter; and the amount of payment determined for such drug or biological under section 1847A(b)(1)(B) or (C) of the Act, as applicable, for such new refund quarter.
- Exceeds an amount equal to the applicable percentage of the estimated total allowed charges for such drug for the new refund quarter.

Section 1847A(h)(3)(B)(i) of the Act establishes an applicable percentage of 10 percent, but provides that, in the case of a refundable drug that has unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, the Secretary, through notice and comment rulemaking, may increase such applicable percentage as determined appropriate by the Secretary. Section 1847A(h)(8)(B)(ii) of the Act describes a drug or biological approved by the Food and Drug Administration (FDA) for which dosage and administration instructions included in the labeling require filtration during the drug preparation process, prior to dilution and administration, and require that any unused portion of such drug after the filtration process be discarded after the completion of such filtration process. Drugs with an increased applicable percentage are listed on the CMS website.[137]

For previous rulemaking in which we finalized to increase the applicable percentage of a drug with unique circumstances involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act, we explained specifically why the loss of product met the statutory requirements. In the CY 2023 Physician Fee Schedule (PFS) final rule (87 FR 69729), we finalized an increase in the applicable percentage for a drug reconstituted with a hydrogel and administered via ureteral catheter or nephrostomy tube into the kidneys, where a substantial amount of reconstituted hydrogel adheres to the vial wall during preparation and cannot be withdrawn for administration. Because this unavoidable preparation-related loss is similar to the loss described in section 1847A(h)(8)(B)(ii) of the Act, we stated that such a drug that is reconstituted with a hydrogel and has variable dosing based on patient-specific characteristics (for example, Jelmyto® (mitomycin for pyelocalyceal solution)) should be considered to have unique circumstances as described in section 1847A(h)(3)(B)(ii) of the Act that would warrant an increased applicable percentage.

In the CY 2024 PFS final rule (88 FR 79052), we increased the applicable percentage for certain drugs with low volume doses and stated that such drugs have unique circumstances because certain FDA-labeled amounts on the vial or package are unused and discarded after administration of the labeled dose and these amounts are not available to be administered. The unique circumstances described for such drugs are similar to loss of product from filtration described in section 1847A(h)(8)(B)(ii) of the Act because in both circumstances, such amounts lost are amounts that are not part of the recommended dose and are not available to be administered to the patient (one being loss due to labeled amounts remaining in the filter and the other due to labeled amounts remaining in other areas such as the vial or syringe).

In the CY 2024 PFS final rule, we also finalized an increased applicable percentage for certain orphan drugs furnished to fewer than 100 unique beneficiaries per calendar year. We explained (88 FR 79053 through 79057) that because of the substantial statistical variation (based on demonstrated JW modifier claims data from 2021 and 2022) from quarter to quarter for such drugs, we believe it would be difficult to optimize the presentation of the drug to consistently minimize the discarded amounts to less than 10 percent given the small number of patients receiving the drug. We considered the higher percentage of unused and discarded amounts from such drugs as

[137] *https://www.cms.gov/medicare/payment/part-b-drugs/discarded-drugs.*

unavoidable loss due to both the low number of unique beneficiaries receiving the drug contributing statistically higher variability in discarded amounts. Also, due to the low numbers of patients available to study for rare disease, it may be more difficult to determine the most efficient vial size for the patient population who receive the drug post-marketing. We stated this is similar to the loss of product due to filtration described in section 1847A(h)(8)(B)(ii) of the Act because the loss is unavoidable in both circumstances. In the case of filtration described in statute, the loss is unavoidable because certain amounts of product will be left within the filter and unavailable for administration; in the case of rarely utilized orphan drugs, the loss is unavoidable because of the variability of potential doses (and low number of patients receiving the drug) leading to an inability to develop a package size that will result in a consistent average percentage of discarded units.

We stated in the CY 2024 PFS final rule (88 FR 79057) that we do not consider the following to be unique circumstances warranting an increased applicable percentage at this time: weight-based doses, body surface area (BSA)-based doses, varying surface area of a wound, loading doses, escalation or titration doses, tapering doses, and dose adjustments for toxicity because we believe manufacturers can optimize the availability of products for these circumstances to limit the percentage of discarded units for a drug, unlike the circumstances of manufacturers of drugs that require filtration during the preparation process, as described in section 1847A(h)(8)(B)(ii) of the Act.

We also explained in the CY 2024 PFS final rule (88 FR 79060) that, while we cannot anticipate future drug development or what unique circumstances might arise, we can offer our analysis of the unique circumstances we consider involving similar loss of product as that described in section 1847A(h)(8)(B)(ii) of the Act for drugs that are reconstituted in hydrogel and with variable dosing based on patient-specific characteristics (87 FR 69727 through 69731), drugs with low volume doses, and rarely utilized orphan drugs (88 FR 79052 through 79057). Regarding examples of evidence, we noted minimum vial fill studies and dose preparation studies in the CY 2024 PFS proposed rule, both of which are suitable for justifying increased applicable percentages because they can establish that certain unusable amounts of a product are necessarily included in a container to safely and consistently administer the labeled therapeutic dose to a patient.

b. Application for Increased Applicable Percentage

Section 1847A(h)(3)(B)(ii) of the Act permits the Secretary to increase the applicable percentage for a refundable drug that has unique circumstances through notice-and-comment rulemaking. In the CY 2024 PFS final rule (88 FR 79057 through 79060), we finalized an application process (CMS–10835, OMB 0938–1435) by which manufacturers can apply for an increased applicable percentage for a drug and may request that we consider an individual drug to have unique circumstances for which an increased applicable percentage is appropriate. Under § 414.940(e)(2), an application must be submitted by February 1 of the CY prior to the year the increased applicable percentage would apply; for a drug that is not FDA-approved by February 1, the application must have FDA approval by August 1, and the manufacturer must notify CMS and submit the FDA-approved label by September 1 of that year. The application must include a written request that the drug be considered for an increased applicable percentage based on its unique circumstances; FDA-approved labeling for the drug (or, if the drug is not approved by the February 1 application deadline described in paragraph (e)(2) of this section, documentation of FDA acceptance of the application for review); justification for the consideration of an increased applicable percentage based on such unique circumstances; and justification for the requested increase in the applicable percentage. Following review of timely applications, CMS will summarize its analyses of applications and propose appropriate increases in rulemaking. If adopted, the increased applicable percentage will be the applicable percentage beginning January 1 of the following calendar year.

We received one application requesting an increased applicable percentage for consideration for CY 2027 from the manufacturer of Leukine® (sargramostim),[138] who resubmitted a request for a 72 percent applicable percentage after applying the previous 2 years. The applicant submitted the information required at § 414.940(e)(1), including, as applicable, FDA-approved labeling for the drug, justification for consideration of an increased applicable percentage, and justification for the requested applicable percentage.

Leukine® is a leukocyte growth factor with five FDA-approved indications related to hematological conditions and hematopoietic recovery, as well as one indication to increase survival following acute exposure to myelosuppressive doses of radiation. The applicant's submitted FDA-approved labeling for the drug does not include the adjuvant uses described in the application (further described later in this paragraph) due to ongoing cancer vaccine adjuvant trials. The applicant reemphasized that multiple sponsors are in late-stage development, with a total of 27 Phase II and Phase III clinical trials, an increase from 22 reported in the previous year, investigating Leukine® as a vaccine adjuvant for oncology indications, specifically to stimulate the immune response of dendritic cells when used alongside these vaccines. We note that cancer treatment vaccines differ from the vaccines that protect against viruses, such as the influenza virus. Instead of preventing disease, cancer treatment vaccines aim to stimulate the immune system to attack existing cancer cells in the body.[139] The applicant stated that it has no ownership stake in the development of these cancer treatment vaccines and does not possess control or influence over the design and execution of the clinical trials. The applicant further explained that the estimated completion dates for Phase III clinical trials vary, with the earliest expected in late 2026 [140] [141] and the latest in March 2029.[142]

The adjuvant use of Leukine® in predetermined dosage is distinct from its six FDA-approved indications, all of which have dosages that are based on body weight or body surface area (BSA). The adjuvant use dosages of Leukine® in clinical trials are generally much smaller than dosages for indications in the FDA-approved labeling. The smallest dose of Leukine® used for vaccine adjuvant purposes of which the applicant is aware (that is, 70 mcg) would lead to as much as 72 percent of the drug being discarded from a single-dose 250 mcg lyophilized vial, which is the only size available commercially. The applicant suggests that if use of these small doses were to become more common for an approved indication, the percentage of discarded units could

[138] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/103362s5249lbl.pdf.*

[139] *https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/cancer-vaccines.html.*

[140] *https://clinicaltrials.gov/study/NCT04229979.*

[141] *https://clinicaltrials.gov/study/NCT05232916.*

[142] *https://clinicaltrials.gov/study/NCT05100641.*

increase the discarded drug refund amount that could be owed by the applicant, even though the applicant lacks control or knowledge of the potential variability of the discarded amounts that may occur if Leukine® were used for such purposes. The applicant notes that if another manufacturer were to seek FDA approval for adjuvant use of sargramostim but was not involved in its production, the available single-dose 250-mcg vial presentation of Leukine® would likely not be optimized for the small doses being studied in these trials. The applicant also expresses concern about potential refund liability if small-dose adjuvant use becomes more common.

The application builds on prior submissions by reiterating that Leukine® appears on FDA's list of essential medicines,[143] that the Administration for Strategic Preparedness and Response (ASPR) has documented a requirement to procure and stockpile Leukine® as a medical countermeasure for neutropenia resulting from acute radiation syndrome,[144] and that the applicant continues to collaborate with the Biomedical Advanced Research and Development Authority (BARDA). In this application, the applicant also newly states that Leukine® has been designated a ''Medical Product Priority'' by the Department of Defense (DoD) under Public Law 115–92 (enacted December 12, 2017).[145] DoD maintains a Medical Product Priority list as part of the DoD–FDA coordination framework established following Public Law 115–92 and formalized in the FDA-DoD Memorandum of Understanding.[146] Under this framework, DoD identifies and maintains a list of its highest-priority medical products to support focused, recurring engagement with FDA; however, we could not corroborate a Leukine® designation using resources available for public review. The applicant's 2022 public announcement of an Other Transaction Agreement with the DoD references Leukine® as a potential medical countermeasure for sulfur mustard gas exposure,[147] but it does not reference a ''Medical Product Priority'' designation. Additionally, a study published in 2025 comparing essential medicines across U.S. Federal agencies and the World Health Organization did not identify Leukine® on DoD's operational medicines list. The study noted that the DoD operational medicines list is a subset of FDA's essential medicines list—meaning medicines on the DoD list also appear on FDA's list, but not all medicines on FDA's list appear on the DoD list.[148] Nevertheless, these emergency-response and preparedness-related listings or designations do not, by themselves, demonstrate unique circumstances related to discarded amounts for purposes of an increased applicable percentage because they are designed to support Federal planning, procurement, and interagency coordination to ensure adequate supply of essential products, rather than to provide evidence of drug-specific, unavoidable product loss similar to loss of product as described in section 1847A(h)(8)(B)(ii) of the Act.

As part of CMS' review of the application, we analyzed existing claims data from the first quarter of 2018 through the last quarter of 2025 and found the percentage of units discarded for Leukine® (HCPCS code J2820) ranged from 1.1 percent to 4.9 percent, which is below the applicable percentage of 10 percent. The quarterly discarded percentages during this time frame were stable, with a standard deviation of less than 1 percentage point and values tightly clustered around a mean of approximately 2.4 percent. This is notably lower than the 6.21 percent average standard deviation observed for rarely utilized orphan drugs, as reported in the CY 2024 PFS final rule (88 FR 79053). Accordingly, the applicant's requested applicable percentage relies on assumptions about hypothetical future dosing and utilization that are not evident in Part B claims data available to date.

At the time of the CY 2026 PFS proposed rule, the impact of a potential adjuvant indication with a type of immunotherapy commonly referred to as cancer vaccines [149] on the current percentage of units discarded was uncertain. Additionally, it was not yet known whether sargramostim would be approved for additional indications and dosages described by the applicant, and the available data was insufficient for CMS to determine whether Leukine® had unique circumstances prompting an increase in the applicable percentage. Therefore, we did not propose to increase the applicable percentage in the CY 2026 PFS proposed rule. The applicant agreed with CMS' rationale for this decision.

Although the applicant agreed with CMS's rationale in the CY 2026 PFS proposed rule, they submitted a new application for CY 2027 with updated information on oncology vaccine-adjuvant clinical trials and projected timing for potential FDA approvals, as well as an asserted DoD ''Medical Product Priority'' designation. However, the core uncertainties identified in the CY 2026 PFS proposed rule persist: the absence of FDA-approved labeling for the asserted adjuvant indication(s) or dosage(s) and uncertainty regarding whether such uses would be utilized to an extent that discarded amounts would exceed the applicable percentage in a calendar quarter.

The existing claims data and trends for discarded amounts of sargramostim discussed earlier do not support a determination that Leukine® has qualifying unique circumstances that would support an increased applicable percentage under section 1847A(h)(3)(B)(ii) of the Act. Unlike the analysis leading to an increased applicable percentage for certain orphan drugs as described earlier in the Background section III.A.1.a. of this proposed rule, which relied on evidence indicating that certain orphan drugs have unavoidable loss of drug similar to the loss of product described in section 1847A(h)(8)(B)(ii) of the Act, the justification presented by the applicant for an increased applicable percentage for their product is based largely on projections regarding potential future oncology vaccine-adjuvant use at smaller doses. These projections assume a utilization scenario in which sargramostim use would shift predominantly to the studied indications at the lowest study dose discussed earlier in this section, rather than remaining primarily under the FDA-approved indications, for which claims data currently demonstrate very low discarded amount percentages with no trending increase. In the absence of qualifying unique circumstances, we do not reach the question of whether the requested applicable percentage would be appropriate.

Accordingly, we are not proposing an increase in the applicable percentage for

[143] *https://www.fda.gov/media/143406/download?attachment.*

[144] *https://sam.gov/opp/f4735f1f235847a0bb138c13333097de/view.*

[145] To amend the Federal Food, Drug, and Cosmetic Act to authorize additional emergency uses for medical products to reduce deaths and severity of injuries caused by agents of war, Public Law 115–92, 131 Stat. 2023 (2017).

[146] *https://www.fda.gov/about-fda/domestic-mous/mou-225-19-001.*

[147] *https://www.partnertx.com/partner-therapeutics-announces-contract-with-u-s-department-of-defense-for-advanced-development-of-leukine-to-treat-sulfur-mustard-gas-hd-exposure/.*

[148] ML Janvrin, A Kanagaratnam, VA Suarez et al. A comparison of the essential medicines lists of the U.S. Department of Health and Human Services, the U.S. Department of Defense, the U.S. Food and Drug Administration, and the World Health Organization, Journal of the American Pharmacists Association, 65(5),2025.

[149] *https://www.cancerresearch.org/treatment-types/cancer-vaccines.*

Leukine® for CY 2027. The applicant may reapply in a future application cycle when more information, such as FDA-approved labeling reflecting new indications or dosages, becomes available. We welcome comments on the application for increased applicable percentage.

B. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background on RHC and FQHC Payment Methodologies

As provided in 42 CFR part 405, subpart X of our regulations, RHC and FQHC visits generally are defined as face-to-face encounters between a patient and one or more RHC or FQHC practitioners during which one or more RHC or FQHC qualifying services are furnished. RHC and FQHC practitioners are physicians, nurse practitioners (NPs), physician assistants (PAs), Certified Nurse Midwives (CNMs), clinical psychologists (CPs), licensed marriage and family therapists, mental health counselors, and clinical social workers, and, subject to certain conditions, a registered nurse or licensed practical nurse that is furnishing care to a homebound RHC or FQHC patient in an area verified as having shortage of home health agencies. Transitional Care Management (TCM) services can also be paid by Medicare as an RHC or FQHC visit. In addition, Diabetes Self-Management Training (DSMT) or Medical Nutrition Therapy (MNT) services furnished by a certified DSMT or MNT program may also be considered FQHC visits for Medicare payment purposes. Only medically necessary medical, mental health, or qualified preventive health services that require the skill level of an RHC or FQHC practitioner are RHC or FQHC billable visits. Services furnished by auxiliary personnel acting under the supervision of the RHC or FQHC practitioner, are considered incident to the visit and are included in the per-visit payment.

RHCs generally are paid an all-inclusive rate (AIR) for all medically necessary medical and mental health services and qualified preventive health services furnished on the same day (with some exceptions). The AIR is subject to a payment limit, meaning that an RHC will not receive any payment beyond the specified limit amount per visit. As of April 1, 2021, all RHCs are subject to statutory upper payment limits determined in accordance with section 1833(f) of the Act, as amended by section 130 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260).

FQHCs were paid under the same AIR methodology until October 1, 2014. Beginning on that date, in accordance with section 1834(o) of the Act (as added by section 10501(i)(3) of the Patient Protection and Affordable Care Act (Pub. L. 111–148, March 23, 2010)), FQHCs began to transition to the FQHC PPS system, in which they are paid based on the lesser of the FQHC PPS rate or their actual charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC PPS geographic adjustment factor (GAF). The rate is increased by 34 percent when an FQHC furnishes care to a patient that is new to the FQHC, or to a beneficiary receiving an initial preventive physical examination (IPPE) or has an annual wellness visit (AWV). Section 1834(o)(2)(B)(ii) requires the FQHC PPS base rate be updated annually by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the Medicare Economic Index (MEI) (as defined in section 1842(i)(3)) for the year involved. See section III.B.4 of this proposed rule, for the proposed CY 2027 updates.

Under the general authority of section 1834(o) of the Act, CMS codified at §§ 405.2462 and 405.2464 to pay historically excepted tribal FQHCs using the Medicare outpatient per visit rate established annually by IHS, rather than the FQHC PPS rate (80 FR 71089). These rates are set by IHS under sections 321(a) and 322(b) of the Public Health Service (PHS) Act based on prior-year cost reports. The outpatient per visit rate applies only to provider-based IHS or tribal facilities (§ 413.65(m)) and historically excepted tribal FQHCs. For CY 2026, the rate is $733 per visit in the lower 48 States.

Both the RHC AIR and FQHC PPS payment rates were initially designed to reflect the cost of all services and supplies that an RHC or FQHC furnished to a patient in a single day. These nearly all-inclusive rates are not adjusted at the individual level for the complexity of individual patient health care needs, the length of an individual visit, or the number or type of practitioners involved in the patient's care. Instead for RHCs, all costs for the facility over the course of the year are aggregated, and an AIR is derived from these aggregate expenditures. Section 1834(o)(2)((B)(ii) of the Act requires the FQHC PPS base rate be updated annually by the percentage increase in a market basket of Federally qualified health center goods and services as promulgated through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1842(i)(3)) of the Act for the year involved.

RHCs and FQHCs are also paid for non-face-to-face care management work involved in coordinating care outside of the RHC AIR and FQHC PPS (§ 405.2464(c)). That is, payment is based on the PFS national non-facility payment rate and is made in addition to the otherwise billable visit for patients utilizing chronic care management (CCM), principal care management (PCM), general behavior health integration (BHI), chronic pain management (CPM), remote physiologic monitoring (RPM), remote therapeutic monitoring (RTM), community health integration (CHI), principal illness navigation (PIN), PIN-peer support services, advanced primary care management (APCM), and psychiatric collaborative care model (CoCM). In addition, payment is based on the PFS national non-facility payment rate and is made in addition to the otherwise billable visit for communication technology-based services (CTBS) and remote evaluation services (§ 405.2464(e)).

In the CY 2026 PFS final rule (90 FR 49556 through 49558), we finalized a policy that effective January 1, 2026, services that are established and paid under the PFS and designated as care management services would be considered ''care coordination services'' for purposes of separate payment for RHCs and FQHCs. The care coordination codes can be found in the PFS table entitled ''Designated Care Management Services'', which is published annually with the PFS Final Rule Addenda on the CMS website.

2. Payment for Certain Preventive Services

a. Background

Medicare Part B covers a comprehensive set of preventive services aimed at promoting early detection and reducing the risk of chronic disease.[150] These services include wellness visits (such as the IPPE and AWV), evidence-based screenings for cancer and chronic conditions, behavioral health and risk factor screenings, certain vaccinations, and preventive counseling interventions. Coverage for many of these services was expanded under sections 4103 and 4104 of the Affordable Care Act; the services

[150] *https://www.cms.gov/medicare/prevention/prevntiongeninfo/medicare-preventive-services/mps-quickreferencechart-1.html.*

are covered without beneficiary cost-sharing when furnished according to Medicare requirements. Collectively, they are designed to support proactive, patient-centered care and improve long-term health outcomes, particularly when delivered in primary care settings. CMS has implemented these statutory provisions through regulations at 42 CFR part 410, which define, among other things, the coverage, eligibility, and frequency requirements for preventive services.

CMS also establishes and updates coverage of preventive services through the National Coverage Determination (NCD) process, if such services are recommended with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF). These processes specify the conditions under which preventive services are considered reasonable and necessary for Medicare beneficiaries.

Payment for preventive services is made in accordance with applicable Medicare payment systems, for example, the PFS under 42 CFR part 414. CMS provides additional operational guidance through subregulatory instructions, including manuals and program transmittals, to ensure consistent implementation of coverage and payment policies. Beneficiary copayment and deductible (where applicable) is waived by the Affordable Care Act for the IPPE and AWV, and for Medicare-covered preventive services recommended by the USPSTF with a grade of A or B.

When statutorily permissible, we pay for covered preventive services under Medicare Part B to RHCs and FQHCs pursuant to such facilities' encounter-based payment methodologies, rather than as PFS separately billable services, except where otherwise specified.

RHCs are paid under the AIR methodology for a limited number of qualified preventive health services furnished by an RHC practitioner. FQHCs are paid under the FQHC PPS for qualified preventive health services and preventive primary health services required under section 330 of the PHS Act.[151] A qualified preventive health service refers to a Medicare-covered preventive service that also meets the requirements for a billable RHC or FQHC visit, including a face-to-face encounter with a RHC or FQHC practitioner (that is, the service is at a level that requires the expertise of a RHC or FQHC practitioner). Specifically, RHCs and FQHCs are paid for the professional component of allowable preventive services when the program requirements are met and frequency limits (where applicable) have not been exceeded.[152] In this context, professional component refers to the practitioner's clinical service associated with a preventive service, as opposed to the technical or ancillary elements of the service. Preventive services furnished in other settings, for example, physician offices, are generally paid on a service-by-service basis. However, preventive services that do not constitute a separate billable RHC or FQHC visit must be furnished as part of a qualified RHC or FQHC visit (for example, an evaluation and management (E/M) visit) to be billable to Medicare. If a preventive service, that does not constitute a billable RHC or FQHC visit, is furnished and is not part of a qualified RHC or FQHC visit, it may not be payable under Medicare.

b. Federal Initiatives To Improve Health Outcomes and Access to Care

(1) The Make America Healthy Again (MAHA) Commission

On February 13, 2025, the President signed an Executive Order establishing the MAHA Commission within the Department of Health and Human Services (HHS).[153] The Commission is chaired by the Secretary of HHS and includes representatives from multiple Federal agencies. The Commission was directed to assess contributing factors to chronic disease and to develop a coordinated Federal strategy to improve population health outcomes, with an initial focus on pediatric populations.

In 2025, the Commission released an assessment identifying a range of factors associated with chronic disease, including dietary patterns, environmental exposures, physical inactivity, and other behavioral and upstream drivers of health. The Commission subsequently issued a strategy outlining potential Federal actions to address these factors through cross-agency coordination, research, and programmatic initiatives.[154]

Although the Commission's initial focus is on childhood health, its findings are relevant to Federal health programs serving other populations, including Medicare beneficiaries. Chronic conditions associated with the factors identified by the Commission are prevalent among Medicare beneficiaries and are significant drivers of program expenditures.

(2) The Rural Health Transformation (RHT) Program

The RHT Program was authorized by section 71401 of the Working Families Tax Cut (WFTC) (Pub. L. 119–21, July 4, 2025) legislation and empowers States to strengthen rural communities across America by improving healthcare access, quality, and outcomes by transforming the healthcare delivery ecosystem. On September 15, 2025, we announced the availability of funding under the RHT Program and program objectives for States seeking to participate in this initiative, among other information. The RHT Program represents a $50 billion Federal investment over 5 Federal fiscal years (FY 2026 to FY 2030), with $10 billion available annually, intended to strengthen health care infrastructure, expand access to care, and improve health outcomes in rural communities across the United States.

The program has five strategic goals, grounded in the permissible uses of funds under the statute: Make Rural America Healthy Again—Support rural health innovations and new access points to promote preventive health and address the root causes of disease; Sustainable Access—Improve the efficiency and long-term sustainability of rural health care providers as enduring access points for care; Workforce Development—Strengthen recruitment and retention of qualified health care professionals in rural communities; Innovative Care—Advance innovative care models that improve health outcomes, coordinate care, and promote flexible care arrangements; and Technology Innovation—Foster the adoption of innovative technologies that promote efficient care delivery, data security, and access to digital health tools for rural facilities, providers, and patients.[155]

c. Increasing Access to Diabetes Self-Management Training (DSMT) and Medical Nutrition Therapy (MNT) Services in RHCs

Section 4105 of the Balanced Budget Act of 1997 added section 1861(qq) of the Act to permit Medicare coverage of outpatient DSMT services when these services are furnished by a certified provider who meets certain quality

[151] Section 1861(aa)(3) of the Act (42 U.S.C. 1395x(aa)(3)) defines Federally Qualified Health Center (FQHC) services to include services and supplies furnished by an FQHC, including preventive primary health services required under section 330 of the Public Health Service Act (42 U.S.C. 254b).

[152] Pub. 100–02, Chapter 13, Section 220—Preventive Health Services.

[153] Exec. Order No. 14212, Establishing the Make America Healthy Again Commission, 90 FR 9833 (Signed, February 13, 2025).

[154] *https://www.usda.gov/about-usda/news/press-releases/2025/09/09/maha-commission-unveils-sweeping-strategy-make-our-children-healthy-again.*

[155] *https://www.cms.gov/priorities/rural-health-transformation-rht-program/overview.*

standards. This program is intended to educate beneficiaries in the successful self-management of diabetes. The program includes instructions in self-monitoring of blood glucose; education about diet and exercise; an insulin treatment plan developed specifically for the patient who is insulin dependent; and motivation for patients to use the skills for self-management. DSMT services may be covered by Medicare only if the treating physician or treating qualified non-physician practitioner who is managing the beneficiary's diabetic condition certifies that such services are needed. The referring physician or qualified non-physician practitioner must maintain the plan of care in the beneficiary's medical record and documentation substantiating the need for training on an individual basis when group training is typically covered, if so ordered. A designated certified provider bills for DSMT provided by an accredited DSMT program. Certified providers must submit a copy of their accreditation certificate to the contractor. The statute states that a ''certified provider'' is a physician or other individual or entity designated by the Secretary that, in addition to providing outpatient self—management training services, provides other items and services for which payment may be made under title XVIII of the Act, and meets certain quality standards.

We designated all providers and suppliers that bill Medicare for other individual services such as hospital outpatient departments, renal dialysis facilities, physicians and durable medical equipment suppliers, as eligible to be certified providers. All suppliers/providers who may bill for other Medicare services or items and who represent a DSMT program that is accredited as meeting quality standards can bill and receive payment for the entire DSMT program.

Registered dietitians are eligible to bill on behalf of an entire DSMT program on or after January 1, 2002, if the provider employing or contracting with the dietitian has obtained a Medicare provider number. A dietitian may not be the sole practitioner of the DSMT service.[156] Under our regulations at § 410.144(a)(4)(ii), there is an exception for dietitians working in rural areas. In a rural area, an individual who is qualified as a registered dietitian and as a certified diabetic educator who is currently certified by an organization approved by us may furnish training and is deemed to meet the multidisciplinary team requirement. DSMT requirements for coverage, beneficiary eligibility, services and frequency of services and provider certification and accreditation are codified in 42 CFR 410 subpart H and the National Coverage Determination (NCD) 40.1.[157]

Section 1861(s)(2)(V) of the Act authorizes Medicare Part B coverage of MNT for certain beneficiaries who have diabetes or a renal disease. Regulations for MNT were established effective January 1, 2002, at 42 CFR 410 subpart G (66 FR 55246 and 55331). An NCD establishes the duration and frequency limits for the MNT benefit and coordinates MNT and DSMT.[158] MNT services are defined in section 1861(vv) of the Act as nutritional diagnostic, therapeutic, and counseling services provided by a registered dietitian or nutrition professional for the purpose of managing diabetes or a renal disease under a referral by a physician. The provider qualifications for registered dieticians and nutrition professionals are defined in § 410.134.

Effective January 1, 2022, coverage of MNT, for the first year a beneficiary receives MNT, with either a diagnosis of renal disease or diabetes as defined at 42 CFR 410.130 is 3 hours of administration. Coverage in subsequent years for renal disease or diabetes is 2 hours. The dietitian/nutritionist may choose how many units are administered per day as long as all of the other requirements of the NCD and §§ 410.130 through 410.134 are met. Under the exception at § 410.132(b)(5), additional hours are considered to be medically necessary and covered if the physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care. If the physician determines that receipt of both MNT and DSMT is medically necessary in the same episode of care, Medicare will cover both DSMT and MNT initial and subsequent years without decreasing either benefit as long as DSMT and MNT are not provided on the same date of service.

Section 5114 of the Deficit Reduction Act of 2005 amended section 1861(aa)(3) of the Act to add DSMT and MNT services as covered and paid under the FQHC benefit, effective January 1, 2006. Then the Affordable Care Act further expanded the scope of FQHC services to include preventive services defined under section 1861(ddd)(3) of the Act, however, RHCs were not similarly addressed. Under this statutory authority, DSMT and MNT services furnished by certified providers are stand-alone billable visits in FQHCs when all of the requirements are met. If DSMT or MNT services are provided on the same day as another qualified visit, the FQHC is paid for one visit, and the charges associated with DSMT or MNT are waived from coinsurance obligations (79 FR 25447). We note, group DSMT is not payable in FQHCs because Medicare payment is limited to individual, face-to-face encounters under the FQHC PPS, and group training does not meet the definition of a billable visit.

For RHCs, DSMT services and MNT services rendered by registered dietitians or nutrition professionals are included under the RHC benefit, if all relevant program requirements are met. Separate payment under Part B to RHCs for these services provided by these practitioners is precluded as set forth in regulations at §§ 414.63 and 414.64. However, RHCs are permitted to become certified providers of DSMT and MNT services and bundle the cost of such services into their clinic payment rates. The provision of these services would not generate an RHC visit, though their costs may be included in the cost report and used for determining the AIR.[159] Consequently, RHCs are not paid for encounters where only DSMT or MNT services are provided.

For several years, interested parties have expressed concern about access to DSMT and MNT services in RHCs. Commenters stated that because these are preventive services, not treating these services as a separate encounter is impacting access to care for rural beneficiaries. They state that there are additional concerns regarding the payment for DSMT and MNT services between RHCs and FQHCs and rural interested parties have requested aligning payment for these services. They believe that we should recognize DSMT and MNT services as a qualified visit for RHCs when these services are provided by a certified provider and all the requirements are met. They believe that the utilization rate is low for beneficiaries receiving care in RHCs and explained that if we allow RHCs to receive payment for furnishing DSMT

[156] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/b02062.pdf.*

[157] *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=251&ncdver=1&keyword=DSMT&keywordType=starts&areaId=all&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1.*

[158] *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=252.*

[159] *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/a03021.pdf.*

and MNT services, then this rate may increase.

Recent studies highlight a continued need for DSMT and MNT services in rural areas, driven by rising diabetes prevalence and significant access disparities. Some of the barriers identified for people living in rural communities, especially for getting access to diabetes education and prevention programs, include limited number of providers, longer distance to medical facilities, higher costs, outdated cultural beliefs, lack of transportation, and limited community resources. More efforts to reduce these barriers may help reduce the overall high burden of diabetes in the rural US.[160] The necessity of DSMT and MNT in rural areas is supported by findings such that, they are clinically essential, diabetes control is improved, complications are reduced, lower costs, rural populations have equal or greater need, there are higher diabetes burden (widely established in rural health literature), access is systematically worse in rural areas, there are fewer providers, geographic maldistribution, and lower utilization despite need. Therefore, expanding DSMT and MNT in rural areas is not just beneficial, it is necessary to address documented health differences in access and outcomes.[161] In addition, we have observed that utilization for these services is low in rural settings. That is, an analysis of Medicare claims data from 2024 indicate that utilization of DSMT and MNT in RHC settings is substantially lower than in comparable care settings. In CY 2024, DSMT services were furnished to approximately 125 RHC beneficiaries, representing 0.005 percent of the total RHC beneficiary population of approximately 2.3 million. MNT services were furnished to approximately 439 RHC beneficiaries, representing 0.019 percent of the total RHC beneficiary population. On a claims basis, DSMT accounted for 0.002 percent and MNT for 0.007 percent of total RHC claims in CY 2024. By comparison, FQHCs, showed DSMT utilization rates approximately 22 times higher and MNT utilization rates approximately 28 times higher than RHCs on a per-beneficiary basis. On a claim basis, FQHC utilization of DSMT and MNT exceeded RHC utilization by approximately 31 times and 32 times, respectively. Rural physician offices, which share the geographic and demographic characteristics of RHC patient populations, showed DSMT and MNT utilization rates approximately 17 times and 7 times higher than RHCs, respectively, on a per-beneficiary basis. The analysis further demonstrated that within the PFS setting where DSMT and MNT are most readily identifiable in claims data, these services represent a very small share of total Medicare spending—less than 0.01 percent and 0.02 percent of total PFS line payments, respectively, in CY 2024. This could suggest that beneficiaries receiving care in RHCs may have disproportionately lower participation due to potential provider shortages and structural payment barriers when compared to other settings of care. participation due to potential provider shortages and structural payment barriers when compared to other settings of care.

As such, we believe that we should attempt to align access and payment for RHCs and FQHCs to the extent possible, given the statutory differences in benefit design between the two settings of care. Because DSMT and MNT are affirmatively covered Medicare Part B benefits under sections 1861(s)(2)(S) and 1861(s)(2)(V) of the Act, respectively, and are defined under sections 1861(qq) and 1861(vv) of the Act, there is a compelling basis for ensuring these clinically essential services are payable under the RHC benefit. Continuing to exclude these services from RHC payment limits access for rural Medicare beneficiaries and would be inconsistent with both the statutory coverage framework and the foundational purpose of the RHC program. Reducing differences between RHCs and other settings in which DSMT and MNT are furnished and paid, such as in FQHCs and physician office, may help expand access to care for Medicare beneficiaries in rural areas. This policy would strengthen access to services that address chronic conditions prevalent among Medicare beneficiaries which are significant drivers of program expenditures.

Since DSMT and MNT services may be furnished by certified providers other than RHC practitioners as defined in §§ 410.141 and 410.134, respectively, these services could be furnished by certified providers under the direct supervision of an RHC practitioner. Direct supervision does not require the physician (or other supervising practitioner) to be present in the same room. However, the physician (or other supervising practitioner) must be in the RHC or FQHC and immediately available to provide assistance and direction throughout the time the incident to service or supply is being furnished. See definitions at § 405.2401(b) ''Direct Supervision.''

We propose to recognize DSMT and MNT services as qualified preventive services that are covered and paid the AIR as stand-alone billable visits under the RHC benefit. To constitute as a billable RHC visit, these services would need to be furnished by a certified provider under the direct supervision of RHC professional staff. We believe aligning payment policies in RHCs with other settings, for example FQHCs and physician offices, would help expand access to care for Medicare beneficiaries in rural areas while supporting Federal initiatives to strengthen rural healthcare. As such, we are proposing to revise § 405.2463(a) and (b)(2) to allow DSMT and MNT services to be stand-alone billable visits in RHCs. Similar to FQHCs, when DSMT or MNT is furnished on the same day as another qualified visit, the RHC would be paid one AIR for that encounter. We consider these policies to align an incongruency between FQHC and RHC access to preventive services and do not expect in future rulemaking to propose additional preventive services beyond which are currently paid for in FQHCs and physician offices. We invite public comments on these proposals.

3. Services Furnished Using Telecommunication Technology

a. Background

Section 3704 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020) directed the Secretary to establish payment for RHC and FQHC services that are provided as Medicare telehealth services by RHCs and FQHCs serving as a distant site (that is, where the practitioner is located) during the PHE for COVID–19. Specifically, section 1834(m)(8)(B) of the Act, as added by section 3704 of the CARES Act, required that, for the duration of the PHE for COVID–19, the Secretary develop and implement payment methods for FQHCs and RHCs that serve as a distant site. The payment methodology outlined in the CARES Act requires that rates be based on rates that are similar to the national average payment rates for comparable telehealth services under the Medicare PFS. Accordingly, we established payment rates for these services furnished by RHCs and FQHCs based on the average PFS payment amount for all Medicare telehealth services, weighted by volume in a

[160] Khavjou O, Tayebali Z, Cho P, Myers K, Zhang P. Rural-Urban Disparities in State-Level Diabetes Prevalence Among US Adults, 2021. Prev Chronic Dis. 2025 Jan 16;22:E05. doi: 10.5888/pcd22.240199. PMID: 39819894; PMCID: PMC11870018.

[161] Rhudy, C., Schadler, A., & Talbert, J.C. (2020). *Rural/urban disparities in utilization of diabetes self-management training to the fee-for-service Medicare population.* Rural and Underserved Health Research Center, University of Kentucky.

Special Edition Medicare Learning Network Article (SE20016). Congress has extended this payment flexibility beyond the PHE for COVID–19 through a series of statutory amendments, most recently under section 6209(c) of the CAA, 2026, which extended this payment flexibility through December 31, 2027.

We codified this payment policy at 42 CFR 405.2464(g). As amended in the CY 2025 PFS final rule (89 FR 98554), § 405.2464(g) states that for an encounter furnished using interactive, real-time, audio/visual telecommunications technology or for certain audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology services that are not described in § 405.2463(b)(3), payment to RHCs and FQHCs are subject to the national average payment rates for comparable services under the PFS and costs associated with these services shall not be used in determining payments under the RHC all-inclusive rate or the FQHC prospective payment system.

In the CY 2022 PFS final rule (86 FR 65210 and 65211), we revised payment for mental health visits in RHCs and FQHCs furnished via interactive, real-time, audio/visual or audio-only telecommunications technology. Instead of paying for these services under the national average payment rates for comparable services under the PFS, as is done for non-behavioral health services, we amended the regulation at § 405.2463 to permit mental health visits in RHCs and FQHCs furnished via audio/visual or audio-only telecommunication to be paid under the RHC AIR and FQHC PPS rates. In addition, to align with the Medicare telehealth statutory requirements for mental health services, we finalized at §§ 405.2463(b)(3) and 405.2469(d) that there must be an in-person mental health service furnished within 6 months prior to the furnishing of the telecommunications service and that an in-person mental health service (without the use of telecommunications technology) must be provided at least every 12 months while the beneficiary is receiving services furnished via telecommunications technology for diagnosis, evaluation, or treatment of mental health disorders, unless, for a particular 12-month period, the physician or practitioner and patient agree that the risks and burdens outweigh the benefits associated with furnishing the in-person item or service, and the practitioner documents the reasons for this decision in the patient's medical record.

However, beginning with section 304 of the Consolidated Appropriations Act, 2022 (CAA, 2022) (Pub. L. 117–103, March 15, 2022), the in-person visit requirements for mental health visits were delayed. These requirements were further delayed through various laws that included extension of the telehealth flexibilities. Following the publication of the CY 2026 PFS final rule, section 6208 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37, November 12, 2025) extended the delay until January 30, 2026. Most recently, section 6209(d) of the CAA, 2026 extended the abeyance of the RHC/FQHC mental health in-person requirements through December 31, 2027.

b. Proposal for Conforming Regulatory Text Changes

Because section 6209(c) of the CAA, 2026 extended authority for CMS to pay for FQHC and RHC non-behavioral health telecommunication technology services as Medicare telehealth services, we are not proposing any modifications for this provision to § 405.2464(g).

Because section 6209(d) of the CAA, 2026 extended the abeyance of the RHC and FQHC mental health in-person requirements through December 31, 2027, we are proposing to make conforming regulatory text changes at §§ 405.2463(b)(3) and 405.2469(d). This provision, as proposed, would require that the in-person visit requirements not apply to any services furnished through December 31, 2027.

4. Proposed CY 2027 FQHC PPS Market Basket Update

Section 1834(o)(2)(B)(ii) of the Act requires the FQHC PPS base rate be updated annually by the percentage increase in a market basket of Federally qualified health center goods and services as issued through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1842(i)(3) of the Act) for the year involved. For CY 2027 (that is, January 1, 2027, through December 31, 2027), we propose to use an estimate of the percentage increase in the 2022-based FQHC market basket to update payments to FQHCs based on the best available data. Consistent with CMS practice, we propose to use the update based on the most recent historical data available at the time of publication of the final rule. For example, the final CY 2027 FQHC update would be based on the four-quarter moving-average percent change of the 2022-based FQHC market basket through the second quarter of 2026 (based on the final rule's statutory publication schedule). At the time of this proposed rule, we do not have the second quarter of 2026 historical data, and therefore, the proposed CY 2027 FQHC update is based on the most recent projection available at this time. As finalized in the CY 2025 final rule (89 FR 98032), a productivity adjustment is included in the 2022-based FQHC market basket.

For CY 2027, we propose to update the CY 2026 FQHC PPS base rate by the historical percentage increase through the second quarter of 2026 of the productivity-adjusted FQHC market basket (which we refer to as the FQHC market basket update). For CY 2027, the proposed FQHC market basket update is estimated to be 2.5 percent and is based on the expected historical percentage increase of the productivity-adjusted 2022-based FQHC market basket (referred to as the FQHC market basket update). Multiplying the CY 2026 FQHC PPS base rate amount of $207.72 by the proposed CY 2027 FQHC market basket update of 2.5 percent ($207.72 × 1.025) results in a proposed CY 2027 FQHC PPS base rate amount of $212.91. For the final rule, we propose that the CY 2027 market basket update and the productivity adjustment will be updated to reflect historical data through the 2nd quarter of 2026.

5. Proposed Technical Changes

a. Section 405.2464(b)(1) and (2)

We propose revisions at § 405.2464(b)(1) and (2) to correct the references within these paragraphs so that they reference the appropriate paragraph or sections under subpart X of part 405. We propose to revise § 405.2464(b)(1) by replacing ''paragraphs (d) and (e)'' with ''paragraphs (c) and (h)'' since the payment discussed under these paragraphs are not based on the FQHC PPS per diem rate. We propose to revise § 405.2464(b)(2)(i) and (ii) to reference § 405.2462(e). This reference should have been revised when we redesignated this section in the CY 2022 PFS final rule (86 FR 65660).

b. § 405.2464(g)

In the CY 2025 PFS final rule (89 FR 98015 through 98017) we discussed medical visit services furnished via telecommunications technology. We revised § 405.2464 by adding new paragraph (g) to reflect our payment policy for these services. That is, for non-behavioral health services, an encounter furnished using telecommunications technology, payment to RHCs and FQHCs are

subject to the national average payment rates for comparable services under the PFS and costs associated with these services shall not be used in determining payments under the RHC AIR or the FQHC PPS. During a recent review of our regulation, we noticed that we inadvertently used the term ''an encounter'' instead of ''services.'' We are proposing to revise § 405.2464(g) to be consistent with the authority under section 1834(m)(8) of the Act.

c. Section 405.2469(d)

In the CY 2022 PFS final rule (86 FR 65210 and 65211), we explained that § 405.2469(d) was revised to describe the same in-person mental health visit requirement applicable under § 405.2463. In subsequent PFS rulemaking, as discussed previously in this section, we described revisions to both provisions as technical changes intended solely to conform the regulations to the applicable statutory delay of the in-person requirement. Because the current text of § 405.2469(d) separately restates the technology modalities and in-person requirement language, it creates an unnecessary risk of divergence from § 405.2463(b)(3). Accordingly, we propose to revise the regulatory text at § 405.2469(d) to align the description of permissible telecommunications modalities with the language used in § 405.2463. Specifically, § 405.2469(d) currently refers to audio-only interactions in cases where beneficiaries do not wish to use, or do not have access to, devices that permit two-way, audio/video communication. In contrast, § 405.2463 permits the use of audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology. To ensure consistency across these provisions we are proposing to revise the descriptions to match what is described at § 405.2463, namely that the use of audio-only interactions is permissible in cases where the patient is not capable of, or does not consent to, the use of video technology. We are also proposing to revise § 405.2469(d) to align the description of the in-person visit requirement for mental health services with the requirements set forth in § 405.2463(b)(3). We believe that these amendment are non-substantive and clarifying because they do not alter payment policy; they merely align duplicative regulatory text and eliminate any potential internal inconsistency.

C. Clinical Laboratory Fee Schedule (CLFS): Consolidated Appropriations Act (CAA), 2026

1. Background on the Clinical Laboratory Fee Schedule

Prior to January 1, 2018, Medicare paid for clinical diagnostic laboratory tests (CDLTs) on the Clinical Laboratory Fee Schedule (CLFS) under section 1833(a), (b), and (h) of the Act. Under the previous payment system, CDLTs were paid based on the lesser of: (1) the amount billed; (2) the local fee schedule amount established by the Medicare Administrative Contractor (MAC); or (3) a national limitation amount (NLA), which is a percentage of the median of all the local fee schedule amounts (or 100 percent of the median for new tests furnished on or after January 1, 2001). In practice, most tests were paid at the NLA. Under the previous payment system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers (CPI–U), and reduced by a productivity adjustment and other statutory adjustments, but were not otherwise updated or changed. Coinsurance and deductibles generally do not apply to CDLTs paid under the CLFS.

Section 1834A of the Act, as established by section 216(a) of the Protecting Access to Medicare Act of 2014 (PAMA), required significant changes to how Medicare pays for CDLTs under the CLFS. In a final rule that appeared in the June 23, 2016 **Federal Register** (81 FR 41036), entitled Medicare Clinical Diagnostic Laboratory Tests Payment System (hereinafter referred to as the CLFS final rule), we established requirements to implement section 1834A of the Act at 42 CFR part 414, subpart G.

Under the CLFS final rule, ''reporting entities'' must report to CMS during a ''data reporting period'' ''applicable information'' collected during a ''data collection period'' for their component ''applicable laboratories.'' The first data collection period occurred from January 1, 2016, through June 30, 2016. The first data reporting period occurred from January 1, 2017, through March 31, 2017. On March 30, 2017, we announced a 60-day period of enforcement discretion for the application of the Secretary's potential assessment of civil monetary penalties for failure to report applicable information with respect to the initial data reporting period.[162]

In the CY 2018 PFS proposed rule (82 FR 34089 through 34090), we solicited public comments from applicable laboratories and reporting entities to better understand the applicable laboratories' experiences with data reporting, data collection, and other compliance requirements for the first data collection and reporting periods. We discussed these comments in the CY 2018 PFS final rule (82 FR 53181 through 53182) and stated that we would consider the comments for potential future rulemaking or guidance.

As part of the CY 2019 Medicare PFS rulemaking, we finalized two changes to the definition of ''applicable laboratory'' at § 414.502 (see 83 FR 59667 through 59681, 60074; 83 FR 35849 through 35850, 35855 through 35862). First, we excluded Medicare Advantage plan payments under Part C from the denominator of the Medicare revenues threshold calculation to broaden the types of laboratories qualifying as an applicable laboratory. Second, consistent with our goal of obtaining a broader representation of laboratories that could potentially qualify as an applicable laboratory and report data, we also amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill.

2. Payment Requirements for Clinical Diagnostic Laboratory Tests

In general, under section 1834A of the Act, the payment amount for each CDLT on the CLFS furnished beginning January 1, 2018, is based on the applicable information collected during the data collection period and reported to CMS during the data reporting period and is equal to the weighted median of the private payor rates for the test. The weighted median is calculated by arraying the distribution of all private payor rates, weighted by the volume for each payor and each laboratory. The payment amounts established under the CLFS are not subject to any other adjustment, such as geographic, budget neutrality, or annual update, as required by section 1834A(b)(4)(B) of the Act. Additionally, section 1834A(b)(3) of the Act, implemented at § 414.507(d), provides for a phase-in of payment reductions, limiting the amounts the CLFS rates for each CDLT (that is not a new advanced diagnostic laboratory test (ADLT) or new CDLT) can be reduced as compared to the payment rates for the preceding year. Under the original provisions enacted by section 216(a) of PAMA, for the first 3 years after implementation (CY 2018 through CY 2020), the reduction could not be more

[162] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/2017-March-Announcement.pdf.*

than 10 percent per year. For the next 3 years after implementation (CY 2021 through CY 2023), section 216(a) of PAMA stated that the reduction could not be more than 15 percent per year. Under sections 1834A(a)(1) and (b) of the Act, as enacted by PAMA, for CDLTs that are not ADLTs, the data collection period, data reporting period, and payment rate update were to occur every 3 years. As such, the second data collection period for CDLTs that are not ADLTs was originally scheduled to take place from January 1, 2019, through June 30, 2019, and the next data reporting period was originally scheduled to take place from January 1, 2020, through March 31, 2020, with the next update to the Medicare payment rates for those tests based on that reported applicable information scheduled to take effect on January 1, 2021.

Section 216(a) of PAMA established a new subcategory of CDLTs known as ADLTs, with separate reporting and payment requirements under section 1834A of the Act. The definition of an ADLT is set forth in section 1834A(d)(5) of the Act and implemented at § 414.502. Generally, under section 1834A(d) of the Act, the Medicare payment rate for a new ADLT is equal to its actual list charge during an initial period of 3 calendar quarters. After the new ADLT initial period, ADLTs are paid using the same methodology based on the weighted median of private payor rates as other CDLTs. However, under section 1834A(d)(3) of the Act, updates to the Medicare payment rates for ADLTs occur annually instead of every 3 years.

Additional information on the private payor rate-based CLFS is detailed in the CLFS final rule (81 FR 41036 through 41101) and is available on the CMS website.[163]

3. Previous Statutory Revisions to the Data Reporting Period and Phase-In of Payment Reductions

Beginning in 2019, Congress repeatedly extended the data reporting periods for CDLTs that are not ADLTs and revised the phase-in of CLFS payment reductions through multiple laws, including: section 105 of the Further Consolidated Appropriations Act, 2020 (FCAA) (Pub. L. 116–94, December 20, 2019); section 3718 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116–136, March 27, 2020); section 4 of the Protecting Medicare and American Farmers from Sequester Cuts Act (PMAFSCA) (Pub. L. 117–71, December 10, 2021); section 4114 of the Consolidated Appropriations Act, 2023 (CAA, 2023) (Pub. L. 117–328, December 29, 2022); section 502 of the Further Continuing Appropriations and Other Extensions Act, 2024 (FCAOEA, 2024) (Pub. L. 118–22, November 17, 2023); and section 221 of the Continuing Appropriations and Extensions Act, 2025 (CAEA, 2025) (Pub. L. 118–83, September 26, 2024). For a detailed discussion of these statutory revisions, please see the CY 2025 PFS final rule (89 FR 98038 through 98043) and the prior PFS rules referenced in the CY 2025 discussion.

4. Additional Statutory Revisions to the Data Reporting Period, Phase-In of Payment Reductions and Data Collection Period

Section 6209 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (Pub. L. 119–37, enacted November 12, 2025) made further revisions to the CLFS requirements for the next data reporting period for CDLTs that are not ADLTs and to the phase-in of payment reductions under section 1834A of the Act. Specifically, section 6209(b) of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 delayed the next data reporting period for CDLTs that are not ADLTs so that reporting would be required during the period of February 1, 2026 through April 30, 2026, instead of the data reporting period of January 1, 2025, through March 31, 2025 established under the FCAOEA, 2024.

Section 6209 of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 did not modify the data collection period that applies to the next data reporting period for these tests. Thus, under section 1834A(a)(4)(B) of the Act, as amended by section 105(a)(1) of the FCAA, the next data reporting period for CDLTs that are not ADLTs (February 1, 2026, through April 30, 2026) continued to be based on the data collection period of January 1, 2019, through June 30, 2019, as defined in § 414.502.

Section 6209(a) of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 amended the provisions in section 1834A(b)(3) of the Act regarding the phase-in of payment reductions under the CLFS. First, it extended the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2029. It further amended section 1834A(b)(3)(B)(ii) of the Act to specify that the applicable percent for CY 2026 was 0 percent, meaning that the payment amount determined for a CDLT for CY 2026 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2025. Section 6209(b) of this law further amended section 1834A(b)(3)(B)(iii) of the Act to state that the applicable percent of 15 percent would apply for CYs 2026 (January 31, 2026 through December 31, 2026), 2027, and 2028.

Most recently, section 6226 of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75, February 3, 2026) amended section 1834A of the Act to revise the data reporting period, data collection period, and requirements for the phase-in of payment reductions. Specifically, section 6226 of the CAA, 2026 revised the next required data reporting period for CDLTs that are not ADLTs to be May 1, 2026, through July 31, 2026, and specified that the applicable data collection period is January 1, 2025, through June 30, 2025.

Section 6226 of the CAA, 2026 also amended section 1834A(b)(3) of the Act to specify that the applicable percent was 0 percent for all of CY 2026, meaning that the payment amount determined for a CDLT for CY 2026 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2025, and to extend the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2029. Therefore, the applicable percent of up to 15 percent would apply for CYs 2027 through 2029. Section 6226 of the CAA, 2026 further provided that, notwithstanding any other provision of law, the Secretary may implement the amendments made by this section by program instruction or otherwise.

5. Proposed Conforming Regulatory Changes

In accordance with section 6226 of the CAA, 2026, we are proposing to make certain conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we are proposing to revise § 414.502 to update the definitions of both the ''data collection period'' and ''data reporting period,'' specifying that the data collection period is the 6-month period from January 1 through June 30, during which applicable information is

[163] *https://www.cms.gov/medicare/payment/fee-schedules/clinical-laboratory-fee-schedule/clfs-history.*

collected and that precedes the data reporting period, and that the data reporting period for CDLTs that are not ADLTs is the 3-month period, May 1 through July 31, and for ADLTs is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period. We are also proposing to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning May 1, 2026. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 6226 of the CAA, 2026. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2026, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2025, and for CYs 2027 through 2029, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We note that the CYs 2018 through 2026 CLFS payment rates for CDLTs that are not ADLTs are based on applicable information collected in the data collection period of January 1, 2016 through June 30, 2016. Under current law, the CLFS payment rates for those tests for CY 2027 through CY 2029 will be based on applicable information collected during the data collection period of January 1, 2025 through June 30, 2025, and reported to CMS during the data reporting period of May 1, 2026 through July 31, 2026.

6. Technical Correction (§ 414.523(a)(1))

a. Background

Section 1833(h)(3)(A) of the Act generally requires the Secretary to provide for and establish a nominal fee to cover the appropriate costs in collecting the sample on which a CDLT was performed and for which Medicare payment is made, in addition to the amounts provided under the Medicare CLFS. In addition, section 1834A(b)(5) of the Act requires that, when the sample is collected from an individual in a skilled nursing facility (SNF) or by a laboratory on behalf of a home health agency (HHA), the otherwise applicable nominal specimen collection fee be increased by $2.00.

In the CY 2023 PFS final rule (87 FR 69744 through 69760), we finalized a policy to codify specimen collection fee provisions at § 414.523(a)(1), including updating the base specimen collection fee amount and establishing an annual CPI–U update. In that rulemaking, we also stated that the statutory $2.00 increase for specimens collected from a Medicare beneficiary in a SNF or by a laboratory on behalf of an HHA would continue to apply, consistent with section 1834A(b)(5) of the Act. However, due to a drafting or codification error, the operative regulatory text implementing this increase in the CY 2023 PFS final rule (87 FR 70225 through 70226) was not fully included in § 414.523(a)(1), and only a partial introductory clause remains in paragraph (a)(1)(v). Specifically, the introductory text to § 414.523(a)(1) states that payment is made ''[e]xcept as provided in paragraph (a)(1)(v),'' but § 414.523(a)(1)(v), as codified, consists only of the fragment: ''For a specimen collected from a Medicare beneficiary.'' This text is incomplete and does not contain operative language establishing an exception or alternative payment methodology. In addition, other provisions within § 414.523(a)(1), including paragraph (a)(1)(ii), already specify that the specimen must be collected from a Medicare beneficiary, creating an apparent internal inconsistency when read together with the introductory exception clause.

b. Proposed Technical Correction

To resolve this internal inconsistency and accurately reflect the statutory provisions and longstanding policy, we are proposing to revise § 414.523(a)(1) to restore the complete and operative language implementing the statutory $2.00 increase. That is, we propose revising § 414.523(a)(1)(v) to state that for a specimen collected from a Medicare beneficiary in a skilled nursing facility or on behalf of a home health agency, the specimen collection fee otherwise paid under paragraph (a)(1) of this section is increased by $2.00.

We do not believe that this proposal reflects a substantive policy change. In the CY 2023 PFS proposed rule (87 FR 46043), we proposed to codify existing specimen collection fee policies and to incorporate the statutory $2.00 increase for SNF and HHA collections into § 414.523(a)(1) as a discrete paragraph. Specifically, we proposed that, beginning April 1, 2014, for a specimen collected from a Medicare beneficiary in a SNF or on behalf of an HHA, the specimen collection fee otherwise paid under § 414.523(a)(1) would be increased by $2.00, consistent with section 1834A(b)(5) of the Act. In the CY 2023 PFS final rule (87 FR 69744 through 69760), we finalized policies consistent with this framework, including the continued application of the statutory $2.00 increase.

We note that it has been, and continues to be, CMS' policy to pay the specimen collection fee only for qualifying specimens collected from Medicare beneficiaries, and to apply the additional $2.00 increase for specimens collected from a Medicare beneficiary in a SNF or by a laboratory on behalf of an HHA, as required by statute. We have consistently implemented this policy operationally through claims processing systems, subregulatory guidance, and annual payment updates.

D. Proposed Changes to the Ambulatory Specialty Model (ASM)

1. Executive Summary and Background

a. Executive Summary

(1) Purpose

We are proposing to make changes to the Ambulatory Specialty Model (ASM or model) effective on the model start date of January 1, 2027.

(2) Summary of Major Provisions

ASM is a mandatory alternative payment model tested by the CMS Center for Medicare and Medicaid Innovation (Innovation Center) under section 1115A of the Act. ASM will have 5 performance years that begin January 1, 2027 and end December 31, 2031 with performance-based payment adjustments occurring 2 calendar years (CYs) following the end of each ASM performance year.

We finalized ASM through notice-and-comment rulemaking in the Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program final rule (hereinafter ''CY 2026 PFS final rule'') (90 FR 49562 through 49720). However, based on the feedback we received after the publication of the CY 2026 PFS final rule and our own internal review, we are proposing several technical refinements and adjustments to the model. As described in detail in section III.D.2 of this proposed rule, we propose the following modifications:

- Revising select ASM definitions and adding new ASM definitions.
- Clarifying ASM participant exceptions from specified model requirements due to taxpayer identification number (TIN) changes before or during an ASM performance year.
- Excepting certain ASM heart failure participants from specified model

requirements due to a redesignated specialty type.

- Incorporating an option to terminate ASM participants under certain circumstances.
- Incorporating an option for data submission for the improvement activities ASM performance category at either the individual or group level.
- Clarifying the scoring of multiple quality measure data submissions from ASM participants in small practices.
- Adding an administrative claims-based low back pain imaging quality measure and replacing the patient-reported outcome measure for low back pain with a functional status outcome process measure.
- Adjusting benchmarking and scoring policies for quality measures.
- Adding a quality ASM performance category scoring incentive for the voluntary submission of patient-reported outcome (PRO) data to support the development of patient-reported outcome performance-based measures (PRO–PM) under ASM.
- Revising requirements of the Promoting Interoperability ASM performance category to align with proposed changes to the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category and adding a Promoting Interoperability measure suppression policy.
- Incorporating a rural scoring adjustment for ASM participants in rural areas.
- Revising the contents of the ASM performance report to include additional information related to scoring-related proposals in this proposed rule.
- Clarifying language on the application of ASM payment adjustments when an ASM participant reassigns billing rights to a new TIN during an ASM payment year.
- Clarifying the availability of the CMS-sponsored model arrangements and patient incentives safe harbor and applicability of programmatic waivers for ASM to reflect that such flexibilities are associated with active performance under ASM and would not be available or applicable during an ASM performance year in which an ASM participant is either ineligible for, or excepted from, specified model requirements.
- Revising provisions establishing collaborative care arrangement (CCA) requirements to improve clarity and update the permissible parties, remuneration conditions, documentation requirements, and compliance terms.
- Clarifying and reorganizing select regulatory text to improve readability and flow.

The proposals in this proposed rule reflect our commitment to ensuring ASM's incentives help drive quality of care improvements for beneficiaries and reductions in Medicare spending.

b. Background

(1) Statutory Authority

Section 1115A of the Act authorizes the Secretary to test innovative payment and service delivery models to reduce program expenditures under Medicare, Medicaid, and the Children's Health Insurance Program (CHIP) while preserving or enhancing the quality of care furnished to beneficiaries. Under this authority, we may test models that modify payment methodologies, establish accountability for quality and cost outcomes, and incorporate financial risk arrangements. Under the authority of sections 1115A and 1871(a)(2) of the Act, through notice-and-comment rulemaking, we finalized ASM in the CY 2026 PFS final rule that appeared in the November 5, 2025, **Federal Register** (90 FR 49562 through 49720).

(2) Background

ASM will test whether holding physician specialists accountable for the quality and cost of care associated with the longitudinal management of specific chronic conditions, heart failure and low back pain, can reduce Medicare expenditures while preserving or enhancing quality of care for Original Medicare beneficiaries. Clinical decisions made by specialists in ambulatory settings can meaningfully influence disease progression as well as downstream utilization and spending. ASM's design, in its goal to reduce Medicare expenditures while preserving or enhancing the quality of care, aims to: (1) improve the management of chronic disease and slow disease progression through more effective risk assessment; (2) increase active collaboration between specialists and primary care providers, and (3) reduce avoidable hospitalizations and low-value procedures (that is, procedures that provide little clinical benefit or the risk of harm outweighs its potential benefit).

In developing ASM, we considered specialist-managed conditions that often require ongoing outpatient management, diagnostic evaluation, medication management, coordination by specialists with other clinicians across different care settings, and, in some cases, procedural or surgical intervention (90 FR 49562 through 49564). Based on these factors, ASM selects individual specialists who manage one of two ASM targeted chronic conditions, heart failure or low back pain. As we designed ASM's participation criteria and performance evaluation framework to cover multiple conditions and associated specialists, we continue to explore whether including additional conditions and specialists would be appropriate.

Our goal with the model test is to select specialists who have a meaningful level of engagement in the care of Original Medicare beneficiaries with ASM targeted chronic conditions as ASM participants. Under the provisions finalized in the CY 2026 PFS final rule (90 FR 49571 through 49596), we select ASM participants by a combination of a TIN and a National Provider Identifier (NPI). ASM participants are clinicians who meet four ASM participant eligibility criteria: (1) bill claims under the Medicare Physician Fee Schedule, (2) have a selected physician specialty type relevant to an ASM targeted chronic condition, (3) meet a historical volume threshold of condition-specific episode-based cost measure (EBCM) episodes, and (4) have a service location in a selected mandatory geographic area (that is, selected Core-Based Statistical Areas (CBSAs) and metropolitan divisions). ASM heart failure participants include cardiologists, and ASM low back pain participants include physicians with specialty types of anesthesiology, interventional pain management, neurosurgery, orthopedic surgery, pain management, and physical medicine and rehabilitation.

ASM evaluates ASM participants across four ASM performance categories: quality, cost, improvement activities, and Promoting Interoperability. The evaluation of ASM participant performance leverages the MIPS Value Pathways (MVP) framework, which utilizes a cohesive set of measures and activities focused on performance in furnishing care for a particular specialty or clinical condition. ASM participants must meet each ASM performance category's requirements and report required data. We use data reported by ASM participants and other administrative data, such as inputs gathered from claims, to evaluate each ASM participant's performance on an annual basis. We determine a composite final score for each ASM participant based on performance across the four ASM performance categories and adjust final scores to account for beneficiary medical and social complexity as well as practice size.

Based on performance relative to other specialists treating the same ASM targeted chronic condition in an ASM cohort, ASM participants will receive a positive, neutral, or negative payment adjustment on all Medicare Part B claims for covered professional services during the CY 2 years following the applicable ASM performance year (for example, performance during the 2027 ASM performance year results in the application of ASM payment adjustments during the 2029 ASM payment year). Payment adjustments will range from negative 9 percent to positive 9 percent in the first 2 ASM payment years, gradually increasing to 12 percent in the final ASM payment year.

We refer readers to the CY 2026 PFS final rule (90 FR 49562 through 49720) and ASM's provisions at 42 CFR part 512, subpart G, for additional information on all finalized provisions.

2. Proposed Changes to Provisions of the Ambulatory Specialty Model (ASM)

a. Definitions

In the CY 2026 PFS final rule, we finalized certain terms for ASM. We described these finalized definitions in context throughout section III.C.2 of the CY 2026 PFS final rule and codified them at § 512.705 (90 FR 49569).

After internal review of ASM's provisions, we believe minor modifications to select definitions would improve the readability and overall clarity of ASM's provisions.

Accordingly, we propose at § 512.705 to modify the definition of ''ASM beneficiary'' to clarify this term means a Medicare FFS beneficiary who is being treated by an ASM participant for an ASM targeted chronic condition. We believe this edit would improve the precision of the definition by using the finalized definition of ''ASM targeted chronic condition'' that is used throughout ASM's provisions, rather than just ''targeted chronic condition'' as the definition currently reads.

We also propose to revise the definition of ''Dual eligible proportion'' at § 512.705 for clarity. Specifically, we propose to clarify that the definition of ''Dual eligible proportion'' means ''the share of an ASM participant's beneficiaries who are dually eligible Medicare beneficiaries''. This revision would more clearly refer to an ASM participant.

We refer readers to section III.D.2.f.(3) of this proposed rule for the proposed definition of ''Rural area'' as it is described in context of the proposed rural scoring adjustment.

We seek comment on the proposed revisions to the ''ASM beneficiary'' and ''Dual eligible proportion'' definitions at § 512.705.

b. Participation

(1) Background

As discussed in the CY 2026 PFS final rule (90 FR 49571 through 49596), we designed ASM with a focus on clinicians who commonly treat Original Medicare beneficiaries in an ambulatory setting, develop longitudinal relationships with patients, and co-manage beneficiaries with primary care providers (PCP). In addition, we believe clinicians who treat ASM targeted chronic conditions are well-positioned to benefit from improved integration between specialty and primary care, creating greater opportunities to incentivize high-value care and tertiary prevention.

We determined the model would assess quality of care provided at the individual clinician level, as identified by a combination of TIN and NPI, rather than at the level of a group practice or facility, with limited exceptions, to align accountability with individual clinical decision-making and to better capture variation in individual clinical practice patterns among clinicians within the same organization (90 FR 49574). As a result, each ASM participant is individually responsible for meeting model requirements and is evaluated independently for the purposes of ASM performance category scoring, final scoring, and determining an ASM payment adjustment factor and corresponding ASM payment multiplier.

(2) Mandatory Participation

In the CY 2026 PFS final rule (90 FR 49571 through 49574), we finalized that once a clinician meets the ASM participant eligibility criteria and is selected as an ASM participant, they remain an ASM participant for the duration of the ASM test period. Once selected as an ASM participant, there may be circumstances where the ASM participant does not meet the ASM participant eligibility criteria for a specific ASM performance year. Accordingly, we developed a policy whereby an ASM participant is only subject to certain ASM requirements for the ASM performance year(s) in which they meet ASM participant eligibility criteria. We also finalized provisions that describe the effect of not meeting ASM participant eligibility criteria for an ASM performance year (90 FR 49571 through 49574). Specifically, under existing provisions, an ASM participant who does not meet ASM participant eligibility criteria for an ASM performance year is: (1) not subject to the requirements for performance assessment described at § 512.715, data submission described at § 512.720, and final scoring described at § 512.745; (2) not subject to payment adjustment described at § 512.750 for the corresponding ASM payment year; and (3) not eligible for Medicare program waivers described at § 512.775 provided under the model for the applicable ASM performance year.

To clarify and better incorporate policies related to exceptions of specific ASM performance requirements and ASM participant terminations discussed later in this section of this proposed rule, we are proposing to revise our regulatory text describing mandatory ASM participation and the effects of not meeting ASM participant eligibility criteria for an ASM performance year.

Specifically, we propose at § 512.710(a)(1) that a clinician who we select as an ASM participant for at least one ASM performance year is considered an ASM participant for the duration of the ASM test period unless we (1) terminate ASM in accordance with Standard Provisions for Mandatory Innovation Center Models described at § 512.165, or (2) terminate the ASM participant as described under proposed § 512.710(h). We believe this proposed revision is consistent with our original policy finalized in the CY 2026 PFS final rule describing that an ASM participant, once selected, remains an ASM participant for the ASM test period. Our proposal also incorporates the effect of a possible ASM participant termination, which we propose later in this section of this proposed rule.

We also propose to add a paragraph heading and revise § 512.710(a)(2) to clarify that this paragraph describes the effects of not meeting ASM participant eligibility criteria for an ASM performance year. We propose to move select regulatory text at current § 512.710(a)(2)(i) to § 512.710(a)(2) to improve readability and to incorporate new proposals on the effects of not meeting ASM participant eligibility criteria for an ASM performance year.

First, we propose to separate select regulatory text included in current § 512.710(a)(2)(i) into separate paragraphs by revising paragraph § 512.710(a)(2)(ii) and adding new paragraph § 512.710(a)(2)(iii). Under this proposal, § 512.710(a)(2)(i) would describe the specified model requirements that an ASM participant would not be required to meet for the applicable ASM performance year, § 512.710(a)(2)(ii) would describe the specific model requirements not applicable for the corresponding ASM

payment year, and § 512.710(a)(2)(iii) would describe an ASM participant's ineligibility for waivers provided under the model for the applicable ASM performance year. These revisions do not introduce substantive changes to finalized provisions describing the effects of an ASM participant not meeting ASM participant eligibility criteria for an ASM performance year; rather, we believe such revisions help clarify that not meeting ASM participant eligibility criteria would not nullify the application of ASM payment adjustments on Medicare Part B claims for covered professional services during the corresponding ASM payment year based on performance in a prior ASM performance year. For example, a clinician may be selected for mandatory participation for the 2027 ASM performance year. If that ASM participant does not meet the ASM participant eligibility criteria for the 2029 ASM performance year, the revisions here help clarify that while the ASM participant would not be subject to the applicable performance assessment, data reporting, and scoring requirements during the 2029 ASM performance year (that is, CY 2029), but that ASM payment adjustments based on the ASM participant's performance from the 2027 ASM performance year would still be applied in CY 2029.

Second, we propose at § 512.710(a)(2)(iv) that an ASM participant who does not meet ASM participant eligibility criteria for an ASM performance year would not be eligible for the CMS-sponsored model arrangements and patient incentives safe harbor described at § 512.765 for the applicable ASM performance year. We believe this proposal is consistent with our intent to make this safe harbor available for ASM performance years where the ASM participant is actively performing in the model (90 FR 49709). We refer readers to section III.D.2.h. of this proposed rule for further explanation of this proposal.

We seek comment on our proposed revisions to §§ 512.710(a)(1) and 512.710(a)(2).

(3) Specialty Type

Participation is limited to clinicians who are within specialties and furnish covered professional services related to ASM targeted chronic conditions—heart failure or low back pain. As finalized in the CY 2026 PFS final rule, we determine specialty type based on the specialty code most frequently reported on a clinician's Medicare Part B claims (90 FR 49583 through 49585). Medicare Administrative Contractors (MACs) derive specialty codes on claims from clinician-reported specialty types provided during Medicare enrollment. Physicians report their specialty type as part of their Medicare enrollment application through the Provider Enrollment, Chain, and Ownership System (PECOS) or through submission of the CMS 855I paper application.[164] The Medicare enrollment form is also used for revalidations and ad hoc changes to certain information. We use data from the CY 2 years prior to each ASM performance year to determine whether a clinician meets the model's specialty type criteria. For example, we use CY 2025 data, including specialty type data, to select final ASM participants for the 2027 ASM performance year.

For the ASM heart failure cohort, we finalized inclusion of physicians with a specialty type of cardiology. Our rationale for including cardiologists as ASM heart failure participants, as explained in the CY 2026 PFS final rule, is that they commonly provide care to Original Medicare beneficiaries with heart failure and are well-positioned to manage outcomes by ensuring patients are optimized on guideline-directed medical therapy to prevent exacerbation of their condition (90 FR 49576). We did not finalize the inclusion of other cardiac-related specialties (for example, cardiac electrophysiology, intensive cardiac rehabilitation, cardiac surgery, interventional cardiology, and advanced heart failure and transplant) as these clinicians are often proceduralists and not commonly involved in the longitudinal management of patients with heart failure (90 FR 49576). Because one of ASM's goals is to measure the performance of clinicians with similar patterns of heart failure care, we include cardiologists, but not other cardiac-related specialties, even though those cardiac-related specialists may be attributed patients with heart failure as measured through the heart failure EBCM (90 FR 49577).

For the ASM low back pain cohort, we finalized inclusion of physicians who have a specialty of anesthesiology, pain management, interventional pain management, neurosurgery, orthopedic surgery, or physical medicine and rehabilitation. In the CY 2026 PFS final rule (90 FR 49577 through 49580), we emphasized that specialty types for the ASM low back pain cohort include physicians who are most directly involved in the evaluation and management of low back pain and whose clinical decision-making is expected to meaningfully influence downstream utilization and spending. We explained that the included specialists commonly furnish services to Original Medicare beneficiaries with low back pain and play a central role in determining the use of imaging, injections, procedures, and surgical interventions. We also noted that we did not include certain other specialties that may occasionally treat low back pain but are not typically responsible for its longitudinal management. By focusing on a defined set of specialties with similar roles in managing low back pain, we aim to support more meaningful comparisons of performance and to align model incentives with opportunities to improve care coordination, reduce unnecessary procedures, and promote evidence-based treatment.

We are not proposing any adjustments to the specialty types included in each ASM cohort as finalized at § 512.710(d) in the CY 2026 PFS final rule (90 FR 49576 through 49580). As part of this proposed rule, we are proposing to correct small typographical errors in the regulatory text at §§ 512.710(d)(1) and 512.710(d)(2). These revisions do not introduce substantive changes to existing provisions.

We seek comment on the proposed correction of the typographical errors at §§ 512.710(d)(1) and 512.710(d)(2).

(4) ASM Participant Exceptions

We recognize that there may be limited circumstances in which an ASM participant selected for participation for an ASM performance year should be excepted from certain ASM requirements for that ASM performance year and should consequently be excepted from the application of an ASM payment multiplier to the ASM participant's Medicare Part B payments for covered professional services during the corresponding ASM payment year. Accordingly, we finalized a narrow set of ASM participant ''exclusions,'' or situations in which an ASM participant is excepted from specified ASM requirements in the CY 2026 PFS final rule to balance operational feasibility with the need for robust evaluation and generalizable findings (90 FR 49582 through 49583). As finalized at § 512.710(c), an ASM participant who stops reassigning billing rights to the TIN we used to select the ASM participant and begins reassigning billing rights to a new TIN during an ASM performance year is not subject to certain ASM requirements—specifically the requirements for performance assessment described at § 512.715, data submission described at § 512.720, final scoring described at § 512.745, and

[164] *https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms019477.*

payment adjustment described at § 512.750—and is no longer eligible for Medicare program waivers provided under the model described at § 512.775 for the applicable ASM performance year. An exception from specified ASM requirements for one ASM performance year does not apply for the entire ASM test period because we consider clinicians who meet ASM participant eligibility criteria for at least one ASM performance year to be an ASM participant for the remainder of the ASM test period. This means that an ASM participant will receive payment adjustments during a corresponding ASM payment year based on performance from an ASM performance year for which they were required to meet these specified ASM requirements (90 FR 49571 through 49574). In other words, if an ASM participant meets the ASM participant eligibility criteria for the 2027 and 2028 ASM performance years, but not the 2029 and 2030 ASM performance years, by continuing to remain an ASM participant, the ASM payment multipliers calculated based on the ASM participant's performance during the 2027 and 2028 ASM performance years would continue to be applied to the ASM participant's Medicare Part B payments for covered professional services during the corresponding ASM payment years (that is, CY 2029 and CY 2030).

After internal review, we believe it would be more precise to refer to the situations in which an ASM participant is not required to meet specified ASM requirements for applicable ASM performance year(s) as ''exceptions'' to ASM requirements rather than ASM participant ''exclusions.'' We believe this revision to the terminology will better capture the intended policy to not require an ASM participant to meet certain ASM requirements for an ASM performance year under certain circumstances. Accordingly, throughout this section of this proposed rule, we are proposing revisions to existing regulatory text to clarify the current circumstances under which an ASM participant may be excepted from certain ASM requirements and are proposing new provisions to include additional circumstances under which an exception would apply.

In the remainder of this section of this proposed rule, we propose, in addition to the current exception due to a change in the reassignment of billing rights (that is, change in TIN), to recognize a new exception. Specifically, we propose that ASM heart failure participants who meet certain specialty type redesignation requirements may be excepted from specified model requirements. For each exception, we discuss proposals around the requirements and process for notifying us of a change that may warrant an exception. Finally, in accordance with the proposed revisions to § 512.710(a)(2) discussed earlier in this section of this proposed rule, we make proposals at § 512.710(c) to describe the effect and duration of an exception due to a change in TIN or redesignation of primary specialty type.

(a) Exceptions Due to TIN Changes

In the CY 2026 PFS final rule (90 FR 49582 through 49583), we finalized that an ASM participant who stops reassigning billing rights to the TIN used to select the ASM participant and begins reassignment to a new TIN during the same ASM performance year would no longer be subject to specified ASM requirements for that ASM performance year under either TIN if the ASM participant notifies us of the reassignment change within 30 days. We explained that a TIN change during an ASM performance year may limit our ability to determine continued ASM participant eligibility and assess performance under the model using consistent claims history and EBCM data.

Since the finalization of the CY 2026 PFS final rule, interested parties have shared examples with us of additional circumstances, beyond changes in reassignment, that impact a clinician's affiliation with a particular TIN (for example, retirement from practice) and inquired whether those circumstances would qualify an ASM participant for exception from specific ASM requirements. Our finalized provisions also do not account for situations when an ASM participant reassigned their billing rights to a new TIN before the start of an ASM performance year. After internal review, we believe that it would be appropriate to address such circumstances in ASM's provisions.

Accordingly, we are making multiple proposals to simplify the exception from specified model requirements based on TIN changes including to recognize additional TIN change scenarios for possible exception from specified ASM requirements.

First, we are proposing to redesignate the provisions at current § 512.710(c)(1), which describes the notification process for TIN changes that occur during an ASM performance year, as new § 512.710(c)(1)(i)(B). We propose to revise § 512.710(c)(1) to describe how we may determine an exception applies. Specifically, we propose that an ASM participant who demonstrates the circumstances described by an exception apply (that is, change in TIN or approved primary specialty type redesignation) would be excepted from specified ASM requirements, subject to CMS determination for the duration specified for each exception. For each of these exception situations, we discuss the proposed requirements that an ASM participant would be required to meet and, later in this section of this proposed rule, the duration of the exception.

Second, we propose at new § 512.710(c)(1)(i) that an ASM participant who (1) stops reassigning billing rights to the TIN we used to select them as ASM participant for an applicable ASM performance year and (2) satisfies the TIN change notification requirements at proposed § 512.710(c)(1)(i)(A) or § 512.710(c)(1)(i)(B), as applicable, may be excepted from specified ASM requirements. We believe the addition of this provision provides additional clarity on how the notification processes proposed at §§ 512.710(c)(1)(i)(A) and 512.710(c)(1)(i)(B) could lead to an exception.

Third, we propose new provisions related to ASM participant TIN changes that occur before the start of an ASM performance year. At § 512.710(c)(1)(i)(A), we propose that an ASM participant who stops reassigning billing rights to the TIN we used to select them as an ASM participant before the applicable ASM performance year must notify us in writing no later than 60 days after the start of the applicable ASM performance year; after receiving such notice, we may determine an exception to specified ASM requirements applies for the ASM performance year. We recognize that ASM participants may change organizational affiliations between the time we select ASM participants and the start of an ASM performance year. Based on our previously finalized provisions related to the TIN change exception in the CY 2026 PFS final rule, we believe that the same challenge of having consistent claims history and EBCM data to evaluate ASM participant eligibility criteria under the new TIN would apply in this circumstance and thus an exception would be appropriate. We believe that requiring the ASM participant to notify us in writing no later than 60 days after the start of the ASM performance year would provide an adequate window to provide us with notice of such change after we release the list of ASM participants for a given ASM performance year.

Finally, we propose at § 512.710(c)(1)(i)(B) that an ASM participant who stops reassigning their

billing rights to the TIN we used to select them for participation in ASM during an ASM performance year is not required to reassign billing rights to a new TIN during the same ASM performance year to be potentially eligible for an exception from specified ASM requirements. We believe the proposed modification would capture additional organizational affiliation changes, such as retirements, that merit an exception from specified ASM requirements. We further believe this proposal is consistent with the original intent of the TIN change exception policy we finalized in the CY 2026 PFS final rule. We are also proposing that an ASM participant who changes their TIN during an ASM performance year must provide written notice of the change in a form and manner determined by us within 30 days of stopping reassignment to that TIN. We believe that adding this additional detail on the form of the notification and required timing clarifies the notification process for ASM participants.

We seek comment on our proposal at § 512.710(c)(1) describing the notice and determination process for an exception from specified model requirements. We also seek comment on our proposal at § 512.710(c)(1)(i) to describe the requirements for an exception from specified model requirements for an ASM participant who stops reassigning billing rights to the TIN we used to select them as an ASM participant. We also seek comment on: (1) our proposed notification process for TIN changes that occur before the start of an ASM performance year described at § 512.710(c)(1)(i)(A); (2) our proposal to remove the requirement that an ASM participant who no longer reassigns their billing rights to the TIN we used to select them as an ASM participant during an ASM performance year must begin reassigning billing rights to a new TIN to be eligible for exception as described at § 512.710(c)(1)(i)(B); and (3) our proposal that an ASM participant must provide written notice of the change in TIN within 30 days of stopping reassignment of billing rights to the ASM participant's TIN as described at § 512.710(c)(1)(i)(B).

(b) Exceptions Due to Heart Failure-Related Specialty Type Redesignations

In the CY 2026 PFS final rule, we did not propose or consider an exception based on redesignations of specialty type made through Medicare enrollment before or during an ASM performance year.

Since publication of the CY 2026 PFS final rule, we have received interested parties' feedback that we should consider adjustments to ASM participant eligibility determinations based on more recent Medicare enrollment information related to specialty type, which is used to derive the Medicare Part B claims-based specialty type that we use to evaluate ASM participant eligibility criteria.

We believe that using historical data to evaluate ASM participant eligibility criteria for each ASM performance year is still appropriate. In the CY 2026 PFS final rule (90 FR 49583 through 49585), we explained that determining a clinician's specialty type based on historical data from 2 CYs before an ASM performance year provides an objective and consistent approach because it allows us to use historical claims data to evaluate clinician specialty type, as well as the EBCM episode threshold, as part of the ASM participant eligibility criteria. This approach also supports operational feasibility because it enables us to provide advance notification for ASM participants to prepare for the start of an ASM performance year.

However, we recognize that clinicians may not have had sufficient time to formally update an out-of-date specialty type before the end of CY 2025 because ASM was not finalized until November 2025. For example, specialty type redesignations made in CY 2026 would not be reflected in the CY 2025 data used to select final ASM participants for the 2027 ASM performance year. Setting an appropriate scope of ASM participant exceptions is important in a mandatory model such as ASM to preserve the integrity of the model design and evaluation, and to ensure a representative ASM participant population. While allowing unrestricted ASM participant exceptions due to specialty type redesignations could introduce selection bias and undermine the model test, we believe that certain limited and clinically appropriate redesignations may warrant consideration based on the timing of ASM's announcement and selection of ASM participants.

Accordingly, we are proposing that ASM heart failure participants who officially redesignate their primary specialty type through an approved Medicare enrollment application (either PECOS or CMS–855 form paper application) to a limited set of specialty types and demonstrate proof of board certification would be excepted from specified ASM requirements and ineligible for Medicare program waivers and the safe harbor provisions available in the model for the applicable ASM performance year and for all remaining ASM performance years in the ASM test period. We further discuss the proposed duration of this specific exception later in this section of this proposed rule.

Specifically, we propose at § 512.710(c)(1)(ii) that we may approve an exception from specified model requirements for an ASM heart failure participant upon receipt of written notification of updated Medicare enrollment to the following redesignated primary specialty types described at § 512.710(c)(1)(ii)(A): cardiac electrophysiology, cardiac surgery, interventional cardiology, advanced heart failure and transplant cardiology, and adult congenital heart disease. We propose at § 512.710(c)(1)(ii)(B) that an ASM heart failure participant who redesignated their primary specialty type through an approved Medicare enrollment application (either PECOS or CMS–855 form paper application) would need to provide us written notification of the approved redesignation, along with verification of board certification in the newly designated primary specialty type described under § 512.710(c)(1)(ii)(A) within 30 days of the effective date of the approved redesignation.

Recognizing an exception for ASM heart failure participants that redesignate their specialty type to one of the proposed specialty types would be appropriate because these specialty types reflect highly specialized or procedure-focused practice areas that are distinct from the broader management of cardiovascular disease and heart failure captured under the cardiology specialty. Excepting cardiac electrophysiology, cardiac surgery, and interventional cardiology would be appropriate because these specialties are predominantly procedure-focused and are generally organized around the performance of invasive or technical interventions rather than the longitudinal medical management of cardiovascular disease. Cardiac electrophysiology primarily involves the diagnosis and treatment of cardiac arrhythmias through procedures such as ablation and device implantation; interventional cardiology centers on catheter-based interventions (for example, percutaneous coronary intervention). Cardiac surgery involves operative treatment for cardiac conditions. Advanced heart failure and transplant cardiology specialists primarily manage patients with end-stage heart failure, mechanical circulatory support, or transplant-related care, while adult congenital heart disease specialists treat individuals with complex congenital conditions that persist into adulthood. Because the specialty types proposed for

exception represent narrower scopes of practice than general heart failure management, their exception from specified requirements helps ensure that ASM remains focused on specialists who manage heart failure in a comprehensive and ongoing manner, thereby improving the specificity and consistency of the ASM heart failure cohort.

To be excepted from the specified ASM requirements under this proposal, we believe that the ASM participant must (1) officially redesignate their primary specialty type to one of the specialty types described earlier through an approved Medicare enrollment application and (2) provide evidence of board certification in the redesignated specialty to ensure that an exception to specified ASM requirements is valid and appropriate. While Medicare enrollment requirements stipulate a clinician must supply documentation supporting eligibility for Medicare enrollment under § 424.510(d), these enrollment regulations do not specify a mechanism for substantiating specialty type. Initial enrollment, revalidation, and any interim changes to an existing enrollment require a physician to select a primary specialty and attest that they meet all state or Federal requirements for their selected primary specialty. Physicians must meet the same requirements for any secondary specialty selected. They must also provide information on the active certification relating to their selected primary specialty type, specifically certification number, effective data, certifying entity, and state where issued. If no certification is associated with the selected primary specialty, then the physician must report the certification relevant to the secondary specialty.[165] MACs have operational authority to validate reported information, including requesting supporting documentation, if needed. In addition to requiring the redesignation through a Medicare enrollment application, we believe that requiring an ASM participant to report additional proof of board certification in one of the proposed specialty types eligible for exception would promote a more accurate approach to the exception process while avoiding unrestricted or unverified exceptions that could introduce selection bias into the model test. Further, all of the proposed specialty types for exception have a certifying entity that provides evidence of board certification. The American Board of Internal Medicine provides board certification for cardiac electrophysiology, interventional cardiology, advanced heart failure and transplant cardiology, and adult congenital heart disease specialty types. The American Board of Thoracic Surgery provides board certification for the cardiac surgery specialty type. Therefore, we believe that an ASM heart failure participant seeking an exception would be able to produce evidence of board certification for all specialty types proposed for exception.

We considered an alternative proposal whereby we would only recognize specific specialty type redesignation-based exceptions that occur during 2027 and 2028 ASM performance years to limit the number of ASM participants potentially excepted. Based on the announcement of ASM in the CY 2026 PFS final rule in November 2025, we believe that potential ASM participants may not have had adequate time to officially redesignate their primary specialty type such that it is reflected in the Medicare Part B claims used to select ASM participants for these ASM performance years. For example, a 2027 ASM participant who redesignated their primary specialty type in CY 2026 would not have that change reflected in the CY 2025 claims data used to evaluate their eligibility. A similar timing challenge could occur for the 2028 ASM performance year because we will use CY 2026 data to select ASM participants for the 2028 ASM performance year. We believe that finalization of ASM in the CY 2026 PFS final rule provided potential ASM participants advanced notice to redesignate their specialty type, if appropriate, for CY 2027, which is the year of data that we will use to select ASM participants for the 2029 ASM performance year. However, we recognize that appropriate specialty type redesignations could occur after the 2028 ASM performance year and that allowing the potential for an exception based on specific specialty type redesignations for a longer period would retain consistency in the application of the proposed exception for specified ASM requirements.

We considered but are not proposing exceptions based on specialty type redesignations for ASM low back pain participants. Unlike cardiac specialties, the specialty types included in the ASM low back pain cohort typically do not have Medicare specialty types that reflect further specialization that would be appropriate for excepting ASM low back pain participants. We also believe that the larger number of specialty types in the ASM low back pain cohort would naturally capture common changes in specialty type by ASM low back pain participants over time. For example, we would capture an anesthesiologist ASM low back pain participant who redesignates their primary specialty type to pain management or interventional pain management over the course of the ASM test period through our existing use of historical Mediare Part B claims to identify specialty type. Our rationale for recognizing exceptions based on specialty type redesignation is to ensure each ASM cohort represents specialists who can be appropriately held accountable for longitudinal management of heart failure or low back pain. Accordingly, we believe that the existing ASM low back pain participant specialty type criteria, together with the minimum episode attribution volume for the low back pain EBCM, accomplishes this objective and allowing unrestricted exceptions based on specialty type redesignations in the ASM low back pain cohort could introduce selection bias into the model test.

We seek comment on the proposed timeline and documentation requirements for notifying us of an ASM heart failure participant specialty type redesignation for the purpose of determining an exception proposed under § 512.710(c)(1)(ii). We also seek comment on the proposed specialty types—cardiac electrophysiology, cardiac surgery, interventional cardiology, advanced heart failure and transplant cardiology, and adult congenital heart disease—to which an ASM heart failure participant may redesignate their primary specialty type through an approved Medicare enrollment application to be considered for an exception from specified ASM requirements. We further seek comment on the proposed requirement to provide us with direct evidence of board certification in one of the proposed specialty types eligible for exception. We also seek comment on our alternative to only consider exceptions for specific specialty type redesignations based on notifications that occur during the 2027 and 2028 ASM performance years. Finally, we seek comment on whether we should consider ASM low back pain participant exceptions based on primary specialty type redesignations, including rationale on specific specialty type redesignations that we could consider for ASM low back pain participants.

(c) Effect and Duration of Exceptions to Specific ASM Performance Requirements

We propose at § 512.710(c)(2) to define the effect of an approved

[165] *https://www.cms.gov/medicare/cms-forms/cms-forms/cms-forms-items/cms019477.*

exception on an ASM participant. Specifically, we propose that the ASM participant with an approved exception would: (1) not be subject to performance assessment described at § 512.715, data submission described at § 512.720, and final scoring described at § 512.745 for the applicable ASM performance year; (2) not be subject to payment adjustments described at § 512.750 for the corresponding ASM payment year; (3) not be eligible for Medicare program waivers available under the model described at § 512.775 for the applicable ASM performance year, and (4) not be eligible for the CMS-sponsored model arrangements and patient incentives safe harbor described at § 512.765 for the period for which we determine an exception applies. We believe that the proposed effect of an exception retains the intent of the finalized provisions related to ASM participant exclusions due to TIN changes in the CY 2026 PFS final rule while adding new elements that strengthen program integrity. This proposal is also similar to the effect of an ASM participant not meeting the ASM participant eligibility criteria for an ASM performance year discussed earlier in this section of this proposed rule.

We propose at § 512.710(c)(3)(i) that an exception related to a TIN change would be effective on the CMS-determined date and would only apply for the applicable ASM performance year. We believe that limiting an exception to a single ASM performance year would allow us to select the ASM participant with the exception (that is, the same TIN/NPI combination) for a future ASM performance year should the NPI again reassign billing rights to that same TIN and meet ASM participant eligibility criteria under that TIN.

We considered whether to extend an exception related to a TIN change for the remainder of the ASM test period. However, we believe that this approach could lead to unnecessary exceptions for later ASM performance years, particularly in the case that an excepted ASM participant begins reassigning billing rights to the same TIN under which we previously selected them as an ASM participant, and excepted them, for a previous ASM performance year.

We provide several illustrative examples of how the proposed exception related to TIN changes would work in practice, including the effect of such exceptions on the application of payment adjustments under ASM. In our first example, ASM participant Dr. A (TIN A/NPI A) receives a final score and an ASM payment multiplier for their performance at TIN A in the 2027 ASM performance year. Dr. A receives an exception for the 2028 ASM performance year based on termination of billing rights to TIN A and reassignment of billing rights to TIN B. Under TIN B, Dr. A remains located in the same mandatory geographic area as they were located under TIN A. Dr. A is not required to meet the specified ASM requirements under TIN A or TIN B for the 2028 ASM performance year. However, because Dr. A began reassigning billing rights to TIN B after the end of the 2027 ASM performance year but before the end of the 2029 ASM payment year, we would apply the ASM payment multiplier determined for the 2027 ASM performance year to payments for Medicare Part B covered professional service claims submitted by Dr. A under TIN B during the 2029 ASM payment year. We refer readers to section III.D.2.g. of this proposed rule and § 512.750(f) for additional information on payment adjustment provisions related to TIN changes that occur after an ASM performance year but before the end of the corresponding ASM payment year. We also note that Dr. A in this example could be selected as an ASM participant under TIN B for the 2030 ASM performance year if they meet ASM participant eligibility criteria under TIN B based on CY 2028 data. In this situation, Dr. A would be included in the list of ASM participants for the 2030 ASM performance year.

We also provide an example of how the proposed exception due to TIN changes would work for an NPI who is selected as an ASM participant under multiple TIN/NPI combinations. As discussed in the CY 2026 PFS final rule, we believe that it would be rare, but possible, for the same NPI to be selected as an ASM participant under multiple TINs for the same ASM performance year (90 FR 49602). An exception based on a TIN change for one TIN/NPI combination does not affect the ASM participant's obligation to meet specified ASM requirements under any other TIN/NPI combination for which we selected the NPI as an ASM participant. For example, Dr. B (NPI B) is selected as an ASM participant under TIN C and TIN D for the 2028 ASM performance year. If Dr. B stops reassigning billing rights to TIN C during the 2028 ASM performance year and receives an exception for the 2028 ASM performance year, then Dr. B is excepted from the specified ASM requirements under TIN C but must continue to meet ASM's requirements under TIN D for the 2028 ASM performance year.

We propose at § 512.710(c)(3)(ii) that an exception related to specialty type redesignation would be effective on the CMS-determined date and would apply for the applicable ASM performance year and remain effective for all ASM performance years in the remainder of the ASM test period. We believe that excepting ASM participants for specified specialty type redesignations for the remainder of the ASM test period would be appropriate since these ASM participants do not represent the target specialty type of an ASM cohort, and would, therefore, improve the specificity and consistency of the ASM cohort for the purposes of performance comparison.

We considered effectuating the exception related to specialty type redesignation type on the CMS-determined date and only having it apply for the applicable ASM performance year. However, we believe that effectuating the exception for the remainder of the ASM test period would be preferrable since we believe an ASM participant would be unlikely to revert to their previous primary specialty type redesignation during the remainder of the ASM test period.

We provide several illustrative examples of how the proposed exception related to specialty type redesignations would work in practice, including the effect of such exception on the application of payment adjustments under ASM. For example, consider ASM heart failure participant Dr. C (TIN E/NPI C) who receives a final score and an ASM payment multiplier for their performance under TIN E for the 2027 ASM performance year. Dr. C receives an exception during the 2028 ASM performance year because they redesignated their primary specialty type to cardiac electrophysiology as part of their Medicare enrollment and met the notification requirements. Dr. C would be excepted from the specified ASM requirements for the 2028 ASM performance year and the remainder of the ASM test period under TIN E. However, they would continue to receive payment adjustments on their Medicare Part B covered professional service claims submitted under TIN E during the 2029 ASM payment year based on the ASM payment multiplier determined for their performance during the 2027 ASM performance year. As we emphasized in the CY 2026 PFS final rule (90 FR 49696 through 49699), our goal is to maintain accountability for an ASM participant's performance for a given ASM performance year through performance-based payment adjustments during the corresponding ASM payment year.

We also note that a specialty type redesignation exception would apply to

all TIN/NPI combinations for which we selected the NPI as an ASM participant, provided the notification requirements are met and we approve an exception for each TIN/NPI combination. For example, Dr. D (NPI D) is considered an ASM heart failure participant under TIN F and TIN G for the 2028 ASM performance year. Dr. D redesignates their primary specialty type to interventional cardiology as part of their Medicare enrollment during the 2028 ASM performance year and meets the notification requirements for both TIN F and TIN G. If we approve the exception, Dr. D would be excepted from specified ASM requirements for the 2028 ASM performance year and the remainder of the ASM test period under both TIN F and TIN G.

We seek comment on the proposed effect of an exception from specified ASM requirements at § 512.710(c)(2). We also seek comment on the proposed duration of an exception related to TIN changes as proposed at § 512.710(c)(3)(i), as well as the alternative we considered of setting the duration of a TIN change-related exception as the remainder of the ASM test period. We seek comment on the proposal at § 512.710(c)(3)(ii) that an exception related to specialty type redesignation would apply for the ASM performance year for which we approve the exception and for the remainder of the ASM test period. Finally, we seek comment on the alternative we considered to effectuate an exception related to specialty type redesignation for the applicable ASM performance year only.

(5) ASM Participant Terminations

In the 2026 PFS final rule, we finalized application of the Standard Provisions for Mandatory Innovation Center Models (42 CFR part 512, subpart A) to ASM (90 FR 49720). These provisions describe actions that we may take to remediate actions associated with risks to program integrity. We discussed how the standard provisions are not intended to encompass all the terms and conditions that would apply to each Innovation Center model, because each model has unique design features and implementation plans that may require additional, more tailored provisions.

In addition to the remedial actions enumerated in the standard provisions at § 512.160(b), we now propose to include an additional remedial action for purposes of ASM whereby we could terminate an ASM participant from participation in the model upon determining that one or more grounds for remedial action described in § 512.160(a) has taken place. Grounds for remedial action include, for example, when a model participant has: failed to comply with terms of the Innovation Center Model or applicable Medicare program requirements; taken action to threaten the health or safety of a patient; submitted false data or made false representations in connection with the Innovation Center model; or undergone a change in control that presents a program integrity risk.

We also propose that we could terminate an ASM participant if we determine that their continued participation would be inconsistent with the purposes of ASM or applicable law.

Under this proposal, any termination of an ASM participant's participation would occur only upon a determination by CMS. For the avoidance of doubt, our proposal would not establish a right for an ASM participant to terminate their participation.

We believe that reserving authority to terminate an ASM participant's participation, where appropriate, such as in circumstances involving egregious conduct, would provide additional protections for the program and for beneficiaries. We propose to codify this provision at § 512.710(h) and to include a corresponding reference to termination in proposed revised § 512.710(a)(1), which addresses the duration of participation under ASM.

We seek comment on this proposal at § 512.710(h).

c. Data Submission

(1) Background

We finalized in the CY 2026 PFS final rule that an ASM participant must meet established data submission requirements across the quality, improvement activities, and Promoting Interoperability ASM performance categories, consistent with §§ 512.725, 512.735, and 512.740, respectively (90 FR 49596 through 49605). We did not establish data submission requirements for the cost ASM performance category or for administrative claims-based quality measures as we will calculate performance on these measures using administrative claims data.

For the quality ASM performance category, we require the submission of numerator and denominator data for at least one required quality measure that satisfies the data completeness criteria (that is, data is submitted on at least 75 percent of the ASM participant's patients that meet a quality measure's denominator criteria). ASM participants in small practices (that is, a TIN with 15 or fewer clinicians) may submit quality data at the group level (that is, TIN level) while ASM participants in non-small practices must submit quality measure data at the individual clinician level (that is, TIN/NPI level). Data submission for the improvement activities ASM performance category requires an ASM participant to attest at the group level (that is, TIN level) that the required activities are completed by all ASM participants within the TIN. Finally, for the Promoting Interoperability ASM performance category, ASM participants must submit all required measure data (or claim any applicable exclusions), attestations, CMS Electronic Health Record (EHR) Certification ID, and performance period dates at the group level (that is, TIN level). Data submission for the Promoting Interoperability ASM performance category may reflect data from clinicians who are not ASM participants. Regardless of the data submission level for each ASM performance category, each ASM participant receives an individual-level final score and corresponding ASM payment adjustment factor and ASM payment multiplier, which is used to adjust payments for each ASM participant's Medicare Part B covered professional service claims.

(2) Quality ASM Performance Category Data Submission for ASM Participants in Small Practices

We finalized policies at § 512.720(a) addressing data submission for the quality ASM performance category, including the requirement that quality measure data be submitted at the individual level (that is, TIN/NPI level). However, as finalized at § 512.720(f), an ASM participant that is in a small practice may report quality ASM performance category data at the group level (that is, TIN level).

After reviewing our provisions finalized in the CY 2026 PFS final rule, we believe it would improve readability and overall clarity of the regulatory text if we addressed the quality data submission policy for ASM participants in small practices together with the generally applicable policies for each ASM performance category, which appear at § 512.720(a).

Accordingly, we propose to remove existing § 512.720(f) and instead address our quality ASM performance category data submission policy for ASM participants in small practices at § 512.720(a)(1)(i)(C). In relocating this regulatory text, we also propose to make technical clarifying edits to better reflect our policy intent that an ASM participant in a small practice has the option to submit ASM quality measure

data at either the group level (that is, TIN level) or the individual level (that is, TIN/NPI level). Our intent is to provide ASM participants in small practices an additional flexibility in reporting ASM quality measure data.

We propose conforming adjustments at § 512.720(a)(1)(i)(A) to correct a minor typographical error and at § 512.720(a)(1)(i)(B) to cross-reference to proposed new § 512.720(a)(1)(i)(C). Our proposed reorganization of these provisions would not substantively change the policy under existing provisions, but we believe the proposed changes would bring greater clarity to the structure of the regulation and regulatory text.

We invite public comment on these proposed adjustments to § 512.720(a)(1)(i).

(3) Improvement Activities ASM Performance Category Data Submission

In the CY 2026 PFS final rule, we finalized that ASM participants submit improvement activity ASM performance category data by attesting to the completion of required improvement activities at the group level (that is, TIN level) (90 FR 49599 through 49602). We believed that group-level data submission would be appropriately reflective of the team-based care and coordination envisioned by the improvement activities (90 FR 49601). We also believed that group-level data submission for the improvement activities ASM performance category would reduce administrative burden (90 FR 49601). In subsequent sub-regulatory guidance, we clarified that a group-level attestation for completing a required improvement activity means that all ASM participants within a TIN successfully completed the requirements of that improvement activity for the applicable ASM performance year. We also clarified that a clinician who is not an ASM participant, but who has reassigned billing rights to a TIN that includes one or more ASM participants, would not be subject to any ASM participation obligations solely on that basis, including the requirements of the improvement activities ASM performance category.

Since the publication of the CY 2026 PFS final rule, we have received feedback from interested parties that group-level data submission for the improvement activities ASM performance category may have unintentional consequences on scoring for ASM participants in certain circumstances. For example, if only 8 ASM participants in a TIN with 10 ASM participants complete a required improvement activity, then the group could not submit an attestation that all ASM participants within the group completed the improvement activity. In this example, each of the 8 ASM participants who completed the improvement activity would receive a 10-point deduction on their final score. While the group-level data submission for the improvement activities ASM performance category may reduce administrative burden related to data reporting, we believe it would be appropriate to adjust these data submission provisions to reduce the likelihood of final score penalties on an ASM participant who fully or partially completes the requirements of the improvement activities ASM performance category and associated data submission requirements.

Accordingly, we propose at § 512.720(a)(1)(ii)(B) to allow an ASM participant to submit data for the improvement activities ASM performance category at either the group level (that is, TIN level) or the individual level (that is, TIN/NPI level). We believe this proposal would offer greater flexibility in how an ASM participant or their affiliated group submits data for the improvement activities ASM performance category depending on their specific circumstances and data submission preferences. While we believe that many of ASM's improvement activities would be jointly implemented by ASM participants within a group to improve team-based care and coordination, we believe that this added data submission flexibility would mitigate the chance of an unintended negative adjustment to the final score of an ASM participant who fully or partially meets the improvement activities ASM performance category requirements. We note that this proposal would not affect how an ASM participant or its affiliated TIN may choose to structure a CCA required under IA–2.

We seek comment on our proposal at § 512.720(a)(1)(ii)(B) to allow ASM participants to attest to completing ASM's improvement activities at either the group level (that is, TIN level) or the individual level (that is, TIN/NPI level).

(4) Treatment of Multiple Data Submissions for the Quality, Improvement Activities, and Promoting Interoperability ASM Performance Categories

In the CY 2026 PFS final rule, we finalized policies addressing the treatment of multiple data submissions for the quality, improvement activities, and Promoting Interoperability ASM performance categories at § 512.720(e) (90 FR 49604 through 49606). For the quality and improvement activities ASM performance categories, when we receive multiple data submissions for an individual ASM participant from multiple organizations (for example, a qualified registry, practice administrator, or an electronic health record (EHR) vendor), we calculate and score each submission and assign the highest score to the ASM participant. When we receive multiple data submissions for an individual ASM participant from the same organization, we score the most recent submission. For the Promoting Interoperability ASM performance category, we calculate each submission and assign the highest score.

We believe our policies for multiple data submissions would be clearer if we addressed each ASM performance category separately, rather than discussing the quality ASM performance category and the improvement activities ASM performance category together. Accordingly, we propose to make technical modifications to regulatory text describing multiple data submissions, such that § 512.720(e)(1) would address the quality ASM performance category, § 512.720(e)(2) would address the improvement activities ASM performance category, and § 512.720(e)(3) would address the Promoting Interoperability ASM performance category. Except for the proposed new policy for small practices at proposed § 512.720(e)(1)(iii), discussed later in this section of this proposed rule, the remaining proposed revisions to § 512.720(e)(1) would not constitute substantive changes from the policies finalized in the CY 2026 PFS final rule. Rather, those proposed revisions would reorganize the existing provisions and make clarifying modifications to the regulatory text.

Specifically, we propose to:

- Address the multiple data submissions policy for the ASM quality performance category at § 512.720(e)(1), the improvement activities ASM performance category at § 512.720(e)(2), and the Promoting Interoperability ASM performance category at § 512.720(e)(3). To accomplish this, we would:

++ Add the informative heading ''Quality ASM performance category'' to § 512.720(e)(1).

++ Revise §§ 512.720(e)(1)(i) and 512.720(e)(1)(ii) to reflect our policy for scoring multiple data submissions for the quality ASM performance category and make technical revisions to the text.

++ Redesignate existing § 512.720(e)(2) describing our multiple data submission policy for the Promoting Interoperability ASM

performance category as new paragraph § 512.720(e)(3)(i).

++ Redesignate the portions of §§ 512.720(e)(1)(i) and 512.720(e)(1)(ii) that address our multiple data submission policy for the improvement activities ASM performance category to §§ 512.720(e)(2)(i) and 512.720(e)(2)(ii).

++ Add the informative heading ''Improvement activities ASM performance category'' at § 512.720(e)(2).

++ Revise newly redesignated §§ 512.720(e)(2)(i) and 512.720(e)(2)(ii) to make technical clarifications for the treatment of multiple data submissions for the improvement activities ASM performance category.

++ Add the informative heading ''Promoting Interoperability ASM performance category'' to new paragraph § 512.720(e)(3).

We invite public comment on this proposed reorganization of § 512.720(e).

(a) Multiple Data Submissions for the Quality ASM Performance Category for ASM Participants in Small Practices

In the CY 2026 PFS final rule, we finalized that ASM participants in small practices may report quality measures in the quality ASM performance category at the group level (that is, TIN level) (90 FR 49602). We finalized this policy because we recognize that reporting quality measures at the individual clinician level (that is, TIN/NPI level) may be particularly burdensome for ASM participants in small practices who may have limited capacity for data aggregation and reporting. We believe that EHR customization for individual-level reporting, and the costs associated with updating reporting mechanisms, may pose a larger burden on ASM participants in small practices compared to ASM participants in larger practices because small practices may not have the requisite support, such as infrastructure or staffing, to facilitate individual-level reporting. Importantly, this reporting flexibility does not change ASM's intention to measure individual ASM participant performance; rather, this flexibility is limited to the reporting and scoring of ASM non-administrative claims-based quality measures. All other reporting and scoring requirements for the cost and quality ASM performance categories remain at the individual ASM participant level regardless of practice size. ASM participants in small practices would retain the option to report quality measure data at the individual level if they choose.

After internal review of the provisions finalized in the CY 2026 PFS final rule, we believe that permitting multiple submissions at different reporting levels within a small practice could create unintended incentives and scoring effects. If multiple reporting levels are permitted within the same small practice, an ASM participant's quality ASM performance category score could depend in part on the reporting level used, rather than on a consistent approach to reporting and evaluating quality performance. For example, a small practice could submit individual-level data for higher-performing ASM participants and group-level data for lower performing ASM participants. This variability could reduce comparability across ASM participants and create inconsistent scoring outcomes among ASM participants in similar practice arrangements. We believe ASM participants in small practice should report quality data at the reporting level that best meets their needs and capabilities.

To ensure fair and consistent scoring of the quality ASM performance category, we are proposing at § 512.720(e)(1)(iii) that if we receive any quality ASM performance category data at the group level (that is, TIN level) from an ASM participant in a small practice, we would score the group-level submission and assign that score to all individual ASM participants in the small practice. This proposal would mean that any individual-level (that is, TIN/NPI-level) submission received for any ASM participants in that small practice would not be scored if any group-level quality data submission is received.

We believe this proposal would maintain the desired reporting flexibility to lower the administrative burden for ASM participants in small practices while preserving the integrity of the ASM scoring framework. Specifically, ASM participants in small practices would continue to have the option to report non-administrative claims-based ASM quality measures at either the group or individual level. Our proposed policy would mitigate the opportunity for ASM participants in small practices to submit data at multiples levels most opportune to achieve a higher score and establish a consistent scoring framework so that ASM participants in small practices are encouraged to submit required data based on needs and capabilities, rather than strategic performance considerations. Table B–D1 in this section of this proposed rule summarizes existing finalized policies and new proposals relating to our treatment of multiple data submissions for the quality ASM performance category.

TABLE B-D1: PROPOSED TREATMENT OF MULTIPLE DATA SUBMISSIONS FOR THE QUALITY ASM PERFORMANCE CATEGORY

ASM Participant in a Small Practice	Multiple Quality Data Submissions Received	Source of Multiple Quality Data Submissions	Group-level Quality Data Submission Received	Quality Data Submission Scored
No	No	N/A	Not Permitted	Individual-level (TIN/NPI)
	Yes	Multiple Organizations	Not Permitted	Highest Individual-level (TIN/NPI)
		Single Organization	Not Permitted	Most Recent Individual-level (TIN/NPI)
Yes	No	N/A	Yes	Group-level (TIN)
			No	Individual-level (TIN/NPI)
	Yes	Multiple Organizations	Yes	Highest Group-level (TIN)
			No	Highest Individual-level (TIN/NPI)
		Single Organization	Yes	Most Recent Group-level (TIN)
			No	Most Recent Individual-level (TIN/NPI)

We seek comment on our proposal at § 512.720(e)(1)(iii) to score any group-level quality data submission received from small practices and assign that score to all ASM participants in the small practice regardless of any individual-level quality data submission received for individual ASM participants in that same small practice.

d. Quality ASM Performance Category

(1) Background

As discussed in the CY 2026 PFS final rule, the quality ASM performance category supports the broader goals of the model by incentivizing improvements in the quality of care and reductions in unnecessary or low-value services for patients with heart failure and low back pain. To accomplish these objectives, we finalized in the CY 2026 PFS final rule the use of ASM cohort-specific quality measure sets at § 512.725(b) (heart failure) and § 512.725(c) (low back pain) (90 FR 49606). ASM participants must report all measures applicable to their ASM cohort, with administrative claims-based measures calculated by us. This structure is similar to other CMS programs, such as MIPS Value Pathways (MVPs), that entail reporting on a clinically relevant subset of measures tailored to an eligible clinician's specialty and patient population. It also minimizes reporting burden, promotes consistency in measurement over the duration of the ASM test period, and supports rigorous evaluation by maintaining a stable set of quality indicators.

In finalizing these policies, we sought to ensure that each ASM cohort-specific quality measure set reflects agency goals to advance value-based care by linking payment to meaningful improvements in clinical outcomes and beneficiary experience. The measures selected for ASM represent a mix of utilization-focused measures, evidence-based care measures, and patient-reported outcome or experience measures. This structure supports nationwide measurement efforts focused on outcomes, safety, and patient experience.

We intend for the quality measure sets applicable to each ASM cohort to remain stable throughout the ASM test period; however, we may propose additions or removals through notice-and-comment rulemaking if refinements to the measure sets are warranted. Such updates may be considered in response to interested parties' feedback, changes in clinical guidelines, updates to measures used in ASM or other CMS programs, or the development of new quality measures. This framework keeps the quality ASM performance category aligned with current clinical practice while providing predictability that may reduce administrative burden over time.

(2) Low Back Pain Quality Measure Set

(a) Low Back Pain Imaging Measure for the ASM Low Back Pain Cohort

In the CY 2026 PFS proposed rule, we proposed inclusion of the ''Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain, Respecified to Be Relevant to ASM Participants Treating Low Back Pain'' measure in the ASM low back pain quality measure set (90 FR 32593 through 32597), but did not finalize its inclusion based on interested parties' feedback (90 FR 49616 through 49618). We indicated in the CY 2026 PFS final rule that we intended to revisit the inclusion of this measure in future notice-and-comment rulemaking (90 FR 49617). We indicated revisiting because the ASM low back pain cohort had only four quality measures, and none were focused on excess utilization or efficiency. As our goal is to have a well-rounded measure set for each ASM cohort that includes this focus area, we sought to include a measure that would complete the ASM low back pain quality measure set.

We are proposing at § 512.725(c)(5) to include the ''Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM)'' measure in the ASM low back pain quality measure set. This proposal would meet the goals of the ASM low back pain cohort's quality measure set of having an excess utilization focused measure. This measure is modified from the

''Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain'' measure that was specified for use in hospital outpatient departments at the facility level and previously included in the Hospital Outpatient Quality Reporting Program (HOQRP) as OP–8 (73 FR 68766).[166] While we removed the measure from the HOQRP in 2017 due to limited reliability from low average facility-level volumes, we have since re-evaluated the measure for use in ASM. In reassessing this measure, we considered interested parties' feedback, technical expert input, and measure reevaluation activities. Commenters and experts indicated that, while the clinical concept remains important for assessing low-value imaging, the prior specification presented challenges related to attribution at the facility level, small sample sizes, and limited applicability to certain care delivery contexts. Interested parties also recommended exploring refinements to improve measure reliability and alignment with clinician decision-making in ambulatory specialty settings.

In response, we have made targeted specification modifications to improve the measure's applicability and statistical reliability in the ASM context. We believe these modifications address the previously identified limitations while preserving the measure's clinical intent of reducing unnecessary imaging for low back pain.

We believe the proposed administrative claims-based quality measure would effectively evaluate overuse and incentivize reductions in inappropriate MRI imaging for low back pain. Routine imaging (such as MRI) is not recommended for patients with non-specific low back pain in the absence of certain clinical indicators and concerning features.[167] However, analyses have shown that a significant proportion of patients with low back pain undergo imaging, often within the first few weeks of symptom onset, despite the lack of clear indication.[168] Overuse of imaging for low back pain can lead to unnecessary health care costs and potential patient harm from the cascade effect, where MRI findings, many incidental, may prompt further unnecessary testing or procedures.[169] [170] By including this measure in the ASM low back pain quality measure set, ASM would aim to incentivize adherence to evidence-based guidelines and a reduction of unnecessary MRIs for patients with uncomplicated low back pain, where an MRI is not clinically indicated, particularly in the initial stages of evaluation and management. We believe this could also improve patient experience to the extent it reduces time spent at medical appointments and out-of-pocket health care costs. Furthermore, as an administrative claims-based quality measure, ASM low back pain participants would not assume new reporting requirements for this measure. We would provide detailed measure information for the MRI Lumbar Spine for Low Back Pain (modified for ASM) on the ASM website before the start of the 2027 ASM performance year, if finalized, to educate ASM participants on how they would be measured.

Our modifications seek to improve clinical validity and reliability for the purposes of ASM. Two of our modifications were related to denominator exclusions and the measure's performance period. We also made modifications to provider attribution, minimum case count, and the lookback period for antecedent care, for which we offer alternative options that seek comment on. We believe the modifications we propose in this proposed rule as part of the ''Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM)'' measure to be appropriately tailored to measure performance of ASM participants ordering inappropriate MRIs for patients with low back pain.

We seek comment on the inclusion of MRI Lumbar Spine for Low Back Pain (modified for ASM) measure in the ASM low back pain quality measure set at § 512.725(c)(5).

We discuss modifications to the measure's specifications in the remainder of this section of this proposed rule, including seeking comment on potential alternatives to the proposed modifications related to provider attribution, minimum case count, and the lookback period for antecedent care.

(i) Denominator Exclusions

We conducted an evaluation of the measure's denominator exclusions to ensure that they reflect current clinical guidelines and appropriately identify cases where early lumbar spine imaging is clinically justified. This evaluation focused on exclusions that previously removed a large number of cases under the OP–8 specifications and involved reviewing each diagnosis code individually. Removing a large number of cases in OP–8 presented risks to the applicability and reliability of the measure.

We identified three clinical areas that had a large number of exclusions: cancer diagnoses, neurological impairment, and autoimmune or inflammatory conditions. Physicians assessed each code under these categories for appropriateness to include in the measure denominator. Most conditions, such as ''red flag'' signs and symptoms and for malignant neoplasms and autoimmune disorders where imaging would be warranted (regardless of completion of conservative therapy), were maintained as denominator exclusions. Conditions, such as benign neoplasm of the colon and hemangioma of skin and subcutaneous tissue, were removed as denominator exclusions since their presence would not warrant an immediate MRI for a patient with low back pain; the condition alone would not preclude a patient with low back pain from attempting conservative therapy prior to receiving a lumbar MRI. To improve clinical validity and acceptability, conditions and diagnoses were not removed as denominator exclusions if they were present in the list of denominator exclusions in the Healthcare Effectiveness Data and Information Set (HEDIS) Use of Imaging Studies for Low Back Pain measure.[171] Under this approach, we ultimately aligned with the same exclusion logic used in the HEDIS Use of Imaging Studies for Low Back Pain measure and only diagnosis codes present in that measure and supported by clinical review remained as denominator exclusions in our ASM measure. As a result of these refinements, the ASM measure's exclusion criteria differ from the prior OP8 specification in these three clinical areas with the goal of

[166] Hospital Outpatient Quality Reporting | Partnership for Quality Measurement. *P4qm.org.* Published 2025. Accessed April 23, 2025. *https://p4qm.org/taxonomy/term/216*.

[167] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020. *https://www.spine.org/Portals/0/assets/downloads/ResearchClinicalCare/Guidelines/LowBackPain.pdf*.

[168] Medicare Payment Advisory Commission. Health Care Spending and the Medicare Program: A Data Book. Medicare Payment Advisory Commission; July 2021. Accessed July 7, 2026. *https://www.medpac.gov/wp-content/uploads/2021/10/July2021_MedPAC_DataBook_Sec7_SEC.pdf*.

[169] Litkowski PE, Smetana GW, Zeidel ML, Blanchard MS. Curbing the Urge to Image. *The American Journal of Medicine.* 2016;129(10):1131–1135. doi: *https://doi.org/10.1016/j.amjmed.2016.06.020*.

[170] Chou R. Diagnostic Imaging for Low Back Pain: Advice for High-Value Health Care From the American College of Physicians. *Annals of Internal Medicine.* 2011;154(3):181. doi: *https://doi.org/10.7326/0003-4819-154-3-201102010-00008*.

[171] National Committee for Quality Assurance. *Use of Imaging Studies for Low Back Pain (LBP).* NCQA, *https://www.ncqa.org/report-cards/health-plans/state-of-health-care-quality-report/use-of-imaging-studies-for-low-back-pain-lbp/*. Accessed 6 Apr. 2026.

more closely aligning to evidence-based practice guidelines.

In our analysis, these changes result in the inclusion of a significant number of imaging studies that would previously have been excluded, representing 52 percent of the cases that would have been removed under the earlier specification. Retaining these cases strengthens this measure by increasing denominator volume and improving our ability to identify potentially unnecessary imaging. We believe these refinements enhance the measure's clinical validity by ensuring that exclusions are limited to diagnoses that represent appropriate indications for more immediate imaging that do not warrant a prior trial of conservative therapy.

(ii) Performance Period

We evaluated the performance period for the measure to ensure that ASM participant-level scores are reliable and suitable for use in the model's quality assessment framework. The original HOQRP version of the measure used a single-year performance period, which limited the number of eligible MRI studies available for scoring and contributed to concerns about measure reliability.[172] To address these issues, we tested an expanded performance period that included all eligible lumbar spine MRI studies occurring within a rolling 24-month window. Under this approach, each MRI meeting denominator criteria during the 2-year period was included in measure calculation, thereby significantly increasing the number of cases available for analysis. Testing showed that the expanded 2-year performance period resulted in approximately a 100 percent increase in denominator volume relative to a 1-year period. This increase in case volume improved the precision of ASM participant-level estimates and reduced small-sample volatility, particularly for clinicians with lower annual MRI volumes. We believe that a 2-year performance period enhances measure stability and supports more dependable performance assessment across all ASM low back pain participants and overcomes limitations and concerns that existed when the measure existed in the HOQRP. This is especially important for utilization measures, where annual case counts can vary substantially among specialties and practice types. Based on these findings, we believe that a rolling 24-month period provides the most robust and actionable representation of clinician imaging practices.

(iii) Provider Attribution

The management of low back pain often involves several specialists over an extended period, and diagnostic and treatment decisions typically develop through multiple clinical encounters rather than a single visit. In modifying the original HOQRP measure for use in ASM, we had to address how to transition the measure from its original hospital outpatient department attribution method, which assigned imaging only to the facility that billed the MRI claim, to an approach that reflects physician-level accountability. This work included evaluating a single-participant attribution method that assigns each MRI to the physician with the highest number of qualifying encounters during the lookback period and a multiple-participant attribution method that assigns the MRI to all physicians who provided qualifying services to the patient. Testing showed that the multiple-participant method increased the number of attributed MRI studies by roughly 26 percent after exclusions, which strengthened measure stability and improved representation of the various physicians involved in that beneficiary's care. Multiple attribution better reflects real-world care patterns, particularly in increasingly common cases where beneficiaries receive longitudinal care by different team members over time. This approach also supports ASM's goals by recognizing the shared nature of clinical responsibility for decisions that influence downstream utilization and patient outcomes. Also, including all clinicians who contributed meaningfully to the beneficiary's care ensures that performance assessment captures the full set of ASM low back pain participants who may influence imaging decisions. We believe this attribution method provides a more complete and accurate understanding of imaging practices within the ASM low back pain cohort. For these reasons, we are proposing multiple-participant attribution.

We also considered an alternative approach that would attribute each MRI to a single physician. Under this option, an MRI would be assigned to the ASM participant who furnished the highest number of qualifying encounters during the attribution window, which reflects a single point of clinical responsibility for many beneficiaries. This approach would provide a more streamlined assignment method and could reduce attribution complexity for the measure, but may not be reflective of real-world practice patterns and results in fewer attributed beneficiaries per ASM participant and thus slightly lower measure reliability.

We seek comment on the proposed use of a multiple-participant attribution method for this quality measure. We also seek comment on the alternate proposal of an attribution method involving a single ASM participant.

(iv) Minimum Case Count

We evaluated the appropriate minimum case count threshold for the MRI Lumbar Spine for Low Back Pain (modified for ASM) measure to ensure that clinician-level performance scores are reliable for use in the model's quality assessment framework. Low case volumes may produce substantial variation in provider scores and a wider distribution of results, which could reduce the measure's ability to distinguish true performance differences. At lower thresholds, such as one or 10 cases, our analysis found that many ASM low back pain participants would have insufficient volume to support stable estimates, and reliability decreased accordingly. At a threshold of 20 cases, the measure showed stronger reliability and a narrower distribution of scores across ASM participants, indicating that estimates were more consistent and reflective of meaningful patterns of imaging use. The threshold of 20 cases aligns with the ASM participant eligibility criteria that, in part, requires an ASM low back pain participant to have historically been attributed at least 20 low back pain EBCM episodes. The threshold of 20 cases also aligns with the case minimums for the other quality measures in the ASM low back pain quality measure set. This alignment ensures that the case count threshold is both operationally feasible and representative of the expected care volume for ASM participants. In addition, maintaining a minimum of 20 cases reduces the influence of isolated or atypical events that may disproportionately affect results when volumes are low. The analysis further showed that a substantial proportion of ASM low back pain participants would continue to meet eligibility for scoring at this case threshold, preserving the ability to assess quality performance across a broad ASM participant population. We believe that maintaining a minimum of 20 cases appropriately balances inclusiveness and methodological rigor. For these reasons, we propose a threshold of 20 cases for the MRI Lumbar Spine for Low Back Pain (modified for ASM) measure.

We also considered an alternative minimum case count of 10 for the MRI

[172] Hospital Outpatient Specifications Manuals, Hospital Outpatient Quality Reporting. *CMS.gov*. Accessed March 27, 2026. *https://qualitynet.cms.gov/outpatient/specifications-manuals*.

Lumbar Spine for Low Back Pain (modified for ASM) measure. A threshold of 10 would allow a greater number of ASM low back pain participants to be scored on the measure, particularly those with smaller patient panels or lower annual imaging volume. Although reliability is lower at this threshold relative to a minimum of 20 cases, a 10-case minimum would offer meaningful insight into specialist practice patterns while expanding the proportion of ASM low back pain participants scored on the measure.

We seek comment on the proposed minimum case count of 20. We also seek comment on the alternate proposal of a minimum case count of 10.

(v) Lookback Period

We evaluated the attribution lookback period to determine the timeframe during which clinician services should be considered for assigning each lumbar spine MRI to ASM low back pain participants. The measure needs a lookback period long enough to capture clinical encounters that inform decisions about imaging, while still maintaining a clear and comprehensive lookback approach. Chronic low back pain is managed over extended periods, and patients frequently receive evaluation and treatment, and require care coordination from multiple clinicians during this time. Based on these care patterns, we examined whether a longer window would more accurately identify the set of clinicians who meaningfully influence imaging decisions. Testing demonstrated that a 365-day lookback period compared to a shorter window like 90-days substantially increased the number of attributed MRI studies by approximately 27 percent. We believe a 365-day period better reflects the longitudinal nature of chronic low back pain management and ensures that attribution captures the full course of care that precedes a patient's imaging event. A full-year window also aligns with the model's annual performance period and improves consistency across the various quality measures included in the model. We believe that adopting a 365-day lookback window strengthens the completeness of performance assessment by ensuring that clinicians who contribute meaningfully to care are appropriately included. For these reasons, we are proposing to use a 365-day lookback period for attribution of MRI studies within the measure.

We also considered an alternative 120-day lookback period. This approach would limit attribution to ASM low back pain participants who furnished lower back pain-related services in closer proximity to the imaging event and, therefore, would provide a more focused reflection of recent clinical decision-making. However, it would also result in fewer cases per ASM participant, which could create a narrower view of the ASM participant's trends related to MRI referral and low back pain.

We seek comment on the proposed 365-day lookback period and the alternative of a 120-day lookback period.

(b) Removing Functional Status Change for Patients With Low Back Impairments (MIPS Q220) and Adding Functional Outcome Assessment (MIPS Q182)

In the CY 2026 PFS final rule (90 FR 49620 through 49622), we finalized inclusion of Functional Status Change for Patients with Low Back Impairments (MIPS Q220) in the ASM low back pain quality measure set because it captures functional outcomes that are directly relevant to patients' experience of low back pain and their ability to perform daily activities. We noted that the measure aligns with the model's emphasis on patient-centered outcomes and longitudinal management and complements the broader set of prevention and utilization-focused measures included in the ASM low back pain quality measure set.

Since publication of the CY 2026 PFS final rule, the measure steward has indicated that they no longer intend to maintain Functional Status Change for Patients with Low Back Impairments (MIPS Q220), including key operational components such as the survey's online portal. Consistent with this change, we are removing this measure from the MIPS measure inventory.

Accordingly, we are proposing at § 512.725(c)(4) to remove the Functional Status Change for Patients with Low Back Impairments (MIPS Q220) from the ASM low back pain quality measure set and replace it with Functional Outcome Assessment (MIPS Q182). This proposal would address the absence of the MIPS 220 measure by replacing one measure of functional status with another.

We believe that Functional Outcome Assessment (MIPS Q182) represents an appropriate replacement as it meets similar goals as the inclusion of MIPS Q220 and may be familiar to many ASM low back pain participants. However, we note that we intend to pursue the future adoption of a more robust patient-reported outcome performance measure (PRO–PM) to further emphasize the importance of functional status improvement within ASM. Such a change to the ASM low back pain quality measure set would be proposed via future notice-and-comment rulemaking.

Functional Outcome Assessment (MIPS Q182) promotes the routine assessment of functional status and requires clinicians to document a care plan when functional outcome deficiencies are identified. As such, the measure supports a more patient-centered approach to care by encouraging ASM participants to incorporate patients' reported experiences and functional status assessments and limitations into clinical decision-making. The measure leverages patient-reported outcome tools and surveys to facilitate meaningful communication between clinicians and their patients regarding symptoms, daily functioning, and treatment goals; as a result, identified concerns can be addressed as part of the evaluation and management of the patient.

We believe that systematic measurement and improvement of functional status can increase patient self-efficacy, improve overall well-being, and potentially reduce downstream healthcare utilization and costs. Additionally, the use of validated and standardized assessment tools may enhance the reliability and sensitivity of detecting functional impairments and monitoring changes over time, particularly among older adults with low back pain.[173]

Although Functional Outcome Assessment (MIPS Q182) does not require the use of a specific instrument, examples of appropriate, validated tools relevant to the ASM low back pain cohort include the Modified Oswestry Disability Index and the Patient-Reported Outcomes Measurement Information System (PROMIS). The use of such tools is supported by clinical guidelines and professional organizations. For example, the American Academy of Orthopaedic Surgeons recommends the Modified Oswestry Disability Index as a preferred instrument for assessing functional outcomes in spine care.[174] [175] These functional status instruments may also capture information related to

[173] Wong AY, Karppinen J, Samartzis D. Low back pain in older adults: risk factors, management options and future directions. *Scoliosis and Spinal Disorders*. 2017;12(1):1–23. doi: *https://doi.org/10.1186/s13013-017-0121-3*.

[174] North American Spine Society. Clinical Guidelines for Multidisciplinary Spine Care: Diagnosis and Treatment of Low Back Pain. North American Spine Society; 2020.

[175] Performance Measures by Orthopaedic Subspecialty. Aaos.org. Published 2025. Accessed April 23, 2025. *https://www.aaos.org/quality/research-resources/patient-reported-outcome-measures/performance-measures-by-orthopaedic-subspecialty*.

modifiable risk factors, such as physical activity levels and social isolation, which can inform clinical discussions and interventions aimed at preventing the progression of low back pain and associated comorbid conditions.

This proposal also responds to interested parties' feedback regarding operational concerns with Functional Status Change for Patients with Low Back Impairments (MIPS Q220). In addition, Functional Outcome Assessment (MIPS Q182) aligns with the Quality Payment Program's Rehabilitative Support for Musculoskeletal Care MIPS Value Pathway (MVP), further supporting its inclusion in the ASM. We also note that Functional Outcome Assessment (MIPS Q182) has a MIPS CQM collection type, the same collection type as the Functional Status Change for Patients with Low Back Impairments (MIPS Q220).

By embedding accountability for assessing and addressing functional status into the ASM quality measure set for ASM participants who treat low back pain, this measure supports a comprehensive, longitudinal approach to low back pain management, including appropriate evaluation, treatment planning, and ongoing monitoring of patient outcomes.

We seek comment on our proposal at § 512.725(c)(4) to remove the Functional Status Change for Patients with Low Back Impairments (MIPS Q220) from the ASM low back pain quality measure set and replace it with Functional Outcome Assessment (MIPS Q182).

(3) Data Completeness Requirement for the Quality ASM Performance Category

As discussed in the CY 2026 PFS final rule (90 FR 49631), we finalized policies to establish a data completeness requirement for applicable quality measures in the quality ASM performance category. Under this requirement, ASM participants reporting MIPS clinical quality measures (MIPS CQMs) or eCQMs would be required to submit data for at least 75 percent of patients who meet the denominator criteria for each measure, regardless of payer.

The regulatory text at § 512.725(f)(3) describing the data completeness requirement includes a non-substantive typographical error of a misplaced possessive ''s'' on ''ASM''.

We propose at § 512.725(f)(3) correct this typographical error so that it would read: ''CMS excludes from an ASM participant's total measure achievement points and total available measure achievement points any measure required under paragraph (b) or (c) of this section that meets the respective measure's data completeness requirement but does not have a benchmark.'' We believe this correction clarifies the regulatory text without substantively changing the policy under existing provisions.

We seek comment on our proposal to modify § 512.725(f)(3) to correct this typographical error.

(4) Scoring and Benchmarks for Quality Measures

As discussed in the CY 2026 PFS final rule (90 FR 49634 through 49635), we finalized policies to benchmark and score ASM quality measures. We will use measure-specific benchmarks where separate benchmarks are calculated for each measure and collection type to reflect meaningful performance differences among ASM participants. Quality measure benchmarks will be derived from ASM participant data from the current or prior ASM performance years, or another CMS-determined period. We determined that separate benchmarks by collection type (for example, MIPS CQM and eCQM) are more appropriate than a single benchmark for each measure aggregated across collection types due to established scoring variation across collection types. Benchmarks will be decile-based percentile distributions, which enable consistent scoring and translate measure performance values uniformly. To score reported data against the benchmarks, ASM participants' performance on each measure will be mapped to decile ranges, with one to 10 achievement points assigned according to the decile in which the measure's reported rate falls.

In the CY 2026 PFS final rule, we explained that administrative claims-based quality measures do not require data submission (90 FR 49616) and finalized corresponding administrative claims-based quality measure scoring policies (90 FR 49630). However, we did not specify whether we would score such measures at the group (that is, TIN) or individual (that is, TIN/NPI) level.

We are now proposing to specify the level at which we would calculate administrative claims-based quality measures. Specifically, we propose at § 512.725(e)(3)(i) to score all administrative claims-based quality measures at the individual (that is, TIN/NPI) level to ensure that performance assessment reflects the individual ASM participant performance regardless of eligibility to report quality measures at the group (that is, TIN) level. Administrative claims-based quality measures do not require ASM participants to submit data, thereby reducing reporting burden for all ASM participants, including those that may be from a small group practice or face resource constraints. Scoring these measures at the individual (that is, TIN/NPI) level preserves the model's intended focus on individual specialist accountability.

We also propose modifications to §§ 512.725(h)(1) and 512.725(h)(2) to clarify quality ASM performance category scoring policies applicable to quality measures reported by an ASM participant, compared to administrative claims-based quality measures calculated by us. These proposals aim to align regulatory text with the nature of quality measure collection types, distinguishing quality measures for which ASM participants actively submit data from administrative claims-based quality measures that we calculate and therefore do not require data submission.

Accordingly, we propose to reorganize and revise regulatory text at § 512.725(h)(1)(i) to clarify the different requirements that administrative claims-based quality measures and non-administrative claims-based quality measures must meet to be scored. Specifically, we propose to remove the phrase ''on which data is submitted'' from § 512.7250(h)(1)(i), which describes how ASM participants are awarded achievement points for quality measures that meet the specified criteria, to conform with the proposed reorganization of this section of regulatory text.

We also propose to describe all scoring requirements for non-administrative claims-based quality measures at § 512.725(h)(1)(i)(A). Specifically, we propose to redesignate former regulatory text § 512.725(h)(1)(i)(A) through (h)(1)(i)(C) as § 512.725(h)(1)(i)(A)(*1)* through (h)(1)(i)(A)(*3*), respectively. We then propose to revise § 512.725(h)(1)(i)(A) to describe that quality measures other than administrative claims-based quality measures must meet the requirements described at § 512.725(h)(1)(i)(A)(*1)* through (h)(1)(i)(A)(*3*) to be scored. We also propose to redesignate regulatory text formerly at § 512.725(h)(1)(i)(D) to § 512.725(h)(1)(i)(B) and to revise text to clarify the scoring requirements for administrative claims-based quality measures. We note that these proposed revisions do not make substantive changes to existing scoring requirements but would provide greater clarity to ASM participants on the specific requirements for quality measures to be scored.

We also propose to clarify our provisions related to the determination of quality measure benchmarks. Specifically, we propose to remove § 512.725(h)(2)(iii), which describes the periods we may use to calculate administrative claims-based quality measure benchmarks. We believe this paragraph is unnecessary in light of § 512.725(h)(2)(i), which sufficiently describes the periods we may use to calculate any quality benchmark, whether administrative claims-based or otherwise. To conform with this proposal, we also propose to remove cross-references to § 512.725(h)(2)(iii) from §§ 512.725(h)(1)(i)(D) and 512.725(h)(2)(i), as well as redesignate former § 512.725(h)(2)(iv) as new § 512.725(h)(2)(iii). These proposals would allow more flexibility in determining appropriate and fair benchmarks and ensure that benchmark time periods align with the performance periods of the administrative claims-based quality measures.

We also propose to clarify quality measure scoring when we are unable to determine a benchmark. Specifically, we propose at § 512.725(h)(2)(iv) that we would exclude any required quality measure for which we cannot calculate a benchmark in the determination of an ASM participant's quality ASM performance category score. We would do so by removing the total measure achievement points (that is, the points calculated for the numerator of the quality ASM performance category score) and the total available measure achievement points (that is, the points calculated for the denominator of the quality ASM performance category score) from the quality ASM performance category score calculation for any quality measure that lacks a benchmark. While we state that a quality measure must have a benchmark to be scored under proposed § 512.725(h)(1)(i), we believe that this proposal clarifies the effect of a quality measure lacking a benchmark on the overall quality ASM performance category score.

We seek comment on our proposal at § 512.725(e)(3)(i) to score all administrative claims-based quality measures at the TIN/NPI level. We also seek comment on our proposed reorganization of regulatory text at § 512.725(h)(1)(i) to separately describe the scoring requirements for non-administrative claims-based quality measures and administrative claims-based quality measures. We seek comment on our proposals at § 512.725(h)(2) to clarify provisions related to the determination of quality measure benchmarks. Finally, we seek comment on our proposal at § 512.725(h)(2)(iv) describing how we would account for quality measures without benchmarks in the quality ASM performance category score calculation.

(5) Voluntary Data Submission for the Development of Patient-Reported Outcome-Based Performance Measures (PRO–PMs)

As discussed in the CY 2026 PFS final rule (90 FR 9612), we are considering future adoption of one or more patient-reported outcome-based performance measures (PRO–PMs) in ASM that would evaluate changes in patient-reported health status, physical function, symptoms, aggregate patient-reported health status, or other related outcomes over time. Unlike a functional status process measure that assesses whether a functional status assessment or other patient-reported assessment was completed, a PRO–PM would collect information directly from patients to assess whether the care furnished by an ASM participant is associated with improvement in, or slowing of decline in, ASM beneficiary-reported outcomes. We believe such measures could better capture outcomes that matter to ASM beneficiaries and support more patient-centered specialty care. Standardized assessment of patient-reported health status using a validated questionnaire can be useful for providing incremental information related to patient functional status and prognosis. It is also an independent predictor of hospitalization and mortality.[176] PRO–PMs may also encourage ASM participants to incorporate the patient voice and lived experience into clinical decision-making, treatment planning, longitudinal monitoring, and shared decision-making. At this time, we are considering the development of PRO–PMs specific to each ASM targeted chronic condition.

We are interested in using the Patient-Reported Outcomes Measurement Information System (PROMIS) as the basis for a PRO–PM as it is a set of standardized, validated patient-reported outcome instruments that can be used to assess domains such as physical function, symptoms, pain interference, mental health, social health, and quality of life.[177] We believe PROMIS would allow for a standardized measurement framework across ASM participants, ASM targeted chronic conditions, and care settings. Unlike other patient-reported outcome (PRO) instruments that exclusively focus on a particular clinical population, PROMIS includes domains relevant across chronic conditions and can be administered through flexible formats, including short forms and computer adaptive tests. It also has condition-specific profiles, like PROMIS+HF, that is relevant to ASM.[178] Finally, other Innovation Center models either use or plan to use PROMIS, such as the Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model.[179] We also note that PROMIS is already a permitted standardized tool to satisfy the Functional Status Assessments for Heart Failure measure (MIPS Q377) in the ASM heart failure cohort quality measure set and the proposed Functional Outcome Assessment measure (MIPS Q182) in the ASM low back pain cohort quality measure set.

We recognize that some ASM participants may currently use different patient-reported assessment instruments. To the extent scientifically appropriate, existing crosswalks or linking methods may help inform transitions from other instruments to PROMIS. For example, PROsetta Stone provides methods for linking PROMIS scores with other patient-reported outcome measures (PROMs) that assess similar concepts, which may support comparability across instruments.[180] This could provide flexibility for ASM participants using other instruments while preserving the standardized measurement framework that would be important for PRO–PM development.

While we are prioritizing PROMIS data collection, we are also interested in collecting data from other PRO instruments where appropriate to support evaluation and validation of PROM-to-PROM crosswalks that may facilitate future PRO–PM implementation.

We believe providing an opportunity for voluntary data submission would be an important step toward developing

[176] Heidenreich PA, Bozkurt B, Aguilar D, et al. 2022 AHA/ACC/HFSA Guideline for the Management of Heart failure: a Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. *Circulation.* 2022;145(18). doi: *https://doi.org/10.1161/cir.0000000000001063.*

[177] ''Patient-Reported Outcomes Measurement Information System (PROMIS).'' *NIH Common Fund,* National Institutes of Health, *https://commonfund.nih.gov/promis.*

[178] Ahmad, Fatima S., et al. ''Validation of PROMIS+HF Profile Instruments in Heart Failure Patients.'' ESC Heart Failure, vol. 9, no. 5, 2022, pp. 3380–3392. PubMed Central, *https://pmc.ncbi.nlm.nih.gov/articles/PMC9715763/.*

[179] ''ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model.'' *Centers for Medicare & Medicaid Services,* U.S. Department of Health and Human Services, *https://www.cms.gov/priorities/innovation/innovation-models/access.*

[180] ''PROsetta Stone.'' *PROsetta Stone, https://www.prosettastone.org.*

meaningful, patient-centered outcome measures for ASM. Incentivizing early submission of PROMIS and, potentially, other PRO data would help us determine whether future PRO–PMs are feasible and appropriate to be proposed for inclusion in the model through notice-and-comment rulemaking. This voluntary data submission approach would also provide ASM participants an opportunity to build PRO data collection infrastructure before any future PRO–PM would be proposed as a quality measure used in evaluating performance under ASM.

(a) Quality ASM Performance Category Scoring Incentive for Voluntary Patient-Reported Outcome (PRO) Data

To support the development of PRO–PMs under ASM, we propose to establish a voluntary data submission opportunity and scoring incentive for ASM participants to report PRO data, including data collected using PROMIS instruments and, as applicable, other CMS-specified PRO instruments. The goal of this data submission would be to support the development, testing, and potential future inclusion of PRO–PMs in ASM's quality measure sets. Since ASM currently does not require ASM participants to submit PROMIS or other PRO data for measure development purposes, we recognize that there may be insufficient incentives for ASM participants to voluntarily collect and submit such data. We believe establishing an appropriate incentive for voluntary data submission by ASM participants would support efforts to collect the data needed to inform PRO–PM development and whether any developed PRO–PM would be feasible for inclusion in an ASM cohort's quality measure set during the ASM test period. We believe this proposal is consistent with the Innovation Center's authority under section 1115A of the Act to test innovative payment and service delivery models that improve the quality and coordination of care, including approaches that support development and assessment of patient-centered quality measurement and beneficiary-reported outcomes.

Specifically, we propose at § 512.725(i) to create a quality ASM performance category scoring incentive by adding 5 points to an ASM participant's quality ASM performance category score for an applicable ASM performance year if the ASM participant submits beneficiary-level PRO data that meets criteria established by CMS, provided such additional points would not cause the ASM participant's score to exceed the maximum quality ASM performance category score otherwise available under the model. We refer readers to the proposed PRO data submission criteria discussed later in this section of this proposed rule. We also refer readers to section III.D.2.f.(4) of this proposed rule where we propose to notify an ASM participant if they meet the data submission requirements to receive the quality ASM performance category scoring incentive through their annual ASM performance report.

We believe that this scoring incentive approach would recognize the additional effort required to collect and submit PRO data and would avoid disadvantaging ASM participants not yet prepared to voluntarily collect and submit PRO data. The proposed 5-point scoring incentive added to the quality ASM performance category score represents half of the maximum quality measure achievement points for a single quality measure. We believe this amount appropriately incentivizes voluntary data submission by offering an increase to the quality ASM performance category score without equaling the maximum achievement points that can be earned through performance on quality measures. We believe such an approach would preserve the integrity and importance of the existing quality measure set required of each ASM participant. We further believe that structuring the scoring incentive so that an ASM participant's total quality ASM performance category score cannot exceed the category's maximum score would preserve the integrity and fairness of performance comparisons while encouraging voluntary data submission.

Eligibility for the scoring incentive for voluntary data submission would be limited to the ASM cohorts for the ASM performance years in which we are actively developing a PRO–PM. For example, if we establish a voluntary heart failure PRO data submission opportunity in the 2027 ASM performance year, only ASM heart failure participants would be eligible to receive the 5-point scoring incentive for the 2027 ASM performance year and ASM low back pain participants would not be eligible for the scoring incentive for that year.

We clarify that we are not proposing at this time to (1) adopt a new PRO–PM in the quality measure for either ASM cohort, (2) evaluate ASM participants on PROMIS performance, or (3) require ASM participants to collect or submit PROMIS or other PRO data. Rather, this proposal is intended to support voluntary data collection to support our evaluation of the feasibility, reliability, validity, and appropriateness of one or more future PROMIS-based or other PRO-based PRO–PMs before any such measure would be proposed for inclusion in an ASM cohort's quality measure set, which we would propose through future notice-and-comment rulemaking.

We considered an alternative approach under which ASM participants could receive a higher number of additional points as this could provide greater incentive to voluntarily submit sufficient data for measure development purposes. We are not proposing a higher number of additional points because it could reduce the distinction between the measure achievement points available for existing performance-based quality measures and the voluntary submission of PRO data for measure development purposes. Conversely, we are not proposing a lower number of additional points to the quality ASM performance category score because we believe this may not provide a sufficient incentive to encourage meaningful participation in voluntary data submission.

We also considered an alternative approach to award 10 points, the maximum quality measure achievement score, for the existing PROM-related process measure for ASM participants who successfully: (1) submit a required PROM-related process measure included in the quality ASM performance category measure set and (2) voluntarily submit the CMS-specified PRO data for an applicable ASM performance year. For example, under this alternative, an ASM heart failure participant who successfully reports the Functional Status Assessments for Heart Failure measure (MIPS Q377) and voluntarily submits the CMS-specified PRO data would automatically receive 10 measure achievement points for the Functional Status Assessments for Heart Failure measure regardless of actual performance as assessed against the applicable benchmark. For the same reasons noted above regarding our intent to draw distinction between performance-based quality measurement and data submission, we are not proposing this alternative. Additionally, we believe this approach would not provide meaningful incremental incentives for some ASM participants because those ASM participants who successfully collect and voluntarily submit the required PRO data may already be likely to perform well on the associated PROM-related process measure.

We also considered establishing a tiered incentive structure under which the number of additional points awarded to the quality ASM

performance category score would be scaled based on the quantity, completeness, representativeness, or other related characteristics of the voluntarily submitted PRO data. For example, ASM participants that submit data for a larger number of ASM beneficiaries, achieve higher response or follow-up completion rates, or submit additional data elements that could support measure development and testing would receive a larger scoring incentive than ASM participants that meet the minimum data submission requirements. We are not proposing this alternative because our goal is that all voluntarily submitted data intended for measure development should meet the minimum requirements necessary to support reliable and scientifically sound measure development and testing. We are concerned that a tiered approach could create an incentive that prioritizes submission volume over data quality or could imply that data meeting the minimum submission requirements is less valuable for measure development purposes. Therefore, we believe a single incentive tied to successful completion of all required data submission requirements is a more appropriate approach.

We also considered whether to encourage voluntary PRO data submission through non-scoring mechanisms, such as providing ASM participants with enhanced feedback reports, analytic tools, educational resources, or other related support. We recognize that such resources could be of operational value to ASM participants while supporting our development of PRO-based quality measures. However, we are not proposing a non-scoring-based incentive as we do not believe this would, by itself, provide sufficient incentive to encourage broad voluntary participation in PRO data collection and submission activities. While we may consider providing operational support or resources in the future, we believe a direct scoring incentive is more likely to generate the quantity and quality of data necessary to support timely PRO–PM development and testing.

We further considered another alternative whereby the maximum quality ASM performance category score would not be capped, allowing an ASM participant's quality ASM performance category score to exceed the maximum points otherwise available for the quality ASM performance category for the limited purpose of encouraging voluntary PRO data submission. For example, under this alternative, an ASM participant who earns a quality ASM performance category score of 46 points and voluntarily submits PRO data for the applicable performance year would receive 51 points out of 50 points available for the final quality ASM performance category. We are not proposing this alternative because it would be inconsistent with the existing quality ASM performance category scoring methodology. The quality and cost ASM performance categories were intentionally designed to have equal weight in the calculation of a final score. Allowing the quality ASM performance category score to exceed its current maximum could disrupt that balance and place disproportionate emphasis on quality scoring relative to cost performance. We believe maintaining the current maximum quality ASM performance category score preserves comparability across ASM participants and the integrity of the quality scoring framework.

Finally, we considered another alternative incentive whereby we would add additional points to the final score of an ASM participant who successfully reports the CMS-specified PRO data for the applicable ASM performance year. Under this approach, the additional points would be added to the final score after calculation of any applicable ASM performance category scores to directly increase the ASM participant's final score. We are not proposing this alternative because it would disconnect the incentive from the quality ASM performance category, where the benefits of collecting and reporting PRO data are most appropriately reflected. In addition, applying additional points directly to an ASM participant's final score could have broader effects on overall model performance and payment adjustment outcomes than intended and would be less consistent with the targeted objective of encouraging voluntary data submission to support future PRO–PM development.

We seek comment on our proposal at § 512.725(i) to provide 5 additional points to the quality ASM performance category score of an ASM participant who voluntarily submits CMS-specified PRO data and meets all data submission requirements for an applicable ASM performance year. We seek comment on all alternatives that we considered. We also invite comment on whether the proposal and alternatives would support voluntary data submission to achieve the goal of developing PRO–PMs applicable to ASM.

(b) Requirements for Successful Voluntary PRO Data Submission

Development of a valid, reliable, and feasible PRO–PM requires sufficient beneficiary-level PRO data prior to implementation and scoring of the measure. In particular, data is needed to: (1) analyze measure reliability and validity, (2) evaluate feasibility of data collection and submission, (3) measure response rates and missingness, (4) examine potential nonresponse bias, (5) identify appropriate risk adjustment variables, and (6) determine whether a measure can meaningfully and fairly distinguish performance across ASM participants within a given ASM cohort. For potential PRO–PMs, development may require that data be collected over an extended episode or longitudinal assessment period, including baseline and follow-up PRO assessments. Accordingly, early collection and submission of PRO data by ASM participants is important to support timely development and testing of PRO–PMs such that we could propose measures for future inclusion in ASM's respective quality measure sets through future notice-and-comment rulemaking.

To support PRO–PM development, we would specify the applicable PRO instrument(s), the required data that an ASM participant would need to voluntarily submit, and applicable data collection periods. Accordingly, we propose to define the data submission requirements that an ASM participant would need to meet to ensure we receive sufficient and reliable data to develop and test PRO–PMs applicable to ASM.

Specifically, at § 512.725(i)(1), we propose to define all data submission requirements an ASM participant would need to meet to receive the proposed scoring incentive in the quality ASM performance category for an applicable ASM performance year.

First, at § 512.725(i)(1)(i), we propose that an ASM participant would need to submit CMS-specified baseline assessment data for at least 20 ASM beneficiaries during the first data collection period specified by us. By baseline data, we mean the initial CMS-specified PRO assessment data collected for an ASM beneficiary during the applicable data collection period that occurs before the collection of any corresponding follow-up assessment data for the beneficiary. After baseline data is collected, an ASM participant would submit CMS-specified follow-up assessment data for at least 20 ASM beneficiaries for whom they previously submitted a baseline assessment during the preceding data collection period specified by us.

Our goal in establishing minimum baseline and follow-up assessment requirements is to ensure we receive sufficient longitudinal PRO data to support development and testing of

future PRO–PMs. We believe that collecting baseline assessment data initially then collecting corresponding follow-up assessment data during a subsequent data collection period would allow us to evaluate changes in beneficiary-reported outcomes over time while reducing operational burden during the initial year of data collection. The specific amount of time between a baseline and follow-up assessment would depend on the selected PRO instrument(s) and ASM targeted chronic condition, however, we anticipate that a collection period of at least 6 months between a beneficiary's baseline and follow-up assessments may be necessary to allow sufficient time to observe meaningful changes in patient-reported outcomes. We would provide specifications regarding the timing of baseline and follow-up assessments and specific data collection periods through sub-regulatory technical guidance.

Second, at § 512.725(i)(1)(ii), we propose that an ASM participant would need to report all required data elements for the applicable PRO instrument as specified by us for the applicable data collection period. We anticipate that required data elements would include at least: (i) the PRO instrument name and version, (ii) ASM participant identification information, (iii) ASM beneficiary identification information and linkage information, (iv) assessment date, (v) baseline or follow-up assessment indicator, (vi) mode of administration, (vii) item-level responses, (viii) nonresponse and missingness indicators, (ix) raw and standardized scores, (x) score calculation method, and (xi) other data elements needed to support measure testing and risk adjustment model testing. If testing would require use of a crosswalk, such as PROsetta, we anticipate that we would also require reporting of data elements specific to the crosswalk. The required data elements and format in which an ASM participant would need to submit the data would be specific to the selected PRO instrument(s) and would be specified by us in sub-regulatory technical guidance.

Third, at § 512.725(i)(1)(iii), we propose that an ASM participant would need to submit data on a minimum set of risk variables for each ASM beneficiary from whom they collect PRO data. Risk adjustment is necessary to ensure that performance results under a PRO–PM reflect quality of care rather than patient complexity to avoid penalizing clinicians who may serve higher-risk beneficiary populations. Reporting a minimum set of risk variables for each ASM beneficiary receiving a PRO assessment would allow us to develop a scientifically acceptable, robust, and reliable risk model for any developed PRO–PM. The reported risk variable data would be used to conduct assessments of association between risk variables and the measured PRO to inform risk variable selection and ensure the risk model captures the most clinically and statistically relevant risk variables. Example risk variables could include but are not limited to age, race, ethnicity, socioeconomic status, clinical comorbidities, baseline clinical severity, physiological measures (for example, body mass index or blood pressure), pain history, surgical history, disease classification, medication usage, behavioral factors, functional and disability status, and other condition-specific characteristics. We believe that the risk variables would be different for each ASM targeted chronic condition for which we would develop a PRO–PM. We intend to provide the minimum risk variables applicable for the selected PRO instrument(s), including each risk variable's technical specifications, through sub-regulatory technical guidance.

Fourth, at § 512.725(i)(1)(iv), we propose that an ASM participant must submit the PRO data for any applicable data collection period by the generally applicable data submission deadline for the applicable ASM performance year, which is March 31st, or later in the calendar year, as specified by as, following the close of the applicable ASM performance year. We recognize that—depending on the applicable PRO instrument, measure concept, and assessment interval—baseline and follow-up assessments for an ASM beneficiary may need to occur across ASM performance years to allow a sufficient interval between the initial and follow-up PRO assessments. In such cases, we would specify through technical guidance how ASM participants would submit baseline and follow-up data for data collection periods that span ASM performance years and how this would impact the availability of the scoring incentive for a given ASM performance year. We believe that aligning the voluntary PRO data submission deadline with the generally applicable data submission deadline for ASM performance category data would streamline and simplify the data submission and would provide us adequate time to confirm if the submitted PRO data meets the requirements to receive the proposed scoring incentive for the quality ASM performance category. We anticipate that the PRO data submission would occur through one or more mechanisms, such as a CMS-specified file format, registry submission, qualified clinical data registry or other intermediary, Health Level Seven Fast Healthcare Interoperability Resources (HL7 FHIR)-based submission, or another electronic submission mechanism specified by CMS. We would provide additional operational details through technical guidance, including applicable submission deadlines, data formats, validation processes, and any minimum data completeness or case minimum requirements. We also seek to preserve flexibility to align submission requirements with existing ASM participant workflows and health information technology capabilities to the extent feasible.

We recognize that in some instances ASM participants may need to correct their voluntary data submission. Accordingly, we propose at § 512.725(i)(2) that ASM participants could correct and resubmit any PRO data corresponding with voluntary data submission by the proposed data submission deadline of March 31st in accordance with the generally applicable data submission deadline for the applicable performance year, or a later date specified by CMS. Because the proposed scoring incentive would affect the quality ASM performance category score, we propose to only accept timely submissions, corrections, or resubmissions and reject those received after the data submission deadline. We believe this approach is necessary to preserve the integrity and finality of the scoring process and payment adjustment methodology and to align voluntary PRO data submission with other ASM performance category data submission requirements. We would consider providing submission error reports or other technical feedback identifying errors, missing data elements, beneficiary linkage issues, data completeness concerns, or other issues before the applicable data submission deadline to support ASM participants.

Relatedly, we propose at § 512.725(i)(3) that an ASM participant may seek review under ASM's timely error notice process for technical errors related to CMS' determination of whether the ASM participant met the voluntary PRO data submission requirements or correctly received the quality ASM performance category scoring incentive for the applicable ASM performance year as provided in the ASM participant's annual ASM performance report. To align with ASM's timely error notice requirements

and process described at § 512.755, the ASM participant may submit a written timely error notice if they believe an error occurred in calculations due to data quality, misapplication of methodology, or other related issues that would relate to whether the ASM participant qualified for the proposed quality ASM performance category scoring incentive for the applicable ASM performance year. Examples of such errors include beneficiary linkage errors, failure to account for data timely submitted by the ASM participant, or other technical errors in our evaluation of the voluntary PRO data submission against data requirements.

We considered requiring that an ASM participant submit PRO data on more than 20 ASM beneficiaries or fewer than 20 ASM beneficiaries during each CMS-specified data collection period specified. We also considered requiring that an ASM participant submit PRO data on a minimum percentage of their ASM beneficiaries (for example, 25 to 100 percent) during the applicable data collection period. However, we believe an adequate number of ASM participants collecting and reporting PRO data on a minimum of 20 ASM beneficiaries each would provide an adequate sample size for PRO–PM development and align with the 20-case minimum for quality measures under ASM.

We also considered requiring an ASM participant to submit PRO data more frequently during an ASM performance year (for example, quarterly or biannually). Multiple data submission time points, such as quarterly or on a rolling basis rather than a single annual submission, may offer several advantages. It would enable the selected submission mechanism (for example, data submission portal) to provide ASM participants who voluntarily submit data with timely, actionable feedback on the quality of the data submitted, flagging inaccuracies and offering opportunities for correction and resubmission before the applicable data collection period and ASM performance year ends. Iterative data collection and feedback could support a continuous improvement process, helping ASM participants identify and resolve data quality issues early. This would be particularly helpful for avoiding the scenario where a provider submits data once annually, only for that data to be found unusable at the point of determining eligibility for the quality ASM performance category scoring incentive. More frequent data submissions would likely improve the quality of data for measure development and testing. While more frequent data submission would offer several advantages, we believe that aligning the voluntary data submission deadline with the overall data submission deadline for ASM performance category data would be administratively simpler for ASM participants.

We also considered requiring ASM participants to submit both baseline and follow-up assessment data for the same ASM beneficiaries during a single ASM performance year. Under this alternative, an ASM participant would be required to collect and submit both the initial and follow-up PRO assessments within the same ASM performance year to receive the voluntary PRO data submission scoring incentive. We recognize that this approach could accelerate collection of matched assessment data and potentially expedite certain measure development and testing activities. However, we are not proposing this alternative because the appropriate interval between baseline and follow-up assessments may vary depending on the selected PRO instrument, the targeted chronic condition, and the future PRO–PM concept under development. We are also concerned that requiring both assessments within a single ASM performance year could limit flexibility, increase operational burden on ASM participants, and reduce the amount of time available to observe meaningful changes in ASM beneficiary-reported outcomes.

For any data collection period following a baseline data collection period, we considered that an ASM participant would need to submit baseline assessment data for additional ASM beneficiaries that were either newly eligible for a selected instrument or had not previously been assessed using a selected instrument. This new baseline data would be in addition to the follow-up assessment data that we propose to require. We believe that this structure could increase the amount of data available to develop a PRO–PM over time. However, we would require additional information to determine the minimum number of new baseline assessments that would be appropriate to require the ASM participant to collect during a subsequent data collection period.

We also considered whether to require additional criteria for successful voluntary PRO data submission, including submission of a denominator file of eligible ASM beneficiaries; use of a CMS-specified sampling methodology, such as consecutive, all-eligible, all-payer, or random sampling; minimum response or completion rates; minimum baseline and follow-up completion thresholds; and documentation of exclusions, where applicable, for identified ASM beneficiaries. We are not proposing these additional requirements at this time because the appropriate denominator, sampling approach, response-rate threshold, completion threshold, and exclusion documentation requirements may vary based on the selected PRO instrument, ASM targeted chronic condition, data submission mechanism, and measure concept under consideration for development.

We seek comment on the proposed requirements for voluntary PRO data submission at § 512.725(i)(1) that an ASM participant would need to meet to receive the proposed quality ASM performance category scoring incentive. We also seek comment on all alternatives considered and other data submission requirements we should consider to support PRO–PM development under ASM. Additionally, we seek comment on the appropriate timing of data submission and the scope of data elements that should be required for successful voluntary data submission, particularly data elements necessary to evaluate a PRO–PM's feasibility, reliability, and validity. We also invite comment on the specific risk variables applicable for each ASM targeted chronic condition that we should require ASM participants to report. We are particularly interested in comments on the earliest feasible timeframe for ASM participants to begin collecting and submitting PROMIS or other CMS-specified PRO data, the operational challenges ASM participants may face, and the types of technical assistance or guidance that would facilitate voluntary data submission. Finally, we seek comment on data submission mechanisms that would simplify the voluntary reporting of PRO data to support PRO–PM development under ASM.

e. Promoting Interoperability ASM Performance Category

(1) Background

As discussed in the CY 2026 PFS final rule (90 FR 49658 through 49661), we believe the Promoting Interoperability ASM performance category measures finalized under § 512.740 support the overall goals of ASM to enhance the quality of care, reduce costs by encouraging upstream chronic condition management, empower patients to engage in their care, and promote collaboration between specialists and primary care. ASM's Promoting Interoperability objectives and measures align with the Promoting

Interoperability goals, objectives, and measures used in other programs, including MIPS.

We finalized at § 512.740(b)(2) that an ASM participant must report on MIPS Promoting Interoperability objectives and measures, as specified in technical documents. Specifically, under §§ 512.740(b)(2)(i) through (iv), we finalized inclusion of the following objectives under the Promoting Interoperability ASM performance category:

- Electronic Prescribing;
- Health Information Exchange (HIE);
- Provider to Patient Exchange; and
- Public Health and Clinical Data Exchange (90 FR 49658).

We aim to align ASM and MIPS Promoting Interoperability requirements where possible to promote consistency across programs and reduce burden and operational complexity for ASM participants who may already be familiar with MIPS Promoting Interoperability measures and attestations.

In support of alignment with MIPS, we propose certain updates in ASM, to include proposals that align with those being issued through this proposed rule for the MIPS Promoting Interoperability performance category, as well as proposals that align with policies previously finalized for inclusion in MIPS that we did not yet adopt for ASM. We refer readers to section IV.A.4.f.(4) of this proposed rule for further discussion on MIPS Promoting Interoperability proposals.

Specifically, we propose to:

- Revise the HIE objective at § 512.740(b)(2)(ii) to reorganize its structure and add an optional measure, Electronic Prior Authorization (Measure ID # PI_HIE_7), for the 2027 ASM performance year at proposed new § 512.740(b)(2)(ii)(B);
- Starting in the 2028 ASM performance year, require the Electronic Prior Authorization measure and require the new Electronic Prior Authorization for Prescription Drugs measure (Measure ID # PI_HIE_8) at proposed new § 512.740(b)(2)(ii)(C);
- Adopt a measure exclusion policy for ASM for measures within the Public Health and Clinical Data Exchange objective at proposed § 512.740(b)(2)(iv), consistent with a longstanding MIPS policy;
- Make technical modifications to the language describing measure-level exclusions for measures that include an option to claim an exclusion at § 512.740(b)(3)(i)(C);
- Remove the requirement to report through attestation the security risk analysis measure by striking § 512.740(b)(3)(ii);
- Remove Office of the National Coordinator for Health Information Technology (ONC) direct review required attestations by striking § 512.740(b)(4)(i);
- Retain the requirement to avoid knowingly and willfully taking actions to limit or restrict interoperability of CEHRT but redesignate it from current § 512.740(b)(4)(ii) to § 512.740(b)(4)(i);
- Redesignate current § 512.740(c)(2) describing the Promoting Interoperability ASM performance category scoring policy as § 512.740(c)(3) without changing the regulatory text; and
- Adopt a measure suppression policy at new § 512.740(c)(2) that aligns with the policy we adopted in the CY 2026 PFS final rule for MIPS.

Table B–D2 summarizes existing finalized requirements and new proposals in this proposed rule for the objectives and measures in the Promoting Interoperability ASM performance category for the 2027 ASM performance year. We discuss new proposals in the remainder of this section of this proposed rule.

TABLE B-D2: PROPOSED ASM PROMOTING INTEROPERABILITY OBJECTIVES AND MEASURES FOR THE 2027 ASM PERFORMANCE YEAR

Objectives	Measures		Available Points (based on performance)	Redistribution if exclusion is claimed
e-Prescribing	e-Prescribing		1 to 10 points	10 points to HIE objective
	Query of PDMP		10 points	10 points to the e-Prescribing measure
Health Information Exchange (HIE)	Select one of the following three reporting options:		30 points for the objective	Measure specific
	Option 1	Support Electronic Referral Loops by Sending Health Information	1 to 15 points	15 points to Provide Patients Electronic Access to Their Health Information measure
		Support Electronic Referral Loops by Receiving and Reconciling Health Information	1 to 15 points	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	Option 2	HIE Bi-Directional Exchange	30 points	No exclusion
	Option 3	Enabling Exchange under TEFCA	30 points	No exclusion
	Option to report the Electronic Prior Authorization measure		No bonus points	Not applicable
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information		1 to 25 points	No exclusion
Public Health and Clinical Data Exchange	Report to the following public health or clinical data registries: 1. Immunization Registry Reporting 2. Electronic Case Reporting		25 points for the objective	25 points to the Provide Patients Electronic Access to their Health Information measure if an exclusion is claimed for both measures.
	Option to report one of the following public health agency or clinical data registry measures: • Public Health Registry Reporting, • Clinical Data Registry Reporting, or • Syndromic Surveillance Reporting		No bonus points	Not applicable

(2) Proposed Update to CEHRT Definition

We refer readers to section IV.A.4.f.(4) of this proposed rule for a discussion of proposed updates to the definition of CEHRT under MIPS. Under § 512.705, we define CEHRT for the purposes of ASM as technology that meets the requirements set forth in MIPS regulations at § 414.1305. We are not proposing to depart from this approach. Therefore, any updates finalized to the definition of CEHRT under MIPS would be incorporated for purposes of ASM under the existing definition at § 512.705. We refer readers to Table C–G1 of this proposed rule for a summary of changes.

(3) Electronic Prior Authorization Measures in the Health Information Exchange Objective

(a) Overview

In the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program'' final rule (89 FR 8758) (hereinafter referred to as the ''2024 CMS Interoperability and Prior Authorization final rule''), we finalized requirements for Medicare Advantage organizations, Medicaid managed care plans, State Medicaid agencies, CHIP agencies, CHIP managed care entities, and issuers of qualified health plans on the Federally-facilitated Exchanges (collectively, ''impacted payers'') to improve the electronic exchange of health care information and streamline prior authorization for medical items and services. Impacted payers must implement and maintain prior authorization application programming interface (API) technology to communicate information related to prior authorization requests (89 FR 8763). As we explained in the 2024 CMS Interoperability and Prior Authorization final rule, the efficiencies associated with payer implementation of these APIs will be more fully realized when requesting providers also use API-enabled processes to submit prior authorization requests.

Accordingly, we finalized the addition of an Electronic Prior Authorization measure as a required measure for MIPS eligible clinicians under the MIPS Promoting Interoperability performance category HIE objective (89 FR 8910 through 8927).

(b) 2027 ASM Performance Year: Electronic Prior Authorization Measure

We believe adopting the Electronic Prior Authorization measure within ASM would support broader Departmental efforts to advance interoperability, modernize prior authorization processes by encouraging ASM participants to develop capabilities that advance the interoperable exchange of data related to prior authorization requests, and support alignment with MIPS. This measure describes requesting a prior authorization electronically using CEHRT to send a request through a payer's Prior Authorization API for at least one medical item or service (excluding prescription drugs) ordered within the applicable performance year.

We now propose to include the Electronic Prior Authorization measure (Measure ID # PI_HIE_7) in the Promoting Interoperability ASM performance category under the HIE objective, consistent with MIPS, starting in the 2027 ASM performance year. For the 2027 ASM performance year, we propose that the Electronic Prior Authorization measure would be available as an optional, unscored ASM Promoting Interoperability measure, without any scoring penalty for non-reporting. We propose to codify this measure for ASM at § 512.740(b)(2)(ii)(B).

We propose to rely on the measure specifications used in MIPS for the Electronic Prior Authorization measure and refer readers to section IV.A.4.f.(4) of this proposed rule for a discussion of the technical specifications for the Electronic Prior Authorization measure under MIPS, including proposed modifications to the measure specifications, which we propose to adopt in ASM.

To report the Electronic Prior Authorization measure, an ASM participant would submit a ''yes'' response attesting they satisfactorily met the requirements of the measure. We do not propose to adopt any exclusions for this measure for the 2027 ASM performance year, since the measure would be optional and attesting ''no'' or not attesting at all would not result in a scoring penalty.

Under our proposal for ASM, the Electronic Prior Authorization measure would be included under the HIE objective, consistent with MIPS. Under the current ASM HIE objective, an ASM participant satisfies the objective by reporting one of three available reporting options:

- Support Electronic Referral Loops by Sending Health Information (Measure ID # PI_HIE_1) and Support Electronic Referral Loops by Receiving and Reconciling Health Information (Measure ID # PI_HIE_4).
- Health Information Exchange (HIE) Bi-Directional Exchange (Measure ID # PI_HIE_5).
- Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) (Measure ID # PI_HIE_6).

We are not proposing to change that an ASM participant must satisfy one of these three reporting options to fulfill the requirements for the HIE objective. Rather, our proposal makes the Electronic Prior Authorization measure available as an optional, voluntary measure that could be reported in addition to one of the required HIE reporting options for the 2027 ASM performance year. While no points would be awarded to ASM participants that report this measure through submission of a ''yes'' attestation, we believe including the Electronic Prior Authorization as an optional measure could encourage ASM participants to develop workflows and infrastructure to support reporting the measure once it is required beginning with the 2028 ASM performance year.

We emphasize that, under our proposal, ASM participants who elect not to report for the Electronic Prior Authorization measure in the 2027 ASM performance year would not be penalized.

We considered, but do not propose, offering 5 bonus points to an ASM participant's Promoting Interoperability ASM performance category score for the 2027 ASM performance year if an ASM participant voluntarily attests ''yes'' to the Electronic Prior Authorization measure as an alternative policy to our proposal to treat this optional measure as unscored for the 2027 ASM performance year. We considered this approach because temporary bonus points during an optional performance year could encourage ASM participants to begin establishing and operationalizing the capabilities needed to use a Prior Authorization API with CEHRT before the measure would be required beginning with the 2028 ASM performance year. We further recognize that MIPS proposes to offer bonus points for this measure. However, we do not propose to offer bonus points for the

Electronic Prior Authorization measure within the Promoting Interoperability ASM performance category because we intend to maintain a more simplified and streamlined scoring framework that does not incorporate the full complexity of MIPS bonus point structures. MIPS offers bonus points for certain optional measures under the Public Health and Clinical Data Exchange objective, however ASM does not offer bonus points for these measures. Our proposal to not offer bonus points for the Electronic Prior Authorization measure is consistent with our approach for optional measures within the Public Health and Clinical Data Exchange objective. We believe that including bonus points in the Promoting Interoperability ASM performance category would add administrative and scoring complexities we do not intend to introduce.

We seek comment on the proposal at § 512.740(b)(2)(ii)(B) to include the Electronic Prior Authorization measure as an optional, unscored measure in the Promoting Interoperability ASM performance category for the 2027 ASM performance year. We also seek comment on the alternative we considered where we would offer bonus points to ASM participants who attest ''yes'' to the Electronic Prior Authorization measure for the 2027 ASM performance year. Specifically, we seek comment on whether offering bonus points would encourage early adoption among ASM participants.

(c) 2028 ASM Performance Year: Electronic Prior Authorization Measure

Beginning with the 2028 ASM performance year, we propose that an ASM participant would be required to report the Electronic Prior Authorization measure through submission of a ''yes'' attestation or, alternatively, claim an applicable exclusion, to satisfy the measure requirements. In such cases, the Electronic Prior Authorization measure would not affect the total score for the Promoting Interoperability ASM performance category. However, if an ASM participant submits a ''no'' response, fails to submit any attestation, or does not claim an applicable exclusion for the Electronic Prior Authorization measure, the ASM participant would receive a score of zero for the Promoting Interoperability ASM performance category. This scoring approach is consistent with the approach taken for MIPS eligible clinicians under proposed and existing policies.

Also starting in the 2028 ASM performance year, we propose to recognize exclusions to this measure and would adopt the same exclusion criteria as MIPS adopted in 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), which are discussed in this proposed rule without proposed modifications.

We believe requiring this measure beginning with the 2028 ASM performance year rather than in the 2027 ASM performance year would provide ASM participants time and flexibility to prepare to successfully report the measure.

We propose to include this requirement at § 512.740(b)(2)(ii)(C)(1). We seek public comment on our proposal to require the Electronic Prior Authorization measure beginning with the 2028 ASM performance year.

(d) 2028 ASM Performance Year: Electronic Prior Authorization for Prescription Drugs Measure

The proposed rule ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges'' (hereinafter referred to as the ''2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule'') introduced proposals that would require impacted payers to support various exchange standards in support of prior authorization for prescription drugs (91 FR 19890). Specifically, beginning on October 1, 2027, impacted payers would be required to support electronic prior authorization for all prescription drugs that require prior authorization.

As more payers support standardized electronic prior authorization capabilities, we believe measuring the use of prior authorization for prescription medications would be a valuable addition to our assessment of meaningful use of CEHRT under the Promoting Interoperability ASM performance category. Standards-based electronic prior authorization may improve timeliness and transparency of medication access by facilitating documents-gathering and tracking of prior authorization status within clinician EHR workflows to support care coordination and close the prescriber-to-dispenser loop.

Accordingly, beginning with the 2028 ASM performance year, we propose at § 512.740(b)(2)(ii)(C)(2) to adopt the Electronic Prior Authorization for Prescription Drugs measure (Measure ID # PI_HIE_8) as a required measure under the Promoting Interoperability ASM performance category. This measure would focus on prescription drugs covered under a pharmacy benefit and dispensed at pharmacies. We propose to include this measure under the HIE objective, consistent with our proposal to include the Electronic Prior Authorization measure under this objective. We propose to include the availability of exclusions for the Electronic Prior Authorization for Prescription Drugs measure, consistent with those recognized under MIPS, starting in the 2028 ASM performance period. We propose to adopt the same measure specification and exclusion criteria for the Electronic Prior Authorization for Prescription Drugs measure that are being proposed under MIPS for the MIPS Promoting Interoperability performance category. We refer readers to section IV.A.4.f.(4) of this proposed rule for discussion on measure specifications and exclusions.

To successfully report this measure, an ASM participant would be required to submit a ''yes'' response attesting that they have requested electronic prior authorization using CEHRT for at least one prescription drug during the performance period, or alternatively, claim an applicable exclusion. Under our proposal, this measure would not contribute to an ASM participant's Promoting Interoperability ASM performance category score; however, if an ASM participant submits a ''no'' response, fails to submit any attestation, or does not claim an applicable exclusion for the Electronic Prior Authorization for Prescription Drugs measure, the ASM participant would receive a score of zero for the Promoting Interoperability ASM performance category starting in the 2028 ASM performance year.

We emphasize that, under our proposal to include the prior authorization measures under the HIE objective for ASM, an ASM participant would continue to be required to report one of the three existing HIE reporting options at current § 512.740(b)(2)(ii).

We also underscore that we are not proposing to require the Prior Authorization measure or the Prior Authorization for Prescription Drugs measure until the 2028 ASM performance year.

As stated, we aim to align proposals for ASM, as appropriate, with the direction of MIPS policy for the Promoting Interoperability performance category. This includes alignment for the Electronic Prior Authorization measures with MIPS and with broader

Departmental goals of improving interoperability and modernizing prior authorization processes. In the 2024 CMS Interoperability and Prior Authorization final rule, we explained that electronic prior authorization policies are intended to encourage provider adoption of electronic prior authorization processes and improve the exchange of information needed to support more efficient prior authorization workflows (89 FR 8910 through 8927). Although that final rule finalized the Electronic Prior Authorization measure only for medical items and services, excluding drugs, we believe those same policy goals support adoption of an Electronic Prior Authorization for Prescription Drugs measure under ASM beginning with the 2028 ASM performance year. We believe requiring both electronic prior authorization measures beginning in the 2028 ASM performance year would promote more consistent electronic prior authorization capabilities and workflows across ASM participants' operations and would support broader movement toward more efficient exchange of prior authorization information.

We seek comment on all aspects of these proposals.

(4) Exclusions to the Public Health and Clinical Data Exchange Objective in the Promoting Interoperability ASM Performance Category

In the CY 2026 PFS final rule, we finalized that an ASM participant must submit a ''yes'' attestation for the two required measures in the Public Health and Clinical Data Exchange objective (the Immunization Registry Reporting and Electronic Case Reporting measures) to earn 25 points for the objective (90 FR 49658 through 49662). We noted the potential availability of exclusions for the Immunization Registry Reporting and Electronic Case Reporting measures in tables published in the preamble to the proposed rule (Table 61; 90 FR 32745) and in the preamble to the final rule (Table B–D6; 90 FR 49659). However, we did not explicitly propose an exclusion policy in the narrative preamble text or memorialize that policy in the regulatory text itself. As a result, the current regulation at § 512.740(b)(2)(iv) reads as though an ASM participant must report both measures to satisfy the objective, without the availability of exclusions for either measure.

We propose to clarify that exclusions are available to ASM participants for the Immunization Reporting Registry and Electronic Case Reporting measures by amending our regulation at § 512.740(b)(2)(iv). Under our proposal, an ASM participant would receive full credit for the Public Health and Clinical Data Exchange objective by reporting both Public Health and Clinical Data Exchange measures (Immunization Registry Reporting and Electronic Case Reporting), reporting one measure and claiming one exclusion, or claiming two exclusions. We believe this proposal would simplify ASM participant reporting requirements by aligning exclusions available in MIPS and redistributing points for excluded measures in accordance with MIPS redistribution policies.

MIPS specifies certain exclusion criteria that apply to each of the Immunization Registry Reporting and Electronic Case Reporting measures. We propose to adopt the same exclusion criteria as specified in MIPS sub-regulatory guidance for ASM, consistent with our aim to drive alignment where possible.

We seek comment on this proposal at § 512.740(b)(2)(iv), including the proposal to use the same exclusion criteria that MIPS uses for the Immunization Registry Reporting and Electronic Case Reporting measures.

(5) Security Risk Analysis Measure

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), as implemented through the HIPAA Security Rule (45 CFR part 160 and subparts A and C of part 164), includes administrative safeguards required of covered entities and business associates, including a risk analysis component and a risk management component. The Security Risk Analysis measure was adopted to require that MIPS eligible clinicians attest to having conducted a security risk analysis and security risk management activities as required by the HIPAA Security Rule. In the CY 2026 PFS final rule (90 FR 49656 through 49568), we incorporated this measure into the Promoting Interoperability ASM performance category by requiring that ASM participants complete the actions included in the MIPS Promoting Interoperability Security Risk Analysis measure. At the time, we believed it would help drive more secure, efficient, and meaningful use of CEHRT under ASM.

To reduce reporting burden, beginning with the 2027 ASM performance year, we now propose to remove the requirement at § 512.740(b)(3)(ii) that an ASM participant submit an affirmative attestation as to completing a security risk analysis within the calendar year . We consider the use of CEHRT to demonstrate security risk analysis and security risk management activities sufficient as it complies with requirements pertaining to the security of data created and maintained by CEHRT in accordance with the HIPAA Security Rule.

Given that ASM participants are covered entities under the HIPAA Security Rule and the requirements of the Security Risk Analysis measure are derived from the HIPAA Security Rule requirements, we do not believe that removing the Security Risk Analysis measure from the Promoting Interoperability ASM performance category will weaken any cybersecurity requirements for ASM participants. Furthermore, our proposal aligns with the proposal in MIPS to remove the Security Risk Analysis from MIPS Promoting Interoperability; we refer readers to section IV.A.4.f.(4) of this proposed rule for further discussion.

To conform with removal of the Security Risk Analysis measure, we propose to redesignate current § 512.740(b)(3)(iii) as § 512.740(b)(3)(ii).

We seek comment on the proposal to remove the Security Risk Analysis measure and attestation requirement from the Promoting Interoperability ASM performance category.

(6) Supporting Providers With the Performance of CEHRT

In the CY 2026 PFS final rule (90 FR 49661), we finalized that an ASM participant must support the performance of CEHRT by submitting certain affirmative attestations to receive a Promoting Interoperability ASM performance category score greater than zero. Specifically, as finalized at §§ 512.740(b)(4)(i)(A)(1) and (2), an ASM participant must support the performance of CEHRT by:

- Providing acknowledgement of the requirement to cooperate in good faith with the Office of the National Coordinator for Health Information Technology (ONC) direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received; and
- If requested, cooperate in good faith with ONC direct review of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its

capabilities as implemented and used by the ASM participant in the field.

An ASM participant may optionally attest to the following:

- The ASM participant acknowledges the option to cooperate in good faith with ONC–ACB surveillance of his or her health information technology certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received.
- If requested, that the ASM participant cooperates in good faith with ONC–ACB surveillance of the ASM participant's health information technology certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the ASM participant in the field.

Consistent with the proposal to remove these attestations from the MIPS Promoting Interoperability performance category, we propose to remove the ONC Direct Review attestation and ONC–ACB Surveillance attestation from the Promoting Interoperability ASM performance category starting in the 2027 ASM performance year.

This proposal aligns with our goals of reducing administrative burden while focusing on high-value, outcome-oriented measures. Removing attestations from the Promoting Interoperability ASM performance category reduces the number of discrete manual steps and reporting fields required for successful adherence to reporting requirements without diminishing central goals of the Promoting Interoperability ASM performance category.

We refer readers to section IV.A.4.f.(4) of this proposed rule for further discussion on the proposal to remove these attestations in MIPS.

We seek comment on the proposal to remove the ONC Direct Review attestation and ONC–ACB Surveillance attestation.

(7) Adopting a Measure Suppression Policy for the Promoting Interoperability ASM Performance Category

We finalized a measure suppression policy under the MIPS Promoting Interoperability performance category beginning with the CY 2026 MIPS performance year (90 FR 49881 through 49887). Under this policy, when circumstances arise that impede effective measurement of a MIPS Promoting Interoperability measure, we may suppress the measure by excluding it from MIPS Promoting Interoperability performance category scoring or from the determination of whether a MIPS clinician is a meaningful EHR user for the applicable MIPS performance year (§ 414.1380(b)(4)(iii)).

A decision to suppress a measure does not eliminate the requirement that MIPS eligible clinicians report the measure. However, regardless of the data, attestation, or other information related to the suppressed measure that is submitted by the MIPS eligible clinician, the suppressed measure would not affect the objective's score or the determination of meaningful EHR user status (90 FR 49883).

We also finalized suppression of the Electronic Case Reporting measure for the CY 2025 MIPS performance year because the Centers for Disease Control and Prevention (CDC) temporarily paused onboarding new health care organizations for production of electronic case reporting data and new local public health agencies for receipt of electronic case reporting data (90 FR 49886 through 49893).

We did not adopt a measure suppression policy for the Promoting Interoperability ASM performance category because ASM performance had not yet begun. We stated we would monitor developments as the first ASM performance year approaches, with the goal of maintaining alignment with the MIPS Promoting Interoperability performance category where possible and indicated we may propose changes in future rulemaking.

After further consideration, we propose at § 512.740(c)(2) to adopt a Promoting Interoperability measure suppression policy within ASM starting in the 2027 ASM performance year. Specifically, we are proposing that if certain circumstances occur that impact our assessment of ASM participant performance on a measure specified for the Promoting Interoperability ASM performance category under § 512.740(b), we may suppress the affected measure by: (1) excluding it from our calculation of the Promoting Interoperability ASM performance category objective score under § 512.740(c); or (2) excluding it from the determination of meaningful EHR user status, if the affected measure is not scored. We propose to redesignate current § 512.740(c)(2) describing the Promoting Interoperability ASM performance category scoring policy as § 512.740(c)(3), without making changes to that existing regulatory text, to describe the measure suppression policy at § 512.740(c)(2).

For an applicable ASM performance year, we propose to determine whether circumstances warrant suppression of an ASM Promoting Interoperability measure based on consideration of the same factors we identified for MIPS (90 FR 49883):

- The nature, breadth, and duration of the circumstance's effect on ASM participants' ability to fulfill the measure requirement;
- The availability of certified health IT modules to fulfill the measure;
- Whether the circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, including with respect to performance or compliance;
- Out-of-date or conflicting technical standards;
- Technical or operational capacity of required partners; or
- Other factors as determined by CMS.

We are further proposing that, if we determine that a measure must be suppressed, we would notify ASM participants through existing communication channels. To the extent technically feasible, we intend to notify ASM participants prior to the beginning of the applicable data submission period. We note that, like in MIPS, the duration of suppression for a measure in ASM would be for an entire ASM performance year. If prolonged issues persist regarding a given circumstance, we would assess the circumstance to determine if a measure would warrant suppression for a subsequent ASM performance year.

We believe this policy would ensure the integrity of the ASM scoring methodology while protecting ASM participants from being penalized for circumstances beyond their control.

We invite public comment on our proposal at § 512.740(c)(2) to adopt the proposed measure suppression policy.

f. Final Score

(1) Background

In the CY 2026 PFS final rule (90 FR 49664 through 49679), we adopted a scoring methodology to evaluate the annual performance of each ASM participant through a final score. The final score represents an ASM participant's aggregate performance on a scale of zero to 100 points based on applicable performance standards for measures and activities in each ASM performance category. This scoring framework promotes accountability for performance across ASM participants within each ASM cohort. We use the final score to determine the ASM payment adjustment factor applied to an

ASM participant's Medicare Part B claims for covered professional services during the corresponding ASM payment year.

We calculate the final score based on performance in the quality, cost, improvement activities, and Promoting Interoperability ASM performance categories (90 FR 49677). We also established policies to award additional points to ASM participants who furnish care to complex patient populations and to ASM participants who are part of small practices or who are solo practitioners (90 FR 49670 through 49676).

(2) Requirements To Receive a Final Score

In the CY 2026 PFS final rule (90 FR 49668 through 49669), we finalized that an ASM participant must meet minimum data submission requirement to receive a final score for an ASM performance year. An ASM participant who does not meet these data submission requirements receives a final score of zero points for the applicable ASM performance year, which results in the maximum negative payment adjustment applicable for the corresponding ASM payment year. Conversely, an ASM participant who meets the minimum data submission requirements but cannot be evaluated on quality and cost performance does not receive a final score and instead receives a neutral payment adjustment for the applicable ASM payment year. We refer readers to Table B–D8 in the CY 2026 PFS final rule for a summary of ASM's final score policies and their impact on payment adjustments (90 FR 49670).

After internal review of ASM's final scoring provisions, we believe we could clarify regulatory text describing when we will not assign an ASM participant a final score. Specifically, we propose to revise § 512.745(a)(2)(iii)(B) by striking the ''Do not receive'' language that starts §§ 512.745(a)(2)(iii)(B)(*1*) and 512.745(a)(2)(iii)(B)(*2*). We then propose to revise § 512.745(a)(2)(iii)(B) to read ''Do not receive either:'', referring to the conditions described at §§ 512.745(a)(2)(iii)(B)(*1*) and 512.745(a)(2)(iii)(B)(*2*). These specific changes do not introduce substantive changes to current requirements.

We seek comment on the proposed changes to clarify the regulatory text at § 512.745(a)(2)(iii)(B).

(3) Rural Scoring Adjustment

In the CY 2026 PFS proposed rule, we considered, but did not propose, including a rural scoring adjustment in the calculation of an ASM participant's final score (90 FR 32604), as our analysis of historic data did not reveal a systematic difference in expected performance between likely ASM participants in rural and non-rural areas. In response to our discussion considering the rural scoring adjustment in the CY 2026 PFS proposed rule, we received interested parties' feedback recommending that we award a rural scoring adjustment to ASM participants in rural areas because ASM participants in rural areas face unique demands (90 FR 49676). However, we finalized ASM's final score policy without including a rural scoring adjustment.

The CY 2026 PFS final rule did establish policies to award additional points on the final score to ASM participants who furnish care to complex patient populations (up to 10 points) and to ASM participants who are part of small practices (10 points for ASM participants in small practices, 15 points for solo practitioner ASM participants) (90 FR 49670 through 49676). In the CY 2026 PFS final rule, we noted that small practice and solo practitioner scoring adjustments better support ASM participants in small practices by compensating for increased administrative burden and additional reporting requirements (90 FR 49676). We noted in the CY 2026 PFS final rule that we expected a high degree of overlap between ASM participants in rural areas and those in small practices based on historical MIPS performance data that we analyzed (90 FR 49677), indicating that ASM participants in rural areas would be eligible for the small practice scoring adjustment and be supported accordingly. We also noted that a rural scoring adjustment could weaken incentives for ASM participants in large rural systems to improve (90 FR 49676).

However, as supported by interested parties' comments on the CY 2026 PFS proposed rule, together with additional research and analysis, the unique circumstances facing ASM participants in rural areas may warrant adjustments to their final scores. We recognize that ASM participants in rural areas may face structural challenges that affect their ability to perform under ASM, including limited resources for technology modernization, workforce shortages that constrain reporting capacity, and barriers to system interoperability. A 2025 analysis of physician participants in the Quality Payment Program found significantly higher physician adoption of EHRs in urban areas (74 percent) compared to rural areas (64 percent).[181] Another recent study suggests that physicians in rural areas were less likely to report ideal interoperability experiences for medication notes.[182] A report from the HHS Assistant Secretary for Technology Policy (ASTP) notes that urban hospitals were more likely to engage in routine interoperable exchange (47 percent were routinely interoperable) than their rural counterparts (36 percent were routinely interoperable).[183] These findings align with interested parties' feedback highlighting additional interoperability barriers faced by rural clinicians. Accordingly, we believe ASM's existing scoring methodology may not adequately address the complex factors that may affect rural ASM participant's performance particularly because ASM has a unique focus on incentivizing interoperability improvements to strengthen care coordination.

Additionally, our analysis of preliminary ASM participants for the 2027 ASM performance year provides an updated understanding of the practice size of ASM participants in rural areas. In previous notice-and-comment rulemaking, we noted that we expected ASM participants in rural areas were primarily practicing in small practices and, therefore, would qualify for ASM's small practice or solo practitioner scoring adjustments (90 FR 49677). An additional rural scoring adjustment, on top of small practice or solo practitioner adjustments, for these ASM participants could have been duplicative and result in a disproportionate scoring benefit. However, upon review of updated data on preliminary ASM participants for the 2027 ASM performance year, we found that ASM participants in rural areas are typically part of larger practices and would be less likely to receive the small practice scoring adjustment.

To address continued interested parties' feedback about ASM participants in rural areas and additional analysis of preliminary ASM participants for the 2027 ASM performance year, we are proposing the

[181] Anzalone AJ, Geary CR, Dai R, Watanabe-Galloway S, McClay JC, Campbell JR. Lower electronic health record adoption and interoperability in rural versus urban physician participants: a cross-sectional analysis from the CMS quality payment program. BMC Health Serv Res. 2025 Jan 23;25(1):128. doi: 10.1186/s12913–024–12168–5. PMID: 39849475; PMCID: PMC11755824.

[182] Everson J, Adler-Milstein J, Phillips RL, Bazemore AW, Patel V. EHR Interoperability Experiences Reported by Family Physicians. JAMA Netw Open. 2025;8(11):e2542460. doi:10.1001/jamanetworkopen.2025.42460.

[183] *https://healthit.gov/data/data-briefs/interoperable-exchange-patient-health-information-among-us-hospitals-2023/.*

inclusion of a rural scoring adjustment in the calculation of an ASM participant's final score. We believe adding a rural scoring adjustment would adequately increase final scores to account for the unique challenges faced by this group of ASM participants.

To determine if an ASM participant is in a rural area, we propose at § 512.705 to adopt the same definition and determinations of a ''rural area'' as defined, interpreted, and updated at § 414.1305 under MIPS. We believe that aligning our rural area definition with MIPS will reduce confusion for ASM participants in rural areas who have previously participated in MIPS and received associated flexibilities with rural special status under MIPS.

To incorporate the rural scoring adjustment proposal into ASM's regulatory text, we first propose to redesignate current § 512.745(a)(5) as new § 512.745(a)(6). We then propose at new § 512.745(a)(5) to add 5 points to the final score of an ASM participant who (1) is in a rural area as proposed to be defined at § 512.705, and (2) meets the requirements to receive a final score greater than zero as described at § 512.745(a)(2)(i) for an applicable ASM performance year. We emphasize that ASM participants in rural areas remain eligible to receive ASM's small practice or solo practitioner scoring adjustment and the complex patient scoring adjustment if they meet such scoring adjustment's eligibility criteria described at § 512.745(a)(4) and § 512.745(a)(3), respectively.

We considered but are not proposing an alternative rural scoring adjustment policy to add 5 points to the final score of each ASM participant who (1) is in a rural area as proposed to be defined at § 512.705, (2) meets the requirements to receive a final score greater than zero as described at § 512.745(a)(2)(i) for an applicable ASM performance year, and (3) does not receive a small practice scoring adjustment as described in § 512.705(a)(4). However, rural practices regardless of size often face thinner operating margins that limit their potential investment in the quality and technology infrastructure necessary to succeed in ASM.[184] Uneven access to affordable broadband may further burden ASM participants in rural areas by financially challenging their ability to leverage health information exchanges and data sharing.[185] We believe that a rural scoring adjustment for ASM participants in small and non-small rural practices alike most accurately accounts for the potential burdens faced by ASM participants in rural areas.

We also considered but are not proposing an alternative policy waiving Improvement Activity 2 (IA–2), Establishing Communication and Collaboration Expectations with Primary Care using CCAs, for ASM participants in rural areas. Although ASM participants in rural areas may face challenges forming partnerships with primary care practices due to limited primary care availability,[186] we believe that a rural scoring adjustment more broadly accounts for challenges that could affect ASM participant performance across the four ASM performance categories compared to only waiving IA–2.

To account for the proposed addition of the rural scoring adjustment, we propose corresponding adjustments to the final score formula at § 512.745(a)(6) We also propose to revise § 512.745(a) to cross-reference the final score formula now described at § 512.745(a)(6).

We seek public comment on our proposed definition of rural area at § 512.705 and our proposal at § 512.745(a)(5) to add 5 points to the final score of an ASM participant who is in a rural area and meets the requirements to receive a final score greater than zero. We also seek comment on the alternative we considered to only add the rural scoring adjustment to the final scores of ASM participants in rural areas who are not eligible to receive a small practice scoring adjustment, as well as the alternative to waive IA–2 for ASM participants in rural areas. We seek comment on our corresponding proposal at § 512.745(a)(6) to incorporate the rural scoring adjustment into the final score formula.

(4) ASM Performance Report

In the CY 2026 PFS final rule (90 FR 49678), we finalized that we will provide performance information to each ASM participant for each ASM performance year through an annual ASM performance report. The ASM performance report will include information on each ASM performance category score, scoring adjustments as applicable, the final score, the ASM payment adjustment factor, and the ASM payment multiplier.

To incorporate additional information on scoring incentives and scoring adjustments proposed in this proposed rule, we propose to revise the structure of the regulatory text on the ASM performance report in § 512.745(b). These proposed structural revisions to the regulatory text's structure are intended to improve readability on the logical flow of components of the annual ASM performance report, starting with each ASM performance category score, scoring incentives, scoring adjustments, final score, and ending with the resulting payment adjustment information. These specific changes do not introduce substantive changes to current requirements.

We also propose at revised § 512.745(b)(2) to provide ASM participants with information on whether they receive the quality ASM performance category scoring incentive for successful voluntary reporting of PRO data through the annual ASM performance report, as applicable. We refer readers to section III.D.2.d.(5) of this proposed rule for additional information on the proposed voluntary PRO data submission and associated quality ASM performance category scoring incentive.

We also propose at revised § 512.745(b)(5) to provide ASM participants with information on their rural scoring adjustment, if applicable, in the annual ASM performance report.

We believe these proposals would help an ASM participant understand their performance and whether they qualified for new scoring incentives and scoring adjustments proposed in this proposed rule.

We seek comment on our proposed clarifying revisions to § 512.745(b). We also seek comment on our proposal at § 512.745(b)(2) to provide information on the quality ASM performance category incentive for voluntary reporting of patient-reported outcome data, as applicable, and our proposal at § 512.745(b)(5) to provide information on the rural scoring adjustment, as applicable, in the annual ASM performance report.

g. Payment Approach

(1) Background

In the CY 2026 PFS final rule, we finalized the overall payment approach for ASM (90 FR 49679 through 49699). We will apply performance-based payment adjustments to all payments for Medicare Part B covered professional service claims from ASM participants

[184] HRSA National Advisory Committee on Rural Health and Human Services. *Interoperability and Broadband: Challenges to Rural Information Exchange* (January 2016). *https://www.hrsa.gov/advisory-committees/rural-health/correspondence/20160101.*

[185] Pritzker, Penny, and Tom Vilsack. ''Broadband Opportunity Council Report and Recommendations.'' *USDA, US Department of Commerce,* 20 Aug. 2015, *obamawhitehouse.archives.gov/sites/default/files/broadband_opportunity_council_report_final.pdf.*

[186] *https://www.ers.usda.gov/data-products/charts-of-note/chart-detail?chartId=106208.*

during an ASM payment year based on their performance during the corresponding prior ASM performance year. We explained that this approach will create meaningful financial incentives tied to performance in the model, while maintaining administrative feasibility and transparency (90 FR 49679 through 49680). To determine these payment adjustments, we finalized a methodology to compare ASM participant performance within each ASM cohort using final scores, which reflect ASM participants' performance across the four ASM performance categories (90 FR 49681 through 49683). We also finalized a methodology to calculate ASM payment adjustment factors and ASM payment multipliers used to apply the payment adjustments from the distribution of final scores (90 FR 49685 through 49696). We also finalized the level of two-sided risk (that is, the maximum and minimum payment adjustment), including the gradual increase in the two-sided ASM risk level from 9 percent in the 2027 and 2028 ASM performance years to 12 percent in the 2031 ASM performance year. We explained that this methodology supports strong incentives for performance improvement while maintaining ASM risk levels similar to MIPS during early model years. We will apply the ASM payment multiplier to all payments for Medicare Part B for covered professional services, not only those services related to each ASM cohort's ASM targeted chronic condition, during an ASM payment year (90 FR 49696 through 49699).

(2) Application of ASM Payment Adjustments With Changes in TIN Affiliations

In the CY 2026 PFS final rule, we finalized that Medicare Part B professional service claims submitted by an NPI who is an ASM participant for an ASM performance year but under a TIN (1) that we did not select the NPI as an ASM participant for the applicable ASM performance year and (2) to which the NPI began assigning billing rights after the ASM performance year but before the end of the corresponding ASM payment year would be adjusted using the ASM payment multiplier calculated for the ASM participant. In the limited instances where a single NPI is selected as an ASM participant under multiple TINs for an ASM performance year, we finalized that we would apply the highest of any ASM payment multipliers to all Medicare Part B covered professional service claims submitted under a new TIN during the applicable ASM payment year (90 FR 49696). We refer readers to Table B–D10 in the CY 2026 PFS final rule for additional information on how ASM payment adjustments will be applied under multiple scenarios (90 FR 49697). The goal of these policies is to maintain accountability for the ASM participant's performance through the application of their performance-based payment adjustments. By doing so, we track accountability to the ASM participant regardless of their specific TIN affiliation at the time we make payment adjustments.

While we are not proposing substantive changes to these policies in this proposed rule, we note that there are inconsistencies in the regulatory text describing how we will adjust payment in situations where the ASM participant begins reassigning billing rights to a new TIN during an ASM payment year.

Accordingly, to maintain consistency with the regulatory text governing the application of ASM's payment adjustments as described at § 512.750(a), at §§ 512.750(f)(1) and (f)(2), we propose to revise the regulatory text at § 512.750(f) to replace the phrases ''adjusts payments'' and ''adjust claims'' with ''multiplies the amount otherwise paid under Medicare Part B for covered professional services''. We are also proposing clarifying revisions to § 512.750(f)(1). We propose to remove unnecessary text at § 512.750(f)(1)(i) because we only calculate ASM payment multipliers for ASM participants with final scores as described at § 512.750(c)(1). To improve readability of the provision with the proposed removal of § 512.750(f)(1)(i), we propose to revise § 512.750(f)(1) to incorporate the text previously described at § 512.750(f)(ii).

We are also proposing revisions to clarify how we would adjust payments for NPIs selected as ASM participants under multiple TINs and who reassign billing rights to a new TIN after an ASM performance year. Accordingly, we propose to remove unnecessary language in § 512.750(f)(2) and § 512.750(f)(2)(i) to more clearly describe how we would adjust payments using the highest ASM payment multiplier calculated for an NPI who we select as an ASM participant under multiple TINs. We also propose at § 512.750(f)(2)(ii) to replace the phrase ''assigning billing rights'' with ''reassigning billing rights'' to improve the accuracy of the regulatory text. These proposals do not create substantive changes to the proposed policies but would ensure clarity and consistency in language used to describe the application of payment adjustments under ASM under § 512.750.

We seek comment on our proposals to revise the regulatory text at § 512.750(f)(1) and § 512.750(f)(2).

h. Applicability of CMS-Sponsored Model Safe Harbor at 42 CFR 1001.952(ii)

In the CY 2026 PFS final rule, we determined that the CMS- model arrangements and patient incentives safe harbor at § 1001.952(ii) would be available to ASM participants that comply with applicable requirements (90 FR 49709) and codified the availability of the safe harbor for ASM at § 512.765 in regard to remuneration associated with beneficiary incentives and remuneration exchanged under CCAs.

Once a clinician is selected as an ASM participant for any ASM performance year during the ASM test period, that clinician remains an ASM participant for the duration of the ASM test period. However, in limited circumstances, an ASM participant may not be required to meet specified model requirements for a given ASM performance year. Specifically, if we determine that an ASM participant does not satisfy the ASM participant eligibility criteria as specified under § 512.710(a)(2) or is determined to meet an exception under § 512.710(c) for a given ASM performance year, the ASM participant is not: (1) subject to ASM performance assessment under § 512.715, (2) required to submit data under § 512.720, (3) subject to final scoring under § 512.745, and (4) eligible for the waivers available under the model described at § 512.775 (90 FR 49572, 90 FR 49583).

We finalized the application of these policies in the CY 2026 PFS final rule, however, we did not address the availability of the CMS-sponsored model arrangements and patient incentives safe harbor under § 1001.952(ii), as made available for ASM at § 512.765, in instances where an ASM participant is not subject to specified ASM requirements due to not meeting ASM participant eligibility criteria as described in § 512.710(a)(2) or a determination that an exception applies under § 512.710(c).

We now propose that the CMS-sponsored model arrangements and patient incentives safe harbor would be available only for remuneration attributable to periods during which an ASM participant is performing under the model. Conversely, the CMS-sponsored model arrangements and patient incentives safe harbor would not be available for remuneration

attributable to a period during which an ASM participant is not performing under the model due to not meeting ASM participant eligibility criteria as described at § 512.710(a)(2) or a determination that an exception applies under § 512.710(c).

We believe this proposal appropriately ties the availability of the model-specific safe harbor to underlying model activities performed during a period of model performance. For example, we recognize that remuneration associated with a CCA may not be exchanged contemporaneously with the ASM performance year to which it relates. In such instance, remuneration exchanged pursuant to a CCA may be calculated based on an ASM participant's performance during an ASM performance year in which the ASM participant was eligible for and not excepted from ASM performance but may not be exchanged until a subsequent year because the applicable ASM payment adjustment factor, and net payment adjustment, would not calculated until after the close of the ASM performance year. An ASM participant who reassigns billing rights to a new TIN or redesignates their primary specialty type mid-ASM performance year may be excepted from ASM participation for that performance year under § 512.710(c). In such instance, the ASM participant may rely on the availability of the safe harbor during the portion of the year in which they were performing under the model. Our proposal is not intended to retrospectively render the safe harbor unavailable with respect to remuneration attributable to the period in which the ASM participant was actively performing under the model and all applicable safe harbor requirements were satisfied. The limitation on safe harbor availability described at proposed § 512.765(c) would apply prospectively from the date we determine the exception applies under § 512.710(c).

Accordingly, we propose that the availability of the CMS-sponsored model safe harbor would depend on the period of ASM performance to which the remuneration is attributable.

Specifically, we propose to add § 512.765(c) to state that the CMS-sponsored model arrangements and patient incentives safe harbor is available only with respect to remuneration attributable to a period in which the ASM participant was performing under the model, and is not available with respect to remuneration attributable to any period of the ASM test period for which the ASM participant does not meet ASM participant eligibility criteria under § 512.710(a)(2) or is excepted from specified ASM requirements under § 512.710(c).

Limiting the availability of the safe harbor to remuneration attributable to model performance helps support program integrity and beneficiary protections while preserving flexibility for ASM participants to use incentives that support patient and primary care engagement in performance activities aligned with the model's purpose.

We seek comment on this proposal.

i. Collaborative Care Arrangements (CCAs)

(1) Background

The improvement activities ASM performance category is intended to advance core goals of ASM to drive better outcomes through improved care coordination, increased collaboration between specialists and primary care practices, and interventions that address upstream drivers of health.

We finalized two improvement activities for ASM in the CY 2026 PFS final rule at § 512.735 that we believe best support these aims:

- Improvement Activity 1 (IA–1): Connecting to Primary Care and Ensuring Completion of Health-Related Social Needs Screening; and
- Improvement Activity 2 (IA–2): Establishing Communication and Collaboration Expectations with Primary Care using CCAs (90 FR 49648 through 49655).

To receive the maximum score available for the improvement activities ASM performance category, an ASM participant must attest ''yes'' to both improvement activities.

IA–2 specifications require an ASM participant to enter into at least one collaborative care arrangement (CCA) with a primary care practice with which the ASM participant shares a patient who is an ASM beneficiary. IA–2 also requires that a CCA address at least three of the five elements specified at § 512.735(c)(2)(ii): data sharing, co-management, transitions in care planning, closed-loop connection, and care coordination integration.

In addition to IA–2 specifications at § 512.735(c)(2)(ii), we outline requirements for CCAs at § 512.771. The function of the CCA is to memorialize the coordination activities central to ASM and described in IA–2.

We now propose certain updates to the CCA provisions at § 512.771 to improve implementation by ASM participants and primary care practices and to more closely align CCA conditions with IA–2 by revising § 512.771(a) and adding new paragraph § 512.771(d). In summary, and as discussed in detail in respective sections of this proposed rule, our proposed changes to § 512.771 include:

- Permitting one or more ASM participant to enter into a CCA with the same primary care practice, provided each ASM participant reassigns billing rights through the same entity's TIN and are named as parties to the CCA;
- Clarifying the requirement that an ASM participant and a primary care practice share a patient who is an ASM beneficiary and how this requirement applies in the context of the limitation on considering the volume or value of referrals;
- Streamlining the provision containing an illustrative list of authorities with which parties to a CCA must comply to simplify it, improve clarity, and reduce ambiguity;
- Updating the provisions that currently reference any elective exchange of payments between CCA parties to instead refer to the elective exchange of remuneration, to reflect a broader scope of value that may be exchanged under a CCA;
- Reorganizing regulatory requirements under § 512.771(a) that are associated only with the exchange of any elective remuneration under a CCA such that they appear together under a new paragraph at § 512.771(d) to bring greater clarity and to distinguish between those requirements that apply to all CCAs and those that apply only to CCAs that electively include the exchange remuneration;
- Revising the payment limitation that caps the exchange of remuneration based on an ASM participant's performance adjustment such that it can be more readily calculated in a timely manner and requiring that parties that elect to exchange remuneration before the limitation can be calculated reconcile any amounts that exceed the limitation following reconciliation;
- Clarifying that current requirements relating to traceability will continue to apply to monetary remuneration;
- Updating the contemporaneous documentation requirements to reflect any remuneration exchanged and add requirements to bring transparency into the methodologies used to determine the value of such remuneration; and
- Relocating the conditions associated with remuneration at current §§ 512.771(a)(7) and 512.771(a)(8) to new paragraphs §§ 512.771(d)(2) and 512.771(d)(3), respectively, in accordance with our proposal to address requirements associated with CCAs that include an exchange of remuneration

together under one paragraph. To conform with this relocation, we would redesignate existing sections §§ 512.771(a)(9) through 512.771(a)(13) to §§ 512.771(a)(7) through 512.771(a)(11). We would revise newly redesignated § 512.771(a)(7) (former § 512.771(a)(9)) to reference ''[a]ll parties'' rather than ''[b]oth parties'' and revise newly redesignated § 512.771(a)(9) (former § 512.771(a)(11)) to update documentation requirements as described, but otherwise would not revise text at newly redesignated § 512.771(a)(8) (former § 512.771(a)(10)), § 512.771(a)(10) (former § 512.771(a)(12)), or § 512.771(a)(11) (former § 512.771(a)(13)).

(2) Parties to a CCA

In the CY 2026 PFS final rule, we finalized at § 512.771(a)(1) a requirement that a CCA be in writing, signed by both parties, and contain the effective date of the arrangement. We also finalized at § 512.771(a)(2) a requirement that a CCA be exclusively between an ASM participant and a primary care practice with which the ASM participant shares at least one established patient who is an ASM beneficiary. At that time, we considered, but declined to permit, multiple ASM participants reassigning billing rights through the same TIN to be parties to a single CCA with a primary care practice party, citing concerns around the ability of ASM participants to accurately track any remuneration exchanged under a multi-ASM participant arrangement (90 FR 49712).

Following publication of the CY 2026 PFS final rule, we received interested party feedback anticipating significant burden associated with establishing separate CCAs for each individual ASM participant when more than one ASM participant is in the same group practice and such ASM participants wish to collaborate with the same primary care practice. As an example, 20 ASM participants operate within a single health system and reassign their billing rights to that system's TIN. Even if such ASM participants coordinate care regularly with the same primary care practice and wish to establish a CCA with the same primary care practice, the current regulation would require negotiation, execution, documentation, and tracking of 20 separate CCAs.

We believe that requiring a separate CCA for each ASM participant could impose administrative burden without a corresponding programmatic benefit. We now believe that concerns related to tracking remuneration under CCAs involving multiple ASM participants could be addressed through more targeted safeguards that apply to CCAs that elect to include remuneration, rather than a broader restriction applicable to all CCAs, including those that do not involve any exchange of remuneration.

Accordingly, we propose to amend §§ 512.771(a)(1) and 512.771(a)(2) to permit one or more ASM participants to be parties to the same CCA, subject to defined conditions. First, each ASM participant would be required to be explicitly named as a party to the CCA. Second, we propose that for multiple ASM participants to participate in the same CCA, all such ASM participants would be required to reassign billing rights to the same TIN. We would maintain the existing requirements at § 512.771(a)(1) that the CCA be in writing and specify an effective date; we would also maintain the requirement that a CCA be signed by the parties but propose to amend regulatory text to stipulate CCA execution would be required for ''all'' parties rather than ''both'' parties.

We believe restricting a multi-ASM participant CCA to ASM participants within the same TIN is appropriate as clinicians who practice under the same group practice are more likely to be supported by shared operations, such as shared EHR systems, clinical support staff, and standardized administrative workflows. Accordingly, we believe terms of a CCA could be standardized across ASM participants within the same organization (that is, TIN) without compromising the level of detail needed to support meaningful care coordination. In contrast, ASM participants from separate, unaffiliated TINs may have distinct infrastructure, care coordination needs, support structures, and operational workflows. It is therefore unclear how a single arrangement could establish cohesive terms regarding shared responsibilities with a primary care partner in a manner consistent with the intent of CCAs. We are concerned that attempting to encompass these different capabilities and variable workflows within a single agreement could result in vague, overly broad, or highly fragmented contractual terms, which could undermine the intent of the CCA.

Our proposal to permit one or more ASM participants billing under the same TIN to join the same CCA with a primary care partner does not alter ASM's fundamental accountability framework. As noted, we propose to clarify that any ASM participant seeking to join and rely on one CCA be expressly named as a party to the arrangement. We believe such requirement maintains individual ASM participant accountability, while reducing administrative burden. We are not proposing to permit a group practice or TIN to serve as a sole contracting party on behalf of unnamed ASM participants, as this could obfuscate individual ASM participant accountability and introduce operational complexity, particularly when an ASM participant departs a group practice during an ASM performance year. Requiring each ASM participant to be named as a party would mitigate such concerns while still reducing contracting burden.

We wish to emphasize that our proposals do not preclude an ASM participant's group practice from supporting the ASM participant or ASM participants with administrative functions associated with a CCA, such as recordkeeping or maintaining documentation on ASM participants' behalf, provided such support is consistent with other applicable authorities. Such administrative support does not substitute for the requirement that each ASM participant be named as a party and remain accountable for the core responsibilities described by the model and CCAs. Rather, we intend for our proposals to better account for the operational realities of group practices and the nature of the activities envisioned by a CCA, which inherently entails practice-level support. We do not intend for our proposals to disrupt such support arrangements.

We also note that we do not intend, and do not propose, to impose prescriptive requirements around the meaning of a ''primary care practice'' that must be a party to a CCA. Our intent is that a CCA reflects coordination between the ASM participant and their ASM beneficiary's source of primary care services. We refer readers to discussion in response to interested party questions in the CY 2026 PFS final rule for further information (90 FR 49653).

Our proposal is also intended to reduce burden for ASM participants who practice within the same group and coordinate care with the same primary care practice. It is not intended to discourage individual CCAs. ASM participants who belong to the same group may continue to enter into separate CCAs and should consider a separate arrangement when doing so better reflects individual clinical relationships, sources of primary care for their individual ASM beneficiary panel, and care coordination needs. We also continue to encourage ASM participants to consider entering into multiple CCAs to the extent it would support meaningful coordination for a

broader population of ASM beneficiaries but note that only one CCA is required to meet IA–2 specifications.

We seek comment on these proposals, including whether it would reduce administrative burden to permit more than one ASM participant to enter the same CCA while preserving individual accountability, program integrity, and appropriate oversight. We also seek feedback on whether this proposal could be read as disadvantaging ASM participants who are solo practitioners or part of a group practice where they are the only selected ASM participant. We do not believe this proposal would have any negative effect on these ASM participants, but we invite interested party perspectives on this.

(3) Requirement That CCA Parties Share a Patient Who Is an ASM Beneficiary

Sections 512.735(c)(2)(i) and 512.771(a)(2) both require that parties to a CCA share a patient who is an ASM beneficiary. Under our proposal to permit more than one ASM participant to join the same CCA, we would maintain the requirement at proposed revised § 512.771(a)(2) that an ASM participant party or ASM participant parties and the primary care practice party share at least one patient who is an ASM beneficiary. That is, the requirement that an ASM participant party or ASM participant parties and the primary care practice share a patient who is an ASM beneficiary would be satisfied so long as at least one shared patient who is ASM beneficiary exists between any one ASM participant party to the CCA and the primary care practice party, regardless of the total number of ASM participants who are parties to that CCA.

We emphasize that the purpose of the requirement to share ''one or more'' patients who are ASM beneficiaries is to ensure a clear nexus exists between the CCA and coordination activities on behalf of ASM beneficiaries for whom both the primary care practice party and ASM participants have a care relationship. In the absence of shared ASM beneficiaries, there would be no care relationship to coordinate and, therefore, no basis for a CCA. We require only one shared ASM beneficiary as a minimum threshold condition because we believe that parties who commit to meaningfully coordinate care in a manner consistent with the purpose of a CCA will, organically, identify and collaborate on behalf of a much broader shared patient population as the arrangement is implemented. Thus, we continue to underscore, as we did in the CY 2026 PFS final rule (90 FR 49712 through 49713), that we encourage ASM participants to select primary care partners with whom they share multiple ASM beneficiaries as this would more meaningfully fulfill the goals of the CCA.

Lastly, current § 512.771(a)(2) requires that, for the purposes of the shared ASM beneficiary requirement, the ASM beneficiary must be an ''established'' patient. IA–2 specifications at § 512.735(c)(2)(i) does not include the ''established'' qualifier. Upon further review, we do not believe it is necessary to include the term ''established'' in CCA regulations and therefore propose to strike the term ''established'' at § 512.771(a)(2) to conform with IA–2 specifications.

We seek comment on our proposal to require at least one shared patient who is an ASM beneficiary under a CCA regardless of how many ASM participants are parties to such CCA. We invite feedback on whether requiring one shared patient who is an ASM beneficiary is sufficient to encourage the coordination goals envisioned by CCAs. We also seek comment on our proposal to remove the term ''established'' from CCA regulations at § 512.771(a)(2).

(4) Requirement To Comply With Applicable Laws

We finalized in the CY 2026 PFS final rule at § 512.771(a)(5) that both parties to a CCA must comply with all applicable statutes, regulations, and guidance, including without limitation: Federal criminal laws; the False Claims Act (31 U.S.C. 3729 *et seq.*); the anti-kickback statute (42 U.S.C 1320a–7b(b)); the civil monetary penalties law (42 U.S.C. 1320a–7a); and the physician self-referral law (42 U.S.C. 1395nn).

We now believe the illustrative list at § 512.771(a)(5) is unnecessary and that a simplified version of regulatory text may reduce potential confusion. Accordingly, we are proposing to remove the illustrative list of legal authorities and instead retain only the requirement that both parties to a CCA comply with all applicable statutes, regulations, and guidance. To conform with other proposals to § 512.771, we also propose to amend regulatory text to strike reference to ''[b]oth'' parties and instead require that ''[a]ll'' parties comply with this provision.

We invite comment on the proposed changes.

(5) Restriction on Conditioning Remuneration on Referrals

In the CY 2026 PFS final rule, we established that neither the opportunity to enter a CCA nor the amount of any payment under a CCA may be conditioned, directly or indirectly, on the volume or value of past or anticipated referrals or business generated by, between, or among the parties to the arrangement or any other person (90 FR 49711). Separately, § 512.771(a)(2) requires that an ASM participant and a primary care practice party to a CCA share at least one patient who is an ASM beneficiary.

Upon further consideration, we are concerned that the current language at § 512.771(a)(6) on conditioning entry into a CCA, in the context of the requirement for shared ASM beneficiaries at § 512.771(a)(2), may be read to unnecessarily constrain the formation of the type of arrangements the model is designed to promote. Because shared ASM beneficiaries among parties to a CCA may result from existing care relationships between ASM participants and primary care practices, the current language of § 512.771(a)(6) could be read to prohibit potential collaborators from considering the beneficiary-sharing relationship required by § 512.771(a)(2). We did not intend the prohibition on conditioning entry into a CCA on referrals or business generated to prevent parties from considering whether they satisfy the shared-beneficiary requirement that is itself a requirement to CCAs.

Accordingly, we propose to revise § 512.771(a)(6) that an ASM participant may consider, as one criterion for entering into a CCA, whether they share at least one ASM beneficiary with a primary care practice. We propose that this would not violate the volume or value standard in § 512.771(a)(6) if the purpose of such criteria is to further the purpose of the CCA. This clarification is intended to remove an unintended barrier to CCA formation while preserving the prohibition on entering into arrangements based on referral patterns or that reward or induce referrals or other business generated.

This targeted revision would permit parties to consider whether they share one or more ASM beneficiaries only for purposes of satisfying the shared-beneficiary requirement at § 512.771(a)(2) and furthering the purpose of the CCA.

We seek comment on this proposal. We also invite comment on whether the proposed approach is sufficiently clear and appropriately accommodates the operational realities of how practices contemplate establishing CCAs.

(6) CCAs That Include the Exchange of Remuneration

In the CY 2026 PFS final rule, we stated our intent to allow ASM participants and their primary care

partners to negotiate arrangements that are best suited to their practices (90 FR 49712). We also recognized that parties to a CCA may wish to include model-related incentives under a CCA to support shared accountability for the outcomes of ASM beneficiaries and to support coordination activities that benefit shared patients (90 FR 49713). Accordingly, we made the CMS-sponsored model arrangements safe harbor at § 1001.952(ii)(1) available under ASM at § 512.765 to protect remuneration exchanged under a CCA, provided that all requirements of the safe harbor at § 1001.952(ii)(1) and CCA regulations at § 512.771 are met (90 FR 49713).

Upon further review, we believe that provisions of § 512.771 that refer to payments exchanged under a CCA should be revised to apply more broadly to remuneration exchanged under a CCA to the extent applicable. Applying these provisions to remuneration would better align § 512.771 with § 512.765 and the CMS-sponsored model arrangements safe harbor at § 1001.952(ii)(1), both of which address remuneration. It would also more accurately reflect the full range of value that parties may exchange under a CCA, including monetary payments and in-kind items or services that support care coordination and other model-related activities.

Accordingly, we propose to revise § 512.771 such that applicable provisions referencing payment instead reflect and apply more broadly to remuneration exchanged under a CCA. We believe this proposed modification would clarify that safe harbor protections and requirements in § 512.771 apply to both monetary and in-kind remuneration exchanged under a CCA. We emphasize that remuneration is not a required element of a CCA. Rather, parties to a CCAs may elect to include monetary or in-kind incentives that promote improvement activities or the goals of the model, provided that all applicable requirements are met (90 FR 49654). In-kind remuneration, such as shared data analytics platforms, care managers, or technology infrastructure could support the type of care coordination envisioned by ASM.

We also propose to add new paragraph § 512.771(d) to introduce the requirements that apply when parties to a CCA elect to exchange remuneration and to relocate the proposed, revised conditions applicable to remuneration under a CCA such that they appear together under new paragraph § 512.771(d). We believe this construction would more clearly distinguish the regulatory requirements that apply to all CCAs from the additional conditions that apply when remuneration is exchanged under a CCA.

We seek comment on our proposals to address remuneration, as applicable, throughout § 512.771 rather than just payment, and to reorganize § 512.771 such that conditions associated with remuneration at current §§ 512.771(a)(7) and (a)(8) are located under new paragraph § 512.771(d) at §§ 512.771(d)(2) and (d)(3), respectively. We are interested in whether the proposed reorganization would bring greater clarity to our regulations.

We also welcome comment on the types of services and remuneration that specialists and primary care partners exchange or contemplate exchanging to support and encourage coordination and collaboration goals, as we described in the CY 2026 PFS final rule (90 FR 49712). We remain interested in learning about the types of remuneration used to support collaborative care, such as shared personnel, infrastructure, data analytics, care management resources, technology, or other in-kind items or services, so that we may more clearly understand how such incentives are used to promote activities designed to aid coordination and can consider such feedback in future rulemaking.

(a) Requirement for Remuneration to Reasonably Relate to CCA Purpose

In the CY 2026 PFS final rule, we finalized at § 512.771(a)(3) that a CCA must be entered into for the purpose of either furthering the ASM participant's performance in the improvement activities ASM performance category or furthering the clinical goals of the model as described by § 512.771(b) (90 FR 49712 through 49714).

We did not include a corresponding requirement that any remuneration exchanged under a CCA connect to those purposes. Upon further review, we are concerned that, absent such a requirement, remuneration could be structured in a manner that is not sufficiently connected to the objectives the CCA intends to support.

We propose that any remuneration exchanged by the ASM participant party or parties and the primary care practice party to a CCA would be required to have a reasonable relationship to activities undertaken to further the ASM participant's performance in the improvement activities ASM performance category or to advance the model's clinical goals, which are: (1) promoting preventive care through improved management of ASM targeted chronic conditions; (2) empowering patients to actively participate and be accountable for quality and whole health outcomes; and (3) facilitating meaningful and efficient coordination between specialists and primary care providers to increase independent physician participation in value-based payment programs.

Specifically, we propose to require at new § 512.771(d)(1) that any remuneration exchanged by the parties to a CCA be reasonably related to the purpose of the CCA, as defined in § 512.771(a)(3). We believe that aligning the purpose of any exchange of remuneration with the purpose of the CCA would support bona fide care coordination incentives while protecting program integrity. We do not anticipate that this requirement will result in any meaningful increase in compliance burden, particularly since including remuneration under a CCA is voluntary and because we already require that a CCA be entered into for the purposes specified at § 512.771(a)(3).

We seek comment on our proposal at § 512.771(d)(1) to require that any remuneration exchanged under a CCA be reasonably related to the purpose of the arrangement, consistent with § 512.771(a)(3).

(b) Limitation on Remuneration

In the CY 2026 PFS final rule (90 FR 49712 through 49714), we finalized a limitation to the amount of any payments exchanged under a CCA at § 512.771(a)(7). Specifically, we finalized a requirement that any payment exchanged under a CCA must not exceed the sum total of the payment adjustments made to an ASM participant's claims for a given ASM payment year, which would be calculated based on the of application of the ASM payment adjustment factor to the ASM participant's payments for Medicare Part B covered professional services during the corresponding ASM payment year.

Our intent was to ensure that any financial or in-kind exchanges between CCA parties remain appropriately tied to patient outcomes and ASM's clinical goals (90 FR 49712).

Upon further consideration, we believe the current methodology may be difficult for parties to operationalize and warrants revision. ASM payment adjustments are applied 2 CYs after the applicable ASM performance year. As a result, the information needed to determine the maximum amount permitted to be exchanged may not be available until well after the close of the applicable ASM performance year. This could create operational difficulty for

parties that wish to exchange remuneration during or near the ASM performance year when care coordination activities are occurring.

Accordingly, we propose updates to modify the temporal period used to calculate this limitation and provide for a reconciliation and repayment process to support compliance with the limitation. Consistent with our organizational update to § 512.771, we propose to include the revised limitation on remuneration in new § 512.771(d)(2).

We propose to maintain a limitation on the amount of remuneration exchanged under a CCA and to tie that limitation to performance-based payment adjustments made to an ASM participant's payments for Medicare Part B covered professional services. However, we propose that this limitation would be calculated using the ASM participant's ASM payment adjustment factor for the applicable ASM performance year, multiplied by the amount otherwise paid to the ASM participant by CMS under Medicare Part B for covered professional services during that ASM performance year. Stated another way, the proposed revision would change the temporal period used to calculate the limitation amount from the ASM payment year to the ASM performance year. Under both the current and proposed methodologies, the operative component is the ASM payment adjustment factor based on performance for the ASM performance year; the proposed revision changes only the temporal period used to calculate the limitation amount.

In accordance with our proposal permitting more than one ASM participant to join the same CCA, we propose to clarify that the remuneration limitation under proposed § 512.771(d)(2) would be calculated separately for each ASM participant that is a party to a CCA. This means that, where more than one ASM participant is included in the same CCA, the limitation on the amount of remuneration that may be exchanged under the arrangement would be calculated per each ASM participant. Accordingly, the remuneration limitation would be calculated separately for each ASM participant based on that ASM participant's ASM payment adjustment factor and the amount otherwise paid to that ASM participant by CMS under Medicare Part B for covered professional services during the applicable ASM performance year. We believe this clarification is necessary to preserve individual ASM participant accountability while allowing multiple ASM participants to participate in a single CCA where appropriate.

We are also proposing additional safeguards to support consistent implementation of this limitation. Specifically, under proposed § 512.771(d)(2)(i), the CCA would be required to specify a methodology for identifying and calculating the total value of remuneration exchanged under the arrangement for the ASM performance year and determine whether the total value exceeds the applicable limitation. To the extent that remuneration is in-kind, we propose at § 512.771(d)(2)(ii) that the valuation of such remuneration would be based on the offeror's costs using any reasonable accounting methodology, or the fair market value of the in-kind item or service. We believe this would support ASM participants that elect to exchange in-kind remuneration in ensuring such exchange complies with our regulations. Under proposed § 512.771(d)(2)(iii), the arrangement would be required to provide for reconciliation, if applicable, after the limitation is determined. Under proposed § 512.771(d)(2)(iv), if the total value of remuneration exchanged under the arrangement for the ASM performance year exceeds the limitation, the party that received the excess amount would be required to repay that excess amount to the other party within a reasonable time. We believe these provisions would promote consistent administration, clarify compliance requirements, and facilitate CMS oversight. We anticipate that these revisions to the remuneration limitation would establish a more viable pathway for parties to exchange remuneration during or close to the applicable ASM performance year by offering greater regulatory certainty that, should those exchanges exceed the final limitation, there would be a defined mechanism to reconcile the difference later.

We recognize the inherent complexity with a limitation based on a mathematical formula as described in proposed § 512.771(d)(2) in the context of in-kind remuneration. Valuing in-kind remuneration to ensure it does not exceed the calculated threshold, and 'repaying' excess in-kind value during the reconciliation process, may present operational difficulties that could impede good faith exchanges of in-kind items or services intended to support the purpose of the CCA. We considered but are not proposing an alternative where the limitation in proposed § 512.771(d)(2) would apply only to monetary payments (or cash equivalents) exchanged under a CCA. Under such alternative, we would establish a separate limitation for in-kind remuneration, such as requiring that any in-kind items or services exchanged meet a fair market value and commercial reasonableness standard rather than a limitation based on a dollar amount. While a separate safeguard tailored to in-kind remuneration could ease operational burden for ASM participants and their primary care partners, we believe that having one mathematical formula for valuing any remuneration exchanged under a CCA would be simpler for parties to CCAs to implement and therefore did not propose this approach.

We seek comment on these proposals, including the proposed update for calculating the limitation using the ASM performance year rather than the corresponding ASM payment year, the methodology and reconciliation requirements at proposed § 512.771(d)(2) and whether the proposed updates bring greater clarity to requirements that apply to CCAs that elect to include remuneration. We also seek comment on the alternative considered for in-kind remuneration limitations.

(c) Other Requirements for Remuneration Exchanged Under a CCA

We finalized in the CY 2026 PFS final rule that any payment exchanged under a CCA must be solely between the parties and be made by check, electronic funds transfer, or another traceable cash transaction (§ 512.771(a)(8)) (90 FR 49712 through 49714). Consistent with our organizational update to § 512.771, we propose to include this requirement, with revisions to address remuneration more broadly, in new § 512.771(d)(3).

Specifically, we would require that any remuneration exchanged under a CCA be solely between the parties and that, to the extent the exchange is a monetary payment, payment must be made by check, electronic funds transfer, or other traceable transaction at § 512.771(d)(3).

We seek comment on these proposals.

(d) Documentation Requirements

We finalized a requirement that ASM participants maintain contemporaneous documentation regarding all CCAs, including the relevant agreement and date and amount of payment at § 512.771(a)(11).

We propose to update documentation requirements to better support ASM participants and their primary care partners in their compliance with applicable regulations and to update references to conform with other changes proposed under § 512.771, including that we propose to

redesignate existing § 512.711(a)(11) to § 512.711(a)(9).

Specifically, we propose to revise the documentation requirement at proposed revised § 512.771(a)(9) such that an ASM participant would be required to maintain contemporaneous documentation, in accordance with § 512.135, regarding all CCAs entered into, records of all remuneration exchanged for each ASM participant under a CCA, a description of the remuneration, the value of the remuneration, the methodology for determining the value of any in-kind remuneration, and the date on which the remuneration was exchanged.

We also propose to require documentation of the identity of each ASM participant that would be a party to the CCA. We propose this change to conform with our proposal that a CCA may include more than one ASM participant to promote appropriate recordkeeping regarding the identity of each ASM participant covered by a CCA.

Together, we believe these proposed changes would clarify the minimum documentation that must be maintained by an ASM participant, better support compliance, and reduce ambiguity regarding documentation when a CCA includes multiple ASM participants as parties. These proposed changes would be reflected in proposed revised § 512.771(a)(9), if finalized.

We considered requiring that ASM participants maintain documentation supporting that all ASM participants who join the same CCA reassign their billing rights through the same TIN as a safeguard supporting compliance with our proposal that, if more than one ASM participant joins as a party to a CCA, such ASM participants must all reassign billing rights to the same TIN. We did not propose this approach as we believe we would be able to verify this information based on data already available to us.

We seek comment on these proposed changes. We also seek comment on the alternative documentation approach we considered and whether this approach would better support compliance and monitoring.

j. Medicare Program Waivers

In the CY 2026 PFS final rule, we adopted a policy at § 512.775 whereby we waive MIPS reporting obligations for an ASM participant in each ASM performance year in which the ASM participant meets ASM eligibility criteria at § 512.710(b), except as specified in § 512.710(a)(2). Section 512.710(a)(2) describes an ASM participant who does not meet eligibility requirements for mandatory participation in ASM for a given ASM performance year.

We also discussed in the CY 2026 PFS final rule how the waiver pertaining to MIPS reporting obligations would not apply in instances where an ASM participant is not subject to specified ASM performance requirements due to a change in TIN (90 FR 49582). However, the regulatory text at § 512.771(a) does explicitly reflect this policy.

Accordingly, we propose to update § 512.775(a) to replace the reference to ''§ 512.710(a)(2)'' with ''§ 512.710(a)(2) or § 512.710(c)'' such that the regulatory text accurately reflects our policy.

We seek comment on this proposal.

E. Limiting Medicare Coverage of Certain Individuals

1. Background

On July 4, 2025, Public Law 119–21, which we refer to as the ''Working Families Tax Cut'' (WFTC) legislation, was enacted. Section 71201 of the WFTC legislation amended title XVIII of the Social Security Act (the Act) to add a new section 1899C, which provides that, subject to section 1899C(b) of the Act, an individual may be entitled to, or enrolled for, Medicare benefits only if the individual is in one of the following four groups: (1) a citizen or national of the United States; (2) an alien who is lawfully admitted for permanent residence under the Immigration and Nationality Act (INA) (lawful permanent resident or LPR);[187] (3) an alien who has been granted the status of Cuban and Haitian entrant (CHE); or (4) an individual who lawfully resides in the United States[188] in accordance with a Compact of Free Association (COFA migrant).

Prior to enactment of the WFTC legislation, benefits payable under the Medicare program for noncitizens generally depended on whether the individual was ''lawfully present.'' Section 401 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA) (Pub. L. 104–193, August 22, 1996), codified at 8 U.S.C. 1611, generally provides that, subject to certain exceptions, only ''qualified aliens'' are eligible for Federal public benefits. However, section 401(b)(3) of PRWORA provides that Medicare benefits under title XVIII of the Act are not limited solely to ''qualified aliens,'' but instead may be available to individuals who are lawfully present in the United States. Section 401(b)(2) of PRWORA similarly provides that noncitizens who are lawfully present in the United States may be eligible for benefits payable under title II, such as Social Security retirement or disability insurance benefits. Historically, before paying Medicare or title II benefits, the Social Security Administration (SSA) used a common process to verify an individual's lawful presence status by determining whether the applicant was a U.S. citizen or was otherwise lawfully present in the United States and whether the individual resided in the United States. SSA maintains a large set of policy and operational guidance, called Program Operations Manual System (POMS), that CMS and SSA update as needed. The SSA's procedures for verifying lawful presence before payment of title II and Medicare benefits are delineated in POMS. Prior to the statutory changes to Medicare eligibility made by the WFTC legislation, a noncitizen could qualify for payment of Medicare benefits if they met all other eligibility criteria and the individual was in an immigration status or category considered lawfully present under 8 CFR 1.3(a), which encompasses a broad range of immigration classifications. These ''lawfully present'' categories included:

- An alien who is an LPR.[189]
- An alien who is granted asylum.[190]
- A refugee who is admitted to the United States.[191]
- An alien who is paroled into the United States for a period of at least 1 year.[192]
- An alien who is a Cuban and Haitian entrant.[193]
- An individual who lawfully resides in the United States under a Compact of Free Association (COFA).[194]

The WFTC legislation did not modify the requirements for payment of title II benefits under sections 202(y) and 223 of the Act. As such, noncitizens who are lawfully present in the United States, as defined by 8 CFR 1.3(a), may remain eligible for payment of title II benefits. As a result, eligibility for payment of title II benefits is no longer coextensive with eligibility for payment of Medicare benefits under title XVIII of the Act for

[187] As defined in section 501(e) of the Refugee Education Assistance Act of 1980 (Pub. L. 96–422).

[188] See section 402(b)(2)(G) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA).

[189] Under the Immigration and Nationality Act (INA) [8 U.S.C. 1101 *et seq.*].

[190] Under section 208 of INA [8 U.S.C. 1158].

[191] Under section 207 of INA [8 U.S.C. 1157].

[192] Under section 212(d)(5) of INA [8 U.S.C. 1182(d)(5)].

[193] As defined in section 501(e) of the Refugee Education Assistance Act of 1980 (Pub. L. 96–422).

[194] Public Law 99–239; Public Law 99–658; see also 8 U.S.C. 1612(b)(2)(G).

certain noncitizens. Because continued reliance on the lawful presence verification framework used to determine noncitizen eligibility for payment of title II benefits would conflict with section 1899C of the Act when applied to Medicare, we propose to establish Medicare-specific definitions and related enrollment and termination criteria concerning citizenship, nationality, and immigration status.

2. Limiting Coverage Under Medicare Part A and Part B to Certain Individuals

a. Amending the Eligibility Criteria for Part A and Part B

Sections 226 and 226A of the Act establish the conditions under which individuals are entitled to Medicare Part A benefits based on attainment of age 65, disability, or end-stage renal disease (ESRD). Individuals entitled to Medicare Part A under these provisions are not required to pay premiums for such coverage (known herein as premium-free Medicare Part A) and may elect to enroll in Medicare Part B. In general, individuals entitled to title II retirement benefits prior to attaining age 65 or entitled to title II disability benefits, upon attainment of age 65 or after satisfying any applicable waiting period, respectively, are automatically enrolled in premium-free Medicare Part A and will be enrolled automatically in Medicare Part B unless they decline Medicare Part B enrollment.[195] There are no statutory requirements for citizenship, nationality, immigration status, or residency in sections 226 and 226A of the Act. Eligibility determinations, including citizenship and lawful presence verification, for premium-free Medicare Part A have historically been made through the title II lawful presence verification framework administered by the SSA.

Section 1818 of the Act establishes the conditions under which certain individuals who are not entitled to premium-free Medicare Part A may enroll in the hospital insurance program by paying a monthly premium (herein referred to as premium Medicare Part A). Under section 1818 of the Act, an individual who has attained age 65, enrolled in Medicare Part B, and is not otherwise entitled to premium-free Medicare Part A may enroll if the individual is a resident of the United States and is either a citizen of the United States or an alien lawfully admitted for permanent residence who has resided continuously in the United States for the 5 years immediately preceding the month in which the individual applies for enrollment.

Section 1836 of the Act establishes eligibility requirements for Medicare Part B (also known as supplementary medical insurance). Under section 1836 of the Act, an individual may enroll in Medicare Part B if the individual is entitled to Medicare Part A or, alternatively, has attained age 65, is a resident of the United States and is either a citizen of the United States or an alien lawfully admitted for permanent residence who has resided continuously in the United States for the 5 years immediately preceding the month in which the individual applies for enrollment. The WFTC legislation did not eliminate the 5-year continuous residency requirement for LPRs in sections 1818(a)(3) and 1836(a)(2) of the Act and, as a result, we are not proposing to alter this requirement. In other words, LPRs who meet the 5-year continuous residency requirement and other applicable Medicare requirements would maintain their Medicare benefit.

Similar to premium-free Medicare Part A, enrollment in Medicare Part B under section 1836(a)(1) of the Act has historically been administered in coordination with the SSA's lawful presence verification framework for confirming citizenship, nationality, lawful presence, and residency status for payment of title II benefits. However, section 1899C of the Act establishes specific statutory categories of individuals who may be entitled to, or enrolled in, Medicare under title XVIII of the Act. As a result, title II's lawful presence requirements no longer fully align with the Medicare Part B eligibility framework established by section 1899C of the Act.

To align Medicare eligibility regulations with section 1899C of the Act, we are proposing to add a new definition of ''eligible noncitizen'' at 42 CFR 400.200 that includes the categories of noncitizens eligible for Medicare under sections 1899C(a)(2) through (4) of the Act. Specifically, the proposed definition would state that an ''eligible noncitizen'' is an individual who is (1) an alien lawfully admitted for permanent residence under the INA; (2) an alien who has been granted the status of CHE, as defined in section 501(e) of the Refugee Education Assistance Act of 1980 (Pub. L. 96–422); or (3) an individual who lawfully resides in the United States in accordance with a COFA referred to in 8 U.S.C. 1612(b)(2)(G).

The proposed definition of ''eligible noncitizen'' is not intended to apply to noncitizen U.S. nationals who are expressly eligible for Medicare under section 1899C(a)(1) of the Act. The proposed definition of ''eligible noncitizen'' applicable to Medicare eligibility would be distinguishable from the immigration status or category criteria in 8 CFR 1.3 applicable to noncitizen eligibility for title II benefits, which continues to be based on the ''lawfully present'' framework in section 401(b)(2) of PRWORA.

We further propose to amend regulations at 42 CFR part 406 (Medicare Part A) and 42 CFR part 407 (Medicare Part B) to incorporate the proposed definition of ''eligible noncitizen.'' We propose to add that, effective July 4, 2025, an individual must be a citizen or national of the United States or an eligible noncitizen as a basis for entitlement. These proposed changes would be added or included into the following sections:

- Premium-Free Medicare Part A:

++ New paragraph (a)(2) would be added to § 406.5 (Basis of eligibility and entitlement). This proposed new paragraph would add the requirement that, in addition to satisfying the applicable age, disability, or ESRD-based entitlement criteria, an individual must also be a citizen or national of the United States or an eligible noncitizen. This revision would align the eligibility and entitlement criteria for premium-free Medicare Part A with section 1899C(a) of the Act.

++ New paragraph (a)(2) would be added to § 406.10 (Individual age 65 or over who is entitled to Social Security or Railroad Retirement benefits, or who is eligible for Social Security benefits). This proposed new paragraph would clarify that individuals age 65 or over who otherwise qualify for premium-free Part A through Social Security or Railroad Retirement pathways must also satisfy the citizenship, nationality, or immigration status or category requirements established by section 1899C(a) of the Act. This would ensure that automatic or application-based entitlement under this section is limited to U.S. citizens, U.S. nationals, and eligible noncitizens.

++ Paragraph (b)(2) would be revised in § 406.11 (Individual age 65 or over who is not eligible as a Social Security or Railroad Retirement benefits beneficiary, or on the basis of government employment). This proposed revision would align the eligibility language in § 406.11 with section 1899C(a) of the Act and clarify that individuals qualifying under this pathway must also satisfy the citizenship, nationality, or immigration status or category standards in section 1899C(a) of the Act. This change would ensure that entitlement is not available

[195] Section 1837 of the Act and the enrollment process outlined in 42 CFR 407.17.

under this section unless the individual is a U.S citizen, U.S. national, or eligible noncitizen.

++ New paragraph (a)(2) would be added to § 406.12 (Individual under age 65 who is entitled to Social Security or Railroad Retirement disability benefits). This proposed new paragraph would provide that individuals under age 65 who otherwise qualify for premium-free Part A on the basis of disability must also meet the citizenship, nationality, or immigration status or category requirements of section 1899C(a) of the Act. This would align the regulation implementing premium-free Part A entitlement based on disability with the requirements in section 1899C(a) of the Act.

++ New paragraph (c)(4) would be added to § 406.13 (Individual who has ESRD). This proposed new paragraph would clarify that individuals who otherwise qualify for premium-free Part A on the basis of ESRD must also be a citizen or national of the United States or an eligible noncitizen. This revision would align the regulation implementing premium-free Part A entitlement based on ESRD with the eligibility limitations in section 1899C(a) of the Act.

• Premium Medicare Part A:

++ In § 406.20 (Basic Requirements), paragraphs (b)(2)(i) and (b)(2)(ii) would be revised and new paragraphs (b)(2)(iii), (b)(2)(iv), and (c)(5) would be added. These proposed revisions would update the eligibility requirements for enrollment in premium Part A to incorporate the proposed definition of eligible noncitizen. These changes would align premium Part A eligibility with section 1899C(a) of the Act by clarifying that only U.S. citizens, U.S. nationals, and eligible noncitizens may enroll under this pathway.

• Medicare Part B:

++ New paragraphs (a)(2)(ii)(A) through (D) would be added in § 407.10 (Eligibility to Enroll). These proposed revisions would update the Part B enrollment regulation to incorporate the proposed definition of eligible noncitizen. These proposed changes would align the Part B eligibility regulation with section 1899C(a) of the Act and clarify that only U.S. citizens, U.S. nationals, and eligible noncitizens may enroll under this pathway.

We note that the WFTC legislation also has implications for the Medicare Part B Immunosuppressive Drug benefit (Part B–ID) under section 1836(b) of the Act. Part B–ID is a limited Part B benefit that provides coverage only for immunosuppressive drugs for certain individuals whose entitlement to Medicare based solely on end-stage renal disease (ESRD) ended 36 months after a successful kidney transplant and who do not have other disqualifying health coverage. Although eligibility for Part B–ID is governed by the specific criteria set forth in § 407.55, individuals seeking to enroll in, or remain enrolled in, Part B–ID must also satisfy the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act. Accordingly, we propose to revise § 407.55 (Eligibility to Enroll) to add new paragraphs (a)(1) and (2) to clarify that eligibility for Part B–ID is also subject to the limitations established by section 1899C(a) of the Act.

b. Termination of Entitlement for Individuals Who Were Entitled to, or Enrolled for, Medicare as of July 4, 2025, in Accordance With Section 71201 of the WFTC Legislation (''Grace Period'' Population)

Due to the statutory changes to Medicare eligibility made by section 71201 of the WFTC legislation, individuals who are not U.S. citizens or U.S. nationals and who have an immigration status or category other than LPR, CHE, or COFA migrant, and who were entitled to, or enrolled for, Medicare as of July 4, 2025, will no longer be eligible for Medicare on the date that is 18 months after July 4, 2025. As shorthand, we are referring to this 18-month time period as the ''grace period'' and the applicable individuals identified and notified during the grace period as the ''grace period population.'' Section 1899C(b)(2)(A) of the Act directs the SSA to complete a review of all individuals entitled to, or enrolled for, Medicare as of July 4, 2025, and identify those beneficiaries entitled to, or enrolled for, Medicare as of July 4, 2025, who do not meet the requirements of section 1899C(a) of the Act. Section 1899C(b)(2)(A) provides 1 year for SSA to complete this task for the grace period population. Section 1899C(b)(2)(B) of the Act directs the SSA to provide notice to such beneficiaries as soon as practicable after identifying such beneficiaries that their entitlement to, or enrollment in, Medicare will be terminated as of the date that is 18 months after July 4, 2025.

The SSA shall identify all individuals who do not or potentially do not meet one of the eligibility criteria in section 1899C(a) per section 1899C(b)(2) of the Act. In accordance with section 1899C(b)(2)(B) of the Act, upon identifying individuals who do not or potentially do not meet one of the eligibility criteria in section 1899C(a), the SSA will then send, as soon as practicable, a notice to these identified individuals. The notice will inform them that SSA records indicate that they do not meet one of the eligibility criteria in section 1899C(a) of the Act, and their Medicare entitlement and enrollment will be terminated if they cannot provide evidence proving eligibility. Individuals would be instructed to contact the SSA if they believe the information is incorrect and to provide updated evidence of eligibility before their entitlement and enrollment is terminated. If applicable, the notice would state that a formal initial determination of ineligibility will be sent prior to their termination date if the individual takes no action to update their records or if the individual confirms that they do not meet the eligibility criteria in section 1899C(a) of the Act. As proposed, the SSA would provide a termination notice towards the end of December 2026 to all identified individuals determined to be ineligible based on data available to the SSA.. The termination notice would explain that the identified individuals do not satisfy the requirements in section 1899C(a) of the Act and therefore are not entitled to, and may not be enrolled for, Medicare. The notice would state that termination of enrollment will be effective February 1, 2027. The notice would inform individuals of their appeal rights under existing appeals regulations for initial determinations delineated in 42 CFR, part 405, subpart I. Specifically, 42 CFR 405.900(b)(1) establishes that appeals of initial determinations for entitlement to benefits under Part A or Part B of Medicare are administered in accordance with the SSA's regulations governing reconsiderations of these initial determinations at 20 CFR, part 404, subpart J.

We note that entitlement to premium-free Part A and enrollment in premium Part A and Part B are referenced in the Act as ''monthly insurance benefits'' or ''benefits for a month'' (see section 226(c)(1) and (2) of the Act) and entitlement to or enrollment in Medicare always begins on the first day of the month and always ends on the last day of the month (see section 1838(a) and (b) of the Act). Consequently, the termination in proposed §§ 406.14(d)(2), 406.28(g)(3)(ii), and 407.27(e)(3)(ii) would be at the end of the calendar month.

Accordingly, we propose to amend the following regulations to implement termination procedures for individuals who were entitled to, or enrolled for, Medicare as of July 4, 2025, but do not meet or potentially do not meet the

eligibility requirements of section 1899C(a) of the Act:

• Premium-Free Medicare Part A:

++ New § 406.14 (End of Entitlement Due to Change in Citizenship, Nationality, or Immigration Status or Category) would be added, in accordance with section 1899C(b)(1) of the Act, to establish the termination framework for individuals who were entitled to, premium-free Part A as of July 4, 2025, but who either do not meet or potentially do not meet the eligibility requirements of section 1899C(a) of the Act. Specifically, new paragraph (b) would provide that individuals entitled or enrolled as of July 4, 2025, who either do not meet or potentially do not meet the requirements of § 406.5(a)(2) will be identified and notified by the SSA per section 1899C(b)(2) of the Act. Individuals not meeting § 406.5(a)(2) requirements will have their entitlement or enrollment terminated in accordance with paragraph (d).

++ New paragraph (b)(3) would be added to § 406.10 (Individual age 65 or over who is entitled to Social Security or Railroad Retirement benefits, or who is eligible for Social Security benefits) to add a cross reference to the termination provision in the new § 406.14.

++ New paragraph (d)(2)(v) would be added to § 406.12 (Individual under age 65 who is entitled to Social Security or Railroad Retirement disability benefits) to add a cross reference to the termination provision in the new § 406.14.

++ New paragraph (f)(3) would be added to § 406.13 (Individual who has end-stage renal disease) to add cross reference to the termination provision in the new § 406.14(b).

• Premium Medicare Part A:

++ New paragraph (g)(1) would be added to § 406.28 (End of Entitlement Due to Change in Citizenship, Nationality, or Immigration Status or Category) in accordance with section 1899C(b)(1) of the Act, to establish the termination framework for individuals who were entitled to, or enrolled for, premium Part A as of July 4, 2025, but who either do not meet or potentially do not meet the eligibility requirements of section 1899C(a) of the Act. Specifically, the new paragraph (g)(1) would provide that individuals entitled to or enrolled as of July 4, 2025, who either do not meet or potentially do not meet the requirements of § 406.20(b)(2) will be identified and notified by the SSA per section 1899C(b)(2) of the Act. Individuals not meeting § 406.20(b)(2) requirements will have their entitlement or enrollment terminated in accordance with subparagraph (3).

• Medicare Part B:

++ New paragraph (e)(1) would be added to § 407.27 (Termination of entitlement: Individual), in accordance with section 1899C(b)(1) of the Act, to establish the termination framework for individuals who were enrolled in Part B as of July 4, 2025, but who either do not meet or potentially do not meet the eligibility requirements of section 1899C(a) of the Act. Specifically, the new paragraph (e)(1) would provide that individuals enrolled as of July 4, 2025, who either do not meet or potentially do not meet the requirements of § 407.10(a)(2) will be identified and notified by the SSA per section 1899C(b)(2) of the Act. Individuals not meeting § 407.10(a)(2) requirements will have their enrollment terminated in accordance with paragraph (3).

c. Proposed Termination Process for Certain Noncitizens Entitled to, or Enrolled for, Medicare Who Were Not Identified and Notified by the SSA per Section 1899C(b)(2) of the Act (Outside of the ''Grace Period'' Population)

We turn now to the proposed termination processes that would be used for all other individuals whose eligibility for Medicare, including both initial eligibility and continued eligibility, is impacted by the statutory changes to Medicare eligibility made by section 71201 of the WFTC legislation and whose entitlement and enrollment was not terminated by the SSA under the processes implementing section 1899C(b) of the Act. The proposed termination processes for this population provides the framework to terminate enrollment in Medicare if they are not eligible to be entitled or enrolled per section 1899C of the Act while ensuring all impacted individuals are notified of termination and retain their appeal rights. Under this proposal, all terminations made under section 1899C of the Act would be prospective.

We propose that entitlement and enrollment for those not identified during the grace period and found not to meet the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act would end according to the termination processes in the following proposals: § 406.14(c) and (d) for those with premium-free Part A, § 406.28(g)(2) and (3) for those with premium Part A, and § 407.27(e)(2) and (3) for those with Part B benefits. The proposed termination processes in §§ 406.14(d), 406.28(g)(3) and 407.27(e)(3) include providing notice to such individuals that their entitlement and enrollment for Medicare will be terminated if they do not meet section 1899C(a) of the Act, and for terminating entitlement or enrollment where the SSA determines that the individual either does not or no longer meets the requirements of section 1899C(a) of the Act.

As stated, this proposed termination process would apply to anyone enrolled in Medicare whom the SSA determines does not meet eligibility requirements under section 1899C(a) of the Act and was not part of the grace period population per section 1899C(b)(2)(B) of the Act. There is a period of time between enactment of the WFTC legislation on July 4, 2025, and the SSA starting to screen individuals for new Medicare enrollment under the criteria in section 1899C(a) of the Act, which is expected in 2026. Individuals enrolled after enactment of the WFTC legislation but before screening procedures are implemented do not fall into the grace period population because they were not enrolled as of the date of enactment. Thus, individuals enrolled during the previously discussed time period who do not meet the eligibility requirements in section 1899C(a) of the Act would be terminated according to proposed §§ 406.14(d), 406.28(g)(3) or 407.27(e)(3), as appropriate.

Additionally, the proposed termination process would apply to anyone enrolled in Medicare whom the SSA determines does not meet the eligibility requirements in section 1899C(a) of the Act and was not notified as part of the grace period population per section 1899C(b)(2)(B) of the Act. This would include individuals whose status changed prior to the implementation of this proposed rule, if finalized as proposed, such as an individual who was enrolled in Medicare in October 2024 and met the eligibility requirements under section 1899C(a) of the Act based on their conditional LPR status when SSA identified and notified the grace period population. Therefore, they were not included in the grace period population per section 1899C(b)(2)(B) of the Act. However, if SSA's records indicate that their conditional LPR status expires December 2026, this proposed termination process would apply upon expiration of their conditional LPR status and would provide the framework for this individual's Medicare enrollment to be terminated as they would no longer satisfy the requirements of section 1899C(a) of the Act. We emphasize that the same process would also apply to individuals enrolled after this proposed rule is implemented, if finalized as proposed. As an example, consider the case of an individual enrolled in Medicare with conditional LPR status whose enrollment began in April 2028. In

February 2030, SSA records indicate that the individual's conditional LPR status expires in April 2030. Upon expiration of the individual's conditional LPR status in April 2030, the individual would no longer satisfy the requirements of section 1899C(a) of the Act, and the SSA would send notice to the individual that they no longer meet the requirements of section 1899C(a) of the Act. As a result, under the proposed process for termination of enrollment, the individual's Medicare enrollment would be terminated at the end of the month following the month in which the notice is dated.

There are several circumstances in which individuals are identified as no longer meeting the requirements of section 1899C(a) of the Act outside the grace period. We propose the same termination process for individuals in these circumstances in proposed §§ 406.14(d), 406.28(g)(3) or 407.27(e)(3), as appropriate.

For these individuals outside the grace period, we propose that a termination notice from the SSA would be sent to each individual identified as ineligible. We propose the notice would explain that, per data available to the SSA, the individual does not satisfy the requirements of section 1899C(a) of the Act. Under the proposed termination process, an individual would not lose Medicare entitlement or enrollment during the month in which the SSA determines that the individual does not or no longer meets the requirements of section 1899C(a) of the Act. Rather, Medicare entitlement or enrollment would terminate at the end of the month following the month in which the notice is dated. For example, if the date of the termination notice is in March 2027, termination would be effective at the end of April 2027. This proposed termination timeline would be explained in the notice. The SSA will not terminate anyone's entitlement or enrollment prior to notification. Further, no termination of Medicare would occur for any individual entitled to, or enrolled for, Medicare for failure to meet the requirements of section 1899C(a) of the Act prior to the effective date of this rule, if finalized as proposed. We propose an effective date of January 1, 2027.

We propose that individuals whose Medicare entitlement and enrollment are terminated because they do not meet the requirements of section 1899C(a) of the Act would be provided appeal rights under the CMS' existing appeals regulations for initial determinations. Appeals of initial determinations for entitlement to benefits under Medicare Part A or Part B are administered in accordance with 20 CFR, part 404, subpart J. *See* 42 CFR 405.900(b)(1). We propose to include the information about appeal rights in the proposed termination notices.

Under this proposal, termination notices would be sent to affected individuals on an ongoing basis, as applicable, when the SSA receives information that an individual enrolled in Medicare does not meet the requirements of section 1899C(a) of the Act.

These proposals are necessary to ensure implementation of section 1899C of the Act is consistent with the efficient administration of the Medicare program under section 1102(a) of the Act. Therefore, to implement the proposed termination framework, we propose adding and revising the following sections:

- Premium-Free Medicare Part A:

++ New § 406.14 (End of entitlement due to change in citizenship, nationality, or immigration status or category) would be added. The proposed new § 406.14(c) would provide the termination framework for individuals entitled to premium-free Part A who were not identified and notified by the SSA per section 1899C(b)(2) of the Act and were subsequently determined by the SSA as not meeting the requirements of § 406.5(a)(2). Proposed § 406.14(d) describes the proposed termination notice and appeal rights in accordance with existing regulations governing Medicare entitlement determinations, states the effective date of premium-free Part A entitlement termination, and states that the individual should contact the SSA if their citizenship, nationality, or immigration status or category changes such that they may be entitled to, or enrolled for, premium-free Part A benefits.

++ New paragraph (b)(3) would be added to § 406.10 (Individual age 65 or over who is entitled to Social Security or Railroad Retirement benefits, or who is eligible for Social Security benefits). This proposed new paragraph would add a cross-reference to § 406.14 so that individuals entitled to, or enrolled for, premium-free Part A through the age-65 pathway would be subject to the termination procedures in that section if they do not or no longer meet the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act.

++ New proposed paragraph (d)(2)(v) would be added to § 406.12 (Individual under age 65 who is entitled to Social Security or Railroad Retirement disability benefits). This proposed new paragraph would add cross-references to § 406.14(b) and (c) so that disability-based premium-free Part A entitlement would be subject to the proposed termination procedures for an individual who does not or no longer meets the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act.

++ New proposed paragraph (f)(3) would be added to § 406.13 (Individual who has ESRD). This proposed new paragraph would add a cross-reference to § 406.14 to specify that individuals entitled to, or enrolled for, premium-free Part A on the basis of ESRD would be subject to the proposed procedures for termination when an individual does not or no longer meets the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act.

- Premium Medicare Part A:

++ New proposed paragraph (g)(2) would be added to § 406.28 (End of entitlement) for individuals who were entitled to, or enrolled for, premium Part A, who were not identified and notified by the SSA per section 1899C(b)(2) of the Act and were subsequently determined by the SSA as not meeting the requirements of § 406.20(b)(2). Under proposed paragraph (g)(2), entitlement would end as provided under paragraph (g)(3) of this section.

++ New proposed paragraph (g)(3) would be added to § 406.28 (End of entitlement). It describes the proposed termination notice, which would specify the individual's appeal rights in accordance with existing regulations governing Medicare entitlement determinations, state the effective date of premium Part A enrollment termination, and state that the individual should contact the SSA if their citizenship, nationality, or immigration status or category changes such that they may be entitled to, or enrolled for, premium Part A benefits.

++ Paragraphs (a) and (b) of § 406.50 would be revised to change the word ''alien'' to ''eligible noncitizen.''

- Medicare Part B:

++ New proposed paragraph (e)(2) would be added to § 407.27 (Termination of entitlement: Individual enrollment). This new paragraph would specify that individuals who are enrolled in Part B, who were not identified and notified by the SSA per section 1899C(b)(2) of the Act and were subsequently determined by the SSA as not meeting the requirements of § 407.10(a)(2), would have their enrollment terminated under the new proposed paragraph (e)(3) of the section.

++ New proposed paragraph (e)(3) would be added to § 407.27 (Termination of entitlement: Individual enrollment). This new paragraph would describe the termination notice, which would specify the individual's appeal rights in accordance with existing regulations governing Medicare entitlement determinations, state the effective date of Part B enrollment termination, and state that the individual should contact the SSA if their citizenship, nationality, immigration status or category changes such that they may be enrolled for, Part B benefits.

3. Enrollment Pathway for Individuals Who Gain or Regain Eligibility

Section 1899C of the Act limits eligibility for Medicare to specified categories of individuals based on citizenship, nationality, or immigration status or category. As a result, except as provided in section 1899C(b) of the Act, no individual may be entitled to, or enrolled for, Medicare if the individual does not meet the requirements of section 1899C(a) of the Act. Conversely, individuals may later become eligible if their citizenship, nationality, or immigration status or category changes, such that they satisfy section 1899C(a) of the Act, as well as applicable Medicare eligibility requirements.

To address circumstances in which individuals who initially did not meet the eligibility requirements of section 1899C(a) of the Act at the time they met all other Medicare eligibility requirements but, subsequently, do meet the section 1899C(a) of the Act requirements, we propose to establish a special enrollment period (SEP) under §§ 406.27(f) and 407.23(f). The SEP would also apply to those individuals whose Medicare entitlement or enrollment is terminated because they do not or no longer meet the requirements in section 1899C(a) of the Act, but who subsequently experience a change such that they meet the requirements of section 1899C(a) of the Act. Establishing an SEP for these scenarios is within the Secretary's authority under sections 1837(m) and 1838(g) of the Act, which provide for the establishment of SEPs for exceptional conditions. We consider the enactment of the WFTC legislation and addition of section 1899C of the Act to constitute an exceptional condition because it created a new and narrower class of noncitizens who may be eligible for Medicare than are eligible for title II benefits, despite the close associations between title II entitlement and Medicare entitlement, as discussed in section F.1. of this preamble, and despite the fact that lawful presence has been the standard for noncitizen eligibility for both title II and Medicare benefits for decades. In addition, the statutory changes made by the WFTC legislation fundamentally altered the consequences of changes in immigration status. Prior to enactment of the WFTC legislation, noncitizens enrolled in Medicare who had a loss of lawful presence status would have remained enrolled in Medicare, but payment for benefits would have been suspended. Now, in accordance with section 1899C of the Act, an individual who no longer meets the requirements of section 1899C(a) of the Act must have their entitlement and enrollment terminated. If such an individual later meets the requirements of section 1899C(a) of the Act, it may be at a time that does not clearly fall within an established enrollment period. In addition, individuals who otherwise meet the eligibility requirements for Medicare but for the eligibility requirements of section 1899C(a) of the Act may gain eligibility at a time that does not clearly fall within an established enrollment period. For this proposed SEP, we also propose that the general rule in §§ 406.27(a) and 407.23(a) that an individual must have missed an enrollment period due to the exceptional condition would not apply. We believe this is necessary because, for example, as explained below, the 7-month initial enrollment period under sections 1818(c)(1) and 1837(d) of the Act does not align well with the unpredictable nature as to when an individual may experience a change in citizenship, nationality, or immigration status or category, such that they would meet the requirements of section 1899C(a) of the Act. As another example, an individual may lose and subsequently regain eligibility under section 1899C(a) of the Act during a period that does not overlap with an otherwise available enrollment period, such that no enrollment period is actually missed. Accordingly, this SEP would be available to individuals who later meet, or again meet, the requirements of section 1899C(a) of the Act, regardless of whether an enrollment period was missed.

We propose that the special enrollment period would begin in the month in which the individual, upon contacting the SSA, provides sufficient documentation to establish eligibility, and the proposed special enrollment period would end 6 months later. The duration of this proposed special enrollment period would be the same time frame afforded to individuals granted a special enrollment period for exceptional conditions under §§ 406.27 and 407.23. We propose that entitlement and enrollment would be prospective for premium Part A and Part B, beginning with the first day of the month following the month of enrollment. We believe a prospective effective date is appropriate and consistent with the Secretary's authority under section 1818(c)(8) of the Act for premium Part A and section 1838(g) of the Act for Part B to establish the date on which coverage begins for individuals enrolling during an SEP, in a manner consistent, to the extent practicable, with protecting continuity of health benefit coverage. Although an individual may in some cases be able to demonstrate an earlier date on which the requirements of section 1899C(a) of the Act were met, we are proposing a uniform prospective effective date for premium Part A and Part B because citizenship data in SSA records is gathered and verified at a point in time. o and does not provide a reliable or administrable basis for consistently establishing earlier eligibility dates for enrollment purposes. In addition, a retroactive effective date for premium Part A and Part B could require the assessment of back-due premiums for months of coverage that the individual had not yet affirmatively elected, which would add operational complexity and could create unexpected financial obligations for beneficiaries. We believe a prospective-only approach is therefore the most practicable and administrable method for implementing this SEP for premium Part A and Part B.

We considered an alternative pathway which consisted of establishing an initial enrollment period for premium Part A and Part B for eligible noncitizens who would have been eligible for Medicare based on entitlement to benefits under title II of the Act and attainment of age 65 or completion of the 24-month waiting period for disability benefits, as applicable, but whose entitlement was never effectuated because they did not meet the citizenship, nationality, or immigration status or category requirements specified in section 1899C(a) of the Act. However, we note that the 7-month initial enrollment period articulated in sections 1818(c)(1) and 1837(d) of the Act is largely tied to the attainment of age 65 or completion of the 24-month waiting period for disability benefits and begins on the first day of the third month before the month in which an individual meets the eligibility requirements for premium Part A and Part B. Traditionally, this 3-

month pre-eligibility period provides an opportunity for individuals to explore coverage options (for example, original Medicare or Medicare Advantage) and enroll in Part A and Part B. This 3-month period helps individuals avoid delays and gaps in coverage. As a practical matter, such an initial enrollment period could not be applied in an analogous manner to changes that would make an individual eligible for Medicare by virtue of meeting the requirements of section 1899C(a) of the Act because an individual may not be enrolled for Medicare benefits unless and until they meet the requirements of section 1899C(a) of the Act. As a result, establishing an initial enrollment period under sections 1818(c)(2) and 1837(d) of the Act or these individuals would effectively shorten the enrollment period by 3 months because such individuals could not be enrolled in Medicare until the section 1899C(a) of the Act requirements are met, which would conflict with the requirements of the Act. Instead, we opted for a proposed approach of establishing a SEP for individuals enrolling in Medicare for the first time, as well as individuals who lost and regained Medicare, due to changes in citizenship, nationality, or immigration status or category because it comports with the requirements of the Act.

For premium-free Medicare Part A, we propose that entitlement may be retroactive for up to 6 months, but not earlier than the first month in which the individual met all the eligibility requirements in proposed § 406.5(a). Under this proposal, if acceptable evidence establishes the month in which the individual first satisfied the citizenship, nationality, or immigration status or category requirements in § 406.5(a)(2), the SSA would use that month, subject to the applicable retroactivity limit. If the earliest month of eligibility cannot be established based on acceptable documentary evidence, entitlement would instead begin on the first day of the month in which the SSA verifies that the individual satisfies § 406.5(a)(2).

Accordingly, to implement the enrollment processes described earlier for individuals who establish or reestablish eligibility under section 1899C(a) of the Act, we propose to amend the regulations at 42 CFR part 406 (Medicare Part A) and 42 CFR part 407 (Medicare Part B) to specify the availability, duration, and effective date rules for enrollment under these circumstances. We propose to add and revise the following sections:

- Premium-Free Medicare Part A:

++ Paragraph (b) would be revised in § 406.6 (Application or enrollment for hospital insurance) to include the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act for individuals who need not file an application for hospital insurance.

++ New paragraph (f) would be added to § 406.6 (Application or enrollment for hospital insurance) to establish rules for individuals who would otherwise qualify for premium-free Part A based on entitlement to title II benefits, but who were not entitled because they did not meet the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act at the time they otherwise would have become eligible. It would also specify how such individuals may initiate entitlement upon later meeting those requirements and clarify the applicable entitlement effective date, including the circumstances under which premium-free Part A entitlement would begin consistent with current law. Subparagraph (1) applies to those who meet the conditions of paragraph (b) of this section and, as such, need not file an application for hospital insurance. These individuals must contact the SSA to initiate entitlement to hospital insurance. Subparagraph (2) applies to those who meet the conditions of paragraph (c) of this section and, as such, must file an application for hospital insurance. These individuals must contact the SSA to file such application.

- Premium Medicare Part A:

++ Paragraph (f) would be redesignated as paragraph (g) and new paragraph (f) would be added to § 406.27 (Special enrollment periods for exceptional conditions). This new paragraph would establish an SEP for individuals whose premium Part A enrollment was previously terminated because they lost the citizenship, nationality, or immigration status or category required under section 1899C(a) of the Act, but who later regain a qualifying status and again become eligible. The SEP would also apply to individuals who would otherwise meet the eligibility requirements for Medicare, except for those in section 1899C(a) of the Act, and later meet the eligibility requirements of section 1899C(a) of the Act. The new provision would specify the availability and duration of this SEP and clarify that enrollment under this pathway would be prospective, consistent with the Secretary's authority to establish SEPs for exceptional conditions. An individual does not need to miss an applicable enrollment period to be eligible for this SEP.

- Medicare Part B:

++ Paragraph (f) would be redesignated as paragraph (g) and new paragraph (f) would be added to § 407.23 (Special enrollment periods for exceptional conditions). This new paragraph would establish a SEP for individuals whose Part B enrollment was terminated because they no longer met the citizenship, nationality, or immigration status or category requirements in section 1899C(a) of the Act, but who subsequently regain a qualifying status and again become eligible to enroll. The SEP would also apply to individuals who otherwise met the eligibility requirements for Medicare, except for those in section 1899C(a) of the Act, and later meet the eligibility requirements of section 1899C(a) of the Act. It would specify the duration of the SEP and the prospective effective date of Part B coverage for individuals enrolling under this pathway. An individual does not need to miss an applicable enrollment period to be eligible for this SEP.

4. Limiting Coverage Under Medicare Part C, Medicare Part D, and Cost Plans to Certain Individuals

Under section 1851(a)(3) of the Act, Medicare Part C (Medicare Advantage (MA)) is available only to individuals who are entitled to Medicare Part A and are enrolled in Medicare Part B. Medicare Part D (the Medicare prescription drug benefit) is available to individuals who are entitled to Medicare Part A or are enrolled in Medicare Part B, as specified in section 1860D–1(a)(3) of the Act. Section 1876(a)(1)(A) of the Act outlines eligibility requirements to enroll in Medicare cost plans and provides that individuals may enroll in cost plans if they are entitled to Medicare Part A and are enrolled in Part B or are enrolled in Part B only. Eligibility for enrollment in an MA plan, Part D plan, or cost plan is therefore dependent on an individual's underlying entitlement to and/or enrollment in Medicare Part A and/or Part B, as applicable. Prior to the enactment of section 1899C of the Act, individuals who satisfied the statutory conditions for Medicare Part A entitlement and/or Medicare Part B enrollment, as applicable, were likewise eligible to enroll in MA plans, Part D plans, or cost plans, provided they met applicable enrollment requirements. The eligibility requirements in section 1899C of the Act apply to all parts of Medicare. Individuals who do not meet the eligibility requirements of section 1899C of the Act are not eligible for

Medicare Part A or Part B and may not enroll or remain enrolled in MA plans, Part D plans, or cost plans.

Individuals enrolled in MA plans, Part D plans, or cost plans who do not meet the eligibility requirements of section 1899C of the Act must be disenrolled from those plans. Under 42 CFR 417.460(b)(2)(iii), 422.74(b)(2)(ii), and 423.44(b)(2)(ii), individuals who lose eligibility for enrollment are involuntarily disenrolled from the plan. Such disenrollments will be prospective and effective the first day of the calendar month following the last month of entitlement to Part A or Part B as specified under 42 CFR 417.460(h), 422.74(d)(5), and 423.44(d)(3).

Plans do not process these disenrollments. CMS processes these automatically through the MARx system when the SSA provides updated eligibility and entitlement records and CMS will notify the plan of the disenrollment due to loss of entitlement, through MARx transaction reply codes. Plans have the option, but are not required, to provide a notice of disenrollment due to loss of entitlement. Since the SSA provides a loss of entitlement notice for Part A and Part B, there is no need to require plans to provide additional notification.

Accordingly, we propose to amend the regulations at 42 CFR part 417, part 422, and part 423 to incorporate the new eligibility limitations established by section 1899C of the Act. We propose to revise the following sections to reflect the applicability of section 1899C of the Act:

- Paragraph (b) of § 417.2 (Basis and scope): We propose to amend paragraph (b) of § 417.2 to add a reference to section 1899C of the Act, which establishes eligibility limitations applicable to cost plan enrollment.
- Paragraphs (a)(1)(xii) and (a)(2) of § 422.1 (Basis and scope): We propose to amend § 422.1 to add paragraph (a)(1)(xii) to reference section 1899C of the Act, which establishes eligibility limitations applicable to MA enrollment. We further propose to remove and reserve paragraph (a)(2) that references 8 U.S.C. 1611.
- Paragraphs (a)(1) and (3) of § 423.1 (Basis and scope): We propose to amend paragraph (a)(1) of § 423.1 to add a reference to section 1899C of the Act, which establishes eligibility limitations applicable to Part D enrollment. We further propose to remove and reserve paragraph (a)(3) of § 423.1 that references 8 U.S.C. 1611.

We are also proposing to add that effective July 4, 2025, an individual must be a citizen or national of the United States or an eligible noncitizen as a basis for entitlement. We propose to revise the following sections to add this language:

- Paragraph (h) of § 417.422 (Eligibility to enroll in an HMO or CMP).
- Paragraph (a)(7) of § 422.50 (Eligibility to elect an MA plan).
- Paragraph (a)(1)(iii) of § 423.30 (Eligibility and enrollment).

Additionally, we propose to update the regulations at 42 CFR part 417, part 422 and part 423 to clarify the circumstances under which individuals must be disenrolled from MA plans, Part D plans, or cost plans due to failure to meet the eligibility requirements of section 1899C of the Act. Though failure to meet the eligibility requirements of section 1899C of the Act results in a loss of Part A and Part B eligibility, we propose to create an involuntary disenrollment process for MA plans, Part D plans, and cost plans that is separate from the existing loss of entitlement to Part A or Part B disenrollment process. Administratively, separating failure to meet section 1899C of the Act eligibility requirements from all other reasons for loss of Part A or Part B entitlement allows CMS to better track the impact of this provision and create new technical processes with the SSA and internally. Specifically, we propose to revise the following sections to add this language:

- Paragraphs (b)(2)(iv) and (j) of § 417.460 (Disenrollment of beneficiaries by an HMO or CMP): We propose to amend paragraph (b)(2)(iv) of § 417.460 to state that a cost plan must disenroll an enrollee if they no longer meet the requirements of § 417.422(h). We propose to amend paragraph (j) of § 417.460 related to the disenrollment effective date to apply to an enrollee who is not a U.S. citizen, U.S. national, or eligible noncitizen.
- Paragraphs (b)(2)(v) and (d)(9) of § 422.74 (Disenrollment by the MA organization): We propose to amend paragraph (b)(2)(v) of § 422.74 to state that an MA plan must disenroll an enrollee if they no longer meet the requirements of § 422.50(a)(7). We propose to amend paragraph (d)(9) of § 422.74 related to the disenrollment effective date to apply to an enrollee who loses U.S. citizenship or nationality, or eligible noncitizen status.
- Paragraphs (b)(2)(vi) and (d)(8) of § 423.44 (Involuntary disenrollment from Part D coverage): We propose to amend paragraph (b)(2)(vi) of § 423.44 to state that a Part D plan must disenroll an enrollee if they no longer meet the requirements of § 423.30(a)(1)(iii). We propose to amend the heading for paragraph (d)(8) of § 423.44 related to the disenrollment effective date to apply to an enrollee who loses U.S. citizenship or nationality, or eligible noncitizen status.

We also propose to amend the regulations at 42 CFR part 422 and part 423 to replace the SEP that is currently applicable when an individual who is a non-U.S. citizen attains lawful presence status. Under this proposal, the SEP would apply when an individual becomes an eligible noncitizen by attaining the eligibility requirements of section 1899C(a) of the Act. The SEP would begin when the individual provides the SSA with sufficient information to demonstrate that the requirements of § 406.20(b)(2) and § 407.10(a)(2)(ii) have been met. Providing this information to the SSA and establishing eligibility would result in automatic entitlement for Part A, assuming that the individual was otherwise eligible for premium-free Part A. For Part B entitlement, the individual would also need to enroll in Part B under § 407.4(a)(2), after which the individual would become entitled to Part B.

We propose to revise this language in the following sections:

- Paragraph (b)(16) of § 422.62 (Election of coverage under an MA plan).
- Paragraphs (c)(21)(i) and (ii) of § 423.38 (Enrollment periods).

Because eligibility to elect an MA plan requires an individual to be both entitled to Medicare Part A and enrolled in Medicare Part B, the SEP at § 422.62(b)(16) would last for 2 months after the month in which the individual becomes entitled to Medicare Part A and enrolled in Medicare Part B. Similar to the way the MA Initial Coverage Election Period (ICEP) works under § 422.62(a)(1), this SEP would be available as soon as the individual is entitled to Medicare Part A and enrolled in Medicare Part B. As a result, this SEP would be available to individuals who previously had and lost Part A and/or Part B because they were not eligible noncitizens. For such individuals, they would not have access to the ICEP because their new entitlement to Medicare Part A and enrollment in Medicare Part B would not be their ''first'' entitlement, as required by the ICEP. We propose this SEP as a way of ensuring that individuals gaining eligible noncitizen status have the opportunity to enroll in Medicare Advantage upon becoming entitled to Medicare Part A and enrolling in Medicare Part B. Consequently, this SEP will replace the existing SEP for gaining ''lawful presence status,'' which is no longer a relevant eligibility criterion and

needs to be removed. An enrollment using this SEP would be effective the first day of the calendar month following the month in which the election is made, as specified in § 422.68(d).

The Part D SEP at § 423.38(c)(21)(i) and (ii) would last for 2 months after either the individual's Part A or Part B entitlement date, since they can differ and individuals are eligible for Part D with either Part A or Part B. The SEP would end based on the earlier of the two entitlement dates. The Part D SEP needs a different timeline than its Part C equivalent since the eligibility criteria for the two programs differ. Importantly, we intend for this SEP to be used surrounding the period that an individual establishes their eligible noncitizen status with SSA, so we propose that the SEP eligibility window begins upon the entitlement to Part A or Part B, whichever is earlier. This timeline ensures that the SEP is based upon both the eligibility requirements for Part D and the intent to provide these individuals with an opportunity to enroll in Part D when initially eligible to make such an election after establishing eligible noncitizen status. This SEP would also replace the existing SEP for gaining ''lawful presence status.'' An enrollment using this SEP would be effective the first day of the calendar month following the month in which the election is made, as specified in § 423.40(c).

F. Medicare Prescription Drug Inflation Rebate Program

1. Background

a. Overview of the Medicare Prescription Drug Inflation Rebate Program

Sections 11101 and 11102 of the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117–169, enacted August 16, 2022) established requirements under which drug manufacturers must pay inflation rebates if they raise their prices for certain drugs payable under Part B and/or covered under Part D faster than the rate of inflation. Specifically, section 11101 of the IRA amended section 1847A of the Act by adding new subsection (i) which establishes a requirement for drug manufacturers to pay rebates into the Federal Supplementary Medical Insurance Trust Fund for Part B rebatable drugs if the specified amount, as determined under section 1847A(i)(3)(A)(ii) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The IRA also provides for an adjustment to the beneficiary coinsurance amount in cases where the price of a Part B rebatable drug increases faster than the rate of inflation such that the beneficiary coinsurance is calculated based on the lower inflation-adjusted payment amount instead of the applicable payment amount. Section 1847A(i)(2) of the Act defines a ''Part B rebatable drug,'' as a single source drug or biological product (as defined in section 1847A(c)(6)(D) of the Act), including a biosimilar biological product (as defined in section 1847A(c)(6)(H) of the Act), but excluding a qualifying biosimilar biological product (as defined in section 1847A(b)(8)(B)(iii) of the Act) for which payment is made under Part B, except such term also does not include a drug or biological described in clause (i) and (ii) of such section 1847A(i)(2)(A) of the Act.

Section 11102 of the IRA added section 1860D–14B of the Act, which requires drug manufacturers to pay rebates into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund for each 12-month applicable period, starting with the applicable period that began on October 1, 2022, for Part D rebatable drugs if the annual manufacturer price (AnMP) of such drug, which is calculated as set forth in section 1860D–14B(b)(2) of the Act, exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1860D–14B(b)(3) of the Act. Section 1860D–14B(g)(1)(A) of the Act defines a ''Part D rebatable drug,'' as a drug or biological described at section 1860D–14B(g)(1)(C) of the Act that is a ''covered Part D drug'' as that term is defined in section 1860D–2(e) of the Act, and excludes drugs and biologicals described in subparagraph (B) of such section 1860D–14B(g)(1) of the Act. The definition of a Part D rebatable drug includes drugs approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic (FD&C) Act, drugs approved under an abbreviated new drug application under section 505(j) of the FD&C Act that meet certain sole source criteria described at sections 1860D–14B(g)(1)(C)(ii)(I) through (IV) of the Act, and biologicals licensed under section 351 of the Public Health Service (PHS) Act, including biosimilars.

The IRA sets forth different parameters for determining rebates under the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program. In regard to the rebates owed, for each calendar quarter beginning on or after January 1, 2023, the manufacturer of a Part B rebatable drug is required, for such drug, not later than 30 days after the date of receipt of the Rebate Report from us, to pay a rebate into the Federal Supplementary Medical Insurance Trust Fund if the amount specified in section 1847A(i)(3)(A)(ii)(I) of the Act exceeds the inflation-adjusted payment amount (calculated as set forth in section 1847A(i)(3)(C) of the Act) for an applicable calendar quarter. In contrast, for each 12-month applicable period beginning on or after October 1, 2022, the manufacturer of a Part D rebatable drug is required, for such drug, not later than 30 days after the date of receipt of the Rebate Report from us, to pay a rebate into the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund if the amount of the AnMP (calculated as set forth in section 1860D–14B(b)(2) of the Act) exceeds the inflation-adjusted payment amount (calculated as set forth in section 1860D–14B(b)(3) of the Act). In regard to invoicing manufacturers for the rebate amount owed, under section 1847A(i)(1) of the Act, we must report rebate amounts to each manufacturer of a Part B rebatable drug no later than 6 months after the end of each calendar quarter, except that for calendar quarters beginning in 2023 and 2024, section 1847A(i)(1)(C) of the Act provides that we had until September 30, 2025, to invoice manufacturers for rebates. In contrast, under section 1860D–14B(a) of the Act, we must report rebate amounts to each manufacturer of a Part D rebatable drug no later than 9 months after the end of each applicable period, except that for the first two applicable periods (that is, October 1, 2022, to September 30, 2023, and October 1, 2023, to September 30, 2024), section 1860D–14B(a)(3) of the Act provides that we had until December 31, 2025, to invoice manufacturers for Part D inflation rebates. Additionally, there are statutory differences in the inputs (that is, data sources) used to calculate the rebate amounts for Part B and Part D.

In the CY 2025 PFS final rule (89 FR 98228 through 98313), to implement sections 11101 and 11102 of the IRA, we codified these requirements and established other policies at parts 427 and 428 under title 42, chapter IV of the Code of Federal Regulations for Part B and Part D, respectively.

b. Summary of Proposed Policies for the Medicare Prescription Drug Inflation Rebate Program

We are proposing new policies for the Medicare Part B Drug Inflation Rebate Program as follows:

- Proposed § 427.20 would clarify the definition of ''first marketed date'' to

clarify the data sources we would use to identify the first marketed date when relevant Average Sales Price (ASP) data is not available.

- Proposed § 427.101(b)(5) would modify the skin substitutes excluded product category for Part B rebatable drugs so that the exclusion applies only to certain skin substitutes products.
- Proposed §§ 427.302(e)(6) and (f)(1) would clarify what Consumer Price Index for All Urban Consumers (CPI–U) data would be used to determine the benchmark period CPI–U in place of the month for which CPI–U data are unavailable.

We also are proposing new policies for the Medicare Part D Drug Inflation Rebate Program as follows:

- Proposed § 428.20 would clarify the definition of ''applicable period CPI–U'' when the CPI–U data for the first month of the applicable period are not available.
- Proposed § 428.202(e)(6) would clarify what CPI–U data would be used to determine the benchmark period CPI–U in place of the month for which CPI–U data are unavailable.
- Proposed § 428.203(c) would require providers and suppliers that are covered entities as defined at § 10.3 to submit Part D 340B data to the 340B repository beginning with claims with a date of service on or after January 1, 2027.

2. Medicare Part B Drug Rebates for Single Source Drugs and Biological Products With Prices That Increase Faster Than the Rate of Inflation

a. Definitions (§ 427.20)

In the CY 2025 PFS final rule (89 FR 98579), we codified at § 427.20 the definition of ''first marketed date'' to mean the earliest date of first sale of any NDC–11 within a billing and payment code among all products and package sizes under the same FDA application. In that definition, we specify that the first marketed date will be identified using ASP data reported by NDC–11 to CMS by a manufacturer as required under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2) of the Act, if available. We note that we use ''date of first sale'' as reported in the ASP Data Collection System for the first marketed date as specified at § 427.20. There may be scenarios where a drug is being marketed but the first marketed date is not available in the ASP data such as when a manufacturer is not required to report ASP data under sections 1927(b)(3)(A)(iii)(I) or 1847A(f)(2) of the Act. In this example, ASP units sold also would be unavailable in the ASP Data Collection System. Currently we generally use the NDC Directory to identify the first marketed date when it is not available in the ASP Data Collection System. In this proposed rule, to improve transparency of operations to address instances when first marketed date is missing from ASP data, we are proposing to amend § 427.20 with respect to the definition of the term ''first marketed date'' to clarify the data sources we would use to identify the first marketed date when ASP data are not available. Specifically, when the first marketed date is missing from ASP data for any NDC–11 associated with any FDA application number ever associated with the billing and payment code we propose to identify the first marketed date from an alternative public source, such as from the NDC Directory. For example, when the first marketed date is missing from ASP data for a given NDC, we would identify the first marketed date for the NDC–11 from the NDC Directory; and if the first marketed date also is missing from the NDC Directory for a given NDC, we would default to using the FDA approval date as listed in the Orange Book or Purple Book. We note that we believe data in the NDC Directory are accurate, reliable, and up to date. The Food and Drug Administration (FDA) updates the NDC Directory daily with information submitted to FDA by labelers. A labeler may be a manufacturer, including a repackager or relabeler, or the entity named on the product label that is required to list their products with FDA under 21 CFR part 207. The FDA also requires that labelers annually update their data or certify that there were no changes to their data listed in the NDC Directory.

b. Treatment of Skin Substitutes as a Part B Rebatable Drug Excluded Product Category (§ 427.101(b)(5))

In the CY 2025 PFS final rule (89 FR 98580), we codified skin substitutes (that is, products included within the suite of cellular- and tissue-based products that aid wound healing) as an excluded product category at § 427.101(b)(5) and therefore they are not considered Part B rebatable drugs. We finalized this policy because we aimed to create a consistent coding and payment approach for skin substitute products. Since that policy was finalized, in the CY 2026 PFS final rule (90 FR 49496, 50009), we modified how skin substitutes are paid under Part B. In particular, we finalized our proposal to limit application of the ASP payment methodology under section 1847A of the Act to skin substitutes that are approved as a drug or biological product under section 351 of the PHS Act. Additionally, we modified payment for the provision of certain groups of skin substitutes as incident-to supplies.

To avoid an overly broad exclusion at § 427.101(b)(5), we are proposing to clarify that skin substitutes licensed as a drug or biological product under section 351 of the PHS Act would not be excluded from the definition of a Part B rebatable drug, and, as such, would be subject to Part B inflation rebates and subject to the beneficiary coinsurance adjustment under § 427.201. We note that currently there are no skin substitute products licensed as a drug or biological product under section 351 of the PHS Act; however, our proposal would make clear that any future skin substitute products that are licensed as a drug or biological product under section 351 of the PHS Act could be rebatable. We are proposing to amend § 427.101 by revising paragraph (b)(5), which describes skin substitutes as an excluded product category for Part B rebatable drugs, to state a skin substitute is ''[a] product included within the suite of cellular- and tissue-based products that aid wound healing, other than skin substitute products that are licensed as a drug or biological product under section 351 of the Public Health Service Act''. If finalized, this proposal would not impact Rebate Reports for the fourth quarter of 2026 or earlier.

c. Identification of the Benchmark Period CPI–U and Rebate Period CPI–U (§ 427.302)

Section 1847A(i)(3)(C) of the Act provides that, for each Part B rebatable drug by billing and payment code, CMS will calculate the inflation-adjusted payment amount for each quarter using the benchmark period CPI–U and the rebate period CPI–U, among other inputs, as described at § 427.302(g). For each Part B rebatable drug, we identify the applicable benchmark period CPI–U as described at §§ 427.302(e)(1) and (2), and subject to paragraphs (e)(3) through (5). Specifically, under section 1847A(i)(3)(E) of the Act and as described at § 427.302(e)(1), for a Part B rebatable drug first approved or licensed by the FDA on or before December 1, 2020, and with a first marketed date on or before December 1, 2020, the benchmark period CPI–U is the CPI–U for January 2021. Additionally, under section 1847A(i)(4)(A) of the Act and as described at § 427.302(e)(2), for a Part B rebatable drug that is a subsequently approved drug, the benchmark period CPI–U is the CPI–U for the first month of the first full calendar quarter after a drug's first marketed date. For the rebate period CPI–U, we will identify and use

the greater of the benchmark period CPI–U index level or the CPI–U index level for the first month of the calendar quarter that is 2 calendar quarters before the applicable calendar quarter in which the Part B rebatable drug is furnished, under section 1847A(i)(3)(F) of the Act and as described at § 427.302(f).

As stated in the CY 2025 PFS final rule (89 FR 98247), we will retrieve CPI–U index level information from the Bureau of Labor Statistics (BLS). The BLS did not release CPI–U survey data for October 2025 due to a lapse in appropriations.[196] As a result of the October 2025 CPI–U data being unavailable, multiple interested parties, including drug companies and a pharmaceutical industry trade association, requested that we clarify in a timely manner how we would calculate inflation rebates that would otherwise use the October 2025 CPI–U data. To respond to these inquiries and to promote transparency with regard to the most immediate calculations for the Inflation Rebate Program, including particular Part B beneficiary coinsurance calculations for the second quarter of 2026, we released an Health Plan Management System (HPMS) memo on March 6, 2026,[197] affirming our intent to use November 2025 CPI–U data in place of the missing October 2025 CPI–U data for such calculations. As we explained in that memo, we used the November 2025 CPI–U data issued by the BLS in place of the missing October 2025 CPI–U data because November 2025 was the first month with available CPI–U data in the calendar quarter identified by statute and regulation.

We released this memo in accordance with section 1847A(c)(5)(C) of the Act, which permits CMS to implement, by program instruction or otherwise, any of the provisions of section 1847A of the Act. We also noted that, to complete such calculations, it would have been impracticable to engage in notice-and-comment rulemaking to affirm the policy stated in that memo because the timing of this final rule would be after our deadline to publish the April 2026 Medicare Part B Payment Limit files, including Part B rebatable drugs subject to a coinsurance adjustment. We further noted that the absence of October 2025 CPI–U data also would be relevant to calculating Part B and Part D inflation rebate amounts that will be reported to manufacturers in 2027 and later and stated our intent to address the broader need for a gap-filling methodology as part of future rulemaking through the Physician Fee Schedule.

Currently, our regulations do not address explicitly how the agency should identify the CPI–U, for the purposes discussed previously in this section of the preamble, when the otherwise relevant CPI–U index level information is unavailable from BLS, as occurred with respect to the October 2025 CPI–U. Therefore, we are proposing to amend § 427.302 by adding paragraph (e)(6) to ensure that in the event CPI–U data are unavailable, we would use the CPI–U data for the first month for which CPI–U data are available following the month for which CPI–U data are unavailable. This proposal also aligns with the policy and the rationale we provided in the HPMS memo released on March 6, 2026, to address the instance of unavailable CPI–U data for October 2025. Consistent with the reasons we set forth in such memo, this proposed approach most closely aligns with statute because it would result in use of CPI–U data from a month no earlier than the quarter specified by the statute. For the same reasons, we also are proposing to amend § 427.302 by adding paragraph (f)(1) to state that when CPI–U data are unavailable, we would use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.

As an alternative to the proposal at § 427.302(f), we considered using the Treasury Department's index number according to the index contingency provisions for Treasury Inflation-Protected Securities, which is based on the last available 12-month change in the CPI.[198] This alternative approach does not align with statute, which directs us to use the CPI–U value from the first month of the relevant period and makes no reference to an alternate calculated value. Specifically, section 1847A(i)(3)(F) of the Act defines the rebate period CPI–U as, with respect to the applicable calendar quarter, ''the greater of the benchmark period CPI–U and the consumer price index for all urban consumers (United States city average) for *the first month of the calendar quarter that is two calendar quarters prior* to such described calendar quarter'' (emphasis added). We also considered calculating our own inflation factor rather than using the BLS reported CPI–U data; however, it is impracticable for us to administer a CPI–U survey and calculate an alternate CPI–U index. Finally, we considered using the previous month for which CPI–U data are available but this approach is less consistent with statute, which as noted previously specifies that we use the CPI–U value from the calendar quarter that is 2 calendar quarters prior to the relevant quarter. We are not proposing these alternative options for the reasons described.

d. Clarification of Date of Receipt for Rebate Reports

As stated in the CY 2025 PFS final rule (89 FR 98264) which was effective on January 1, 2025 and appeared in the December 8, 2024 **Federal Register**, § 427.500 defines the date of receipt as the calendar day following the day on which a report of a rebate amount (as set forth in § 427.501(b) through (d) and § 427.502(b) and (c)) is made available to the manufacturer of a Part B rebatable drug by CMS. The ''date of receipt'' starts the clock for calculation of deadlines at multiple points in the rebate reporting process, including for manufacturer submission of a suggestion of error and for payment of rebate amounts owed. For example, as set forth in § 427.505(a), a rebate amount owed is due no later than ''the 30th calendar day after the date of receipt of information regarding the rebate amount[.]''

For clarity and transparency, we are making technical corrections to the examples provided in the CY 2025 PFS final rule of the calculation of due dates based on the ''date of receipt''. In the CY 2025 PFS final rule (89 FR 98265), we provided examples of the ''date of receipt'', including: (1) ''if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, will be the date of receipt and, therefore, day 1 of the 10-calendar-day period to submit a Suggestion of Error. In this example, Suggestions of Error would be due by 11:59 p.m. PT on June 10, 2026[ ]''; and (2) ''if the Rebate Report is provided on June 30, 2026, then July 1, 2026, would be the date of receipt and therefore day 1 of the 30-calendar-day payment period; payment would be due no later than 11:59 p.m. PT on July 30, 2026.'' We are correcting these examples to be consistent with the definition of ''date of receipt'' in § 427.500. Specifically, in each example provided, the ''date of receipt'' should be day zero of the relevant calendar period, not day one. Therefore, if the Preliminary Rebate Report is provided on May 31, 2026,

[196] BLS, *https://www.bls.gov/cpi/additional-resources/2025-federal-government-shutdown-impact-cpi.htm#:%7E:text=Yes.,in%20appropriations%E2%80%9D%20will%20be%20included.*

[197] CMS, Medicare Prescription Drug Inflation Rebate Program: Impact of Missing October 2025 CPI–U Data on Medicare Part B Inflation Rebate Program in Second Quarter of 2026, *https://www.cms.gov/files/document/cpi-u-gap-filling-memo-final-508.pdf.*

[198] 31 CFR part 356, Appendix B. *https://www.ecfr.gov/current/title-31/subtitle-B/chapter-II/subchapter-A/part-356#ap31.2.356_135.b.*

then June 1, 2026, will be the ''date of receipt'' and day zero of the 10-calendar-day period to submit a Suggestion of Error, such that Suggestions of Error would be due by 11:59 p.m. PT on June 11, 2026. Likewise, if a Rebate Report is provided on June 30, 2026, then July 1, 2026, will be the ''date of receipt'' and day zero of the 30-calendar-day payment period, such that payment would be due no later than 11:59 p.m. PT on July 31, 2026.

e. Enforcement of Manufacturer Payment of Rebate Amounts (§ 427.600)

In accordance with section 1847A(i)(1)(B) of the Act, the manufacturer of a Part B rebatable drug is required to provide a rebate equal to the rebate amount specified in section 1847A(i)(3) of the Act for the rebatable drug for the calendar quarter not later than 30 days after receipt of the rebate amount from CMS. Section 1847A(i)(7) of the Act gives us the authority to impose a civil money penalty (CMP) equal to at least 125 percent of the rebate amount for each drug for each applicable calendar quarter on a manufacturer that fails to pay the rebate amount for each rebatable Part B drug. Subpart G implements this section of the Act and establishes the procedures for determining and collecting a CMP.

We are clarifying here that the imposition of CMPs under section 1847A(i)(7) of the Act, in accordance with § 427.600, is not the exclusive remedy for a manufacturer's failure to comply with its rebate payment obligations described in § 427.505(a), nor the exclusive remedy for other conduct that may impact obligations, such as rebate amounts owed, under the Part B Inflation Rebate Program. For example, whether imposing CMPs under section 1847A(i)(7) of the Act or not, when warranted, we may refer manufacturers to the Department of Justice, the Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation.

3. Medicare Part D Drug Rebates for Certain Drugs and Biologicals With Prices That Increase Faster Than the Rate of Inflation

a. Definitions (§ 428.20)

As stated in the CY 2025 final rule (89 FR 98276), we codified the definition of ''applicable period CPI–U'' at § 428.20 as ''with respect to an applicable period, the CPI–U for the first month of such applicable period (that is, October)'' based on the definition set forth in section 1860D–14B(g)(5) of the Act. The BLS did not release CPI–U survey data for October 2025 due to a lapse in appropriations.[199] As a result of the October 2025 CPI–U data being unavailable, multiple interested parties, including drug companies and a pharmaceutical industry trade association, requested that we clarify in a timely manner how we would calculate inflation rebates that would otherwise use the October 2025 CPI–U data. We acknowledge that the missing October CPI–U data impacts Preliminary Rebate Reports and Rebate Reports for the applicable period that runs from October 2025-September 2026. The current in-effect regulation at § 428.20 does not address our inability to retrieve CPI–U index level information from BLS. To provide clarity on how to gap fill the missing October CPI–U data, we propose to amend § 428.20 to include, ''in the case where the first month's CPI–U data is unavailable, we will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.'' As applied in the case of missing October 2025 CPI–U data, CMS would use November 2025 CPI–U data.

b. Identification of Benchmark Period CPI–U (§ 428.202(e))

Section 1860D–14B of the Act provides that for each Part D rebatable drug, CMS will identify the benchmark period CPI–U as described at § 428.202(e)(1) and (2) and subject to paragraphs (e)(3) through (5). Specifically, under section 1860D–14B(g)(4) and as discussed in § 428.202(e)(1), for a Part D rebatable drug first approved or licensed by the FDA on or before October 1, 2021, the benchmark period CPI–U is the CPI–U for January 2021. Additionally, under section 1860D–14B(b)(5)(C) of the Act and as described at § 428.202(e)(2), for a subsequently approved drug, the benchmark period CPI–U is the CPI–U for January of the first calendar year beginning after a drug's first marketed date as stated under section 1860D–14B(b)(5)(A) of the Act. Under section 1860D–14B(b)(5)(C) of the Act and as described at § 428.202(e)(5) when a Part D rebatable drug is no longer considered to be a selected drug, the benchmark period CPI–U is the CPI–U for January of the last calendar year of such price applicability period. Due to the BLS not releasing CPI–U survey data for October 2025, we recognized a need to adopt a gap filling methodology in the event that any future CPI–U data are not released. As a result of the October 2025 CPI–U data being unavailable, multiple interested parties, including drug companies and a pharmaceutical industry trade association, requested that we clarify in a timely manner how we would calculate inflation rebates that would otherwise use the October 2025 CPI–U data. To respond to these inquiries and to promote transparency, as well as to align with the HPMS memo released on March 6, 2026,[200] we propose to amend § 428.202 by adding paragraph (e)(6) to state, when CPI–U data are unavailable, CMS will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable. In using the first month of CPI–U data available, this proposed approach most closely aligns with section 1860D–14B(g)(5) of the Act.

As an alternative to the proposal at § 428.202(e)(6), we considered using the Treasury Department's index number according to the index contingency provisions for Treasury Inflation-Protected Securities, which is based on the last available 12-month change in the CPI–U. This alternative approach does not align with statute, which directs CMS to use the CPI–U value from the first month of the relevant period. We also considered calculating our own inflation factor rather than using the BLS reported CPI–U; however, it is impracticable for us to administer a CPI–U survey and calculate an alternate CPI–U index. Finally, we considered using the previous month with available CPI–U data, but this approach is less consistent with statute, which directs CMS to use the CPI–U value from the first month of the relevant period. The previous month's CPI–U data would not fall within the relevant period. We are not proposing these alternative options for the reasons described.

c. Exclusion of 340B Acquired Units From Part D Rebatable Drugs (§ 428.203(b)(2) and (c))

Section 1860D–14B(b)(1)(B) of the Act requires that beginning with the plan year 2026, when calculating the total rebate amount to be paid by a manufacturer for a Part D rebatable drug, CMS shall exclude from the total number of units for a Part D rebatable drug, for an applicable period, those units for which a manufacturer provides a discount under the 340B Program. In the CY 2025 PFS final rule (89 FR 98278 through 98279), we finalized the

[199] BLS, *https://www.bls.gov/cpi/additional-resources/2025-federal-government-shutdown-impact-cpi.htm#:%7E:text=Yes.,in%20appropriations%E2%80%9D%20will%20be%20included.*

[200] *https://www.cms.gov/files/document/cpi-u-gap-filling-memo-final-508.pdf.*

proposal at § 428.201(a) to codify the total rebate amount calculation methodology described in section 40 of the revised Medicare Part D Drug Inflation Rebate Guidance,[201] which provides that the total Part D drug inflation rebate amount is equal to the per unit Part D drug inflation rebate amount, as determined under § 428.202(a), multiplied by the total number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors, as determined in accordance with § 428.203. In the CY 2025 PFS final rule (89 FR 98593), we also finalized the proposal at § 428.203(b)(2)(i), to exclude from the total number of units determined under § 428.203(a), units for which a manufacturer provided a discount under the 340B Program (''340B units''). We also finalized the proposal at § 428.203(b)(2)(ii) to determine the total number of 340B units by using data reflecting the total number of units of a Part D rebatable drug for which a discount was provided under the 340B Program and that were dispensed during the applicable period. As we stated in the CY 2025 PFS final rule (89 FR 98289) and CY 2026 PFS final rule (90 FR 49740), because this exclusion requirement starts after the first quarter of the applicable period that begins on October 1, 2025, the exclusion of 340B units will only apply for the last 3 quarters of such applicable period. That is, we are excluding 340B units from the total number of units for a Part D rebatable drug starting with claims with dates of service on or after January 1, 2026.

As we stated in the CY 2025 PFS final rule (89 FR 98289) and the CY 2026 PFS final rule (90 FR 49740), data on which units dispensed under Part D and covered by Part D plan sponsors were purchased under the 340B Program is unavailable from the data sources specified at section 1860D–14B(d) of the Act (that is, information submitted by manufacturers, States, and Part D plan sponsors), and we do not currently have access to this data through other means. We understand that the 340B status of a Part D drug is usually not known by the dispenser at the point-of-sale, and that 340B covered entities (hereinafter ''covered entities'') typically identify the 340B status of a Part D drug retrospectively. Because the covered entity and CMS do not exchange dispensed Part D drug information confirming the 340B status of a Part D rebatable drug, we are unable to precisely identify 340B units at the claim-level based solely on Part D claims submitted to us by the covered entity (or a contract pharmacy operating on behalf of the covered entity) at this time. For these reasons, in the CY 2026 PFS final rule (90 FR 49747), we adopted a claims-based methodology (described in the CY 2026 PFS final rule and hereinafter as ''Prescriber-Pharmacy Methodology'') that we leverage to exclude 340B units from the total number of units of a Part D rebatable drug dispensed under Part D and covered by Part D plan sponsors during an applicable period, starting on January 1, 2026. Additionally, we adopted our proposal to establish a voluntary Medicare Part D Claims Data 340B Repository (''340B repository'') to collect data about 340B units voluntarily submitted by covered entities (90 FR 49750). The data submitted to the 340B repository will not be used to calculate inflation rebates unless and until we propose and finalize a policy to use such data to exclude 340B units from rebate calculations.

(1) Claims-Based Methodology To Remove 340B Units From Rebate Calculations

As finalized in the CY 2026 PFS final rule (90 FR 49741 through 49749), to implement the exclusion required by section 1860D–14B(b)(1)(B) of the Act and described in § 428.203(b)(2), under the Prescriber-Pharmacy Methodology, beginning on January 1, 2026, we remove 340B units from the Part D inflation rebate calculations by evaluating whether a Prescription Drug Event (PDE) record is potentially 340B-eligible based on (1) the affiliation of the National Provider Identifier (NPI) of the prescriber associated with that PDE record with a registered covered entity, and (2) the designation of the dispensing pharmacy associated with that PDE record as a 340B contract pharmacy. If the NPI of the prescriber associated with the PDE record is affiliated with a registered covered entity for a given month, and the dispensing pharmacy is a contract pharmacy associated with such covered entity for the same month, the PDE record is considered as potentially 340B-eligible, and the units associated with that PDE record are removed from Part D inflation rebate calculations. We refer readers to the CY 2026 PFS final rule for a more detailed explanation of the Prescriber-Pharmacy Methodology (90 FR 49741 through 49749).

In the CY 2026 PFS proposed rule (90 FR 32639 through 32641), we acknowledged that the 340B Office of Pharmacy Affairs Information System (OPAIS) database, which the Prescriber-Pharmacy Methodology relies on, may not list all pharmacies that dispense 340B-eligible drugs, including covered entities that have ''in-house'' pharmacies that are not registered in the 340B OPAIS database or 340B-eligible AIDS Drug Assistance Programs (ADAPs)[202] (also considered covered entities) that collect rebates to receive 340B discounts instead of receiving such discount at the time of purchase from a contract pharmacy registered in the 340B OPAIS database. We solicited comments on whether and how to account for this limitation. Similar to the acknowledgments we made in the proposed rule, we received comments stating that the Prescriber-Pharmacy Methodology may underrepresent 340B claims from Ryan White (RW) clinics and ADAPs. To address this, some commenters recommended that we use an alternative methodology to identify these claims. In the CY 2026 PFS final rule (90 FR 49747), we adopted modifications to the Prescriber-Pharmacy Methodology aimed at improving our ability to identify 340B claims associated with RW clinics, but we did not adopt modifications to the Prescriber-Pharmacy Methodology to address the limitations relating to ADAP claims. Our prior preliminary analyses suggested not modifying the Prescriber-Pharmacy Methodology to address the limitations relating to ADAP claims would have minimal impact. Specifically, the percentage of 340B units identified for drugs commonly covered by ADAPs, such as antiretrovirals, was comparable to the average percentage of 340B units identified overall across all drug classes, indicating no meaningful differential. In the CY 2026 PFS final rule (90 FR 49747), we stated that we may consider methodological refinements in the future to further address commenters' feedback on ADAPs.

Since publishing the CY 2026 PFS final rule, we have reviewed additional evidence relating to the need to adjust the Prescriber-Pharmacy Methodology to sufficiently identify units of drugs for which a manufacturer provided a

[201] See: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-revised-guidance.pdf.*

[202] ADAPs are State- and territory-operated Ryan White HIV/AIDS Program grantees that provide FDA-approved medications (including, in some States, medications beyond those used to treat HIV/AIDS) to low-income people living with HIV/AIDS. Under section 340B(a)(4)(E) of the PHS Act, ADAPs are eligible to be enrolled with the 340B Program as covered entities, and HRSA has affirmed that any individual registered in an ADAP covered entity will be considered to meet the 340B patient definition. See: *https://www.hrsa.gov/sites/default/files/hrsa/opa/patient-entity-eligibility-10-24-96.pdf.*

discount under the 340B Program to account for ADAP enrollees. Consequently, we have become aware of evidence suggesting that, in contrast to our statement in the CY 2026 PFS final rule, the percentage of 340B units identified for drugs commonly covered by ADAPs, such as antiretrovirals, may be higher than the average percentage of 340B units identified overall. One study found that, using 2012 data from Walgreens, (1) antivirals were 10 times more likely to be dispensed through the 340B Program and specialty medications[203] were more than 20 times more likely to be dispensed through the 340B Program compared to all drugs dispensed; and, (2) nearly 80 percent of all specialty medications dispensed under the 340B Program were antiretrovirals indicated for HIV/AIDS.[204] This study hypothesized that these results can be at least partially explained by the types of covered entities participating in contract pharmacy arrangements with Walgreens in 2012, that is, covered entities that disproportionately treat people with HIV/AIDs. Additionally, a Congressional Budget Office (CBO) study published September 2025 found that the majority of spending on anti-infective drugs (including HIV/AIDS treatments) purchased through the 340B Program in 2021 occurred at Federal grantee sites, including ADAPs.[205] In addition to other evidence reviewed, these data points suggest that Federal grantee sites, including ADAPs, may significantly contribute to the percentage of 340B claims for antiretrovirals, that this percentage may be higher than for other drug classes, and that without methodological refinement to fully account for 340B claims dispensed to ADAP enrollees, the Prescriber-Pharmacy Methodology may under-identify 340B units for drug classes such as antiretrovirals to a greater extent than previously assumed during the CY 2026 rulemaking cycle. Based on this review, we have determined it is appropriate, in this proposed rule, to reevaluate whether methodological refinements need to be made to the Prescriber-Pharmacy Methodology. We do not believe that adoption of the Prescriber-Pharmacy Methodology as described in the CY 2026 PFS final rule established significant reliance interests that would prevent us from modifying the Prescriber-Pharmacy Methodology. Given that Rebate Reports impacted by the Prescriber-Pharmacy Methodology (that is, Rebate Reports for applicable periods beginning October 1, 2025) have not yet been issued, CMS believes that any reliance interests that may relate to use of the Prescriber-Pharmacy Methodology would not be outweighed by the need to implement a more accurate methodology. Additionally, as we stated earlier, we provided notice to interested parties in the CY 2026 PFS final rule (90 FR 49747) that we may consider methodological refinements in the future to further address commenters' feedback relating to ADAPs.

As part of this reevaluation, we revisited comments we received on the CY 2026 PFS proposed rule. In particular, we revisited comments that explained the unique nature of ADAPs compared to other covered entity types, and the limitations in the Prescriber-Pharmacy Methodology's ability to identify PDE records for ADAP enrollees as 340B-eligible. As one commenter explained, the Prescriber-Pharmacy Methodology may under-identify 340B-eligible PDE records for ADAP enrollees for two reasons. First, PDE records for ADAP enrollees would typically not meet the first criterion of the Prescriber-Pharmacy Methodology (that is, that the prescriber with the NPI listed on the PDE record provides care at a covered entity). ADAPs are not providers, and a patient enrolled in an ADAP is typically prescribed medications by a provider not affiliated with the ADAP. Therefore, for a PDE record for an ADAP enrollee, the prescriber NPI on the PDE record will not be affiliated with the covered entity that claimed the 340B price for such dispense (that is, the ADAP). Second, the majority of ADAPs access 340B pricing via a rebate model.[206] These ADAPs allow their enrollees to fill medications at a broad network of pharmacies that may not be registered in the OPAIS database as contract pharmacies. A PDE record for an ADAP enrollee will thus not meet the second criterion of the Prescriber-Pharmacy Methodology (that is, that the pharmacy NPI on the PDE record is a contract pharmacy for the same covered entity that the prescriber NPI is affiliated with).

After further review of the additional evidence as discussed above and revisiting comments we received on the CY 2026 PFS proposed rule, we conducted a more comprehensive analysis to assess whether the existing Prescriber-Pharmacy Methodology adequately identifies 340B-eligible drugs obtained through ADAPs for Medicare Part D enrollees. The analysis was conducted in two parts. The first reexamined the preliminary analyses described in the CY 2026 PFS final rule (90 FR 49747) assessing whether the Prescriber-Pharmacy Methodology systematically under-identifies drugs used in the treatment of HIV/AIDS as 340B-eligible relative to all other drugs, and it built upon this analysis by examining whether the Prescriber-Pharmacy Methodology under-identifies drugs used in the treatment of HIV/AIDS as 340B-eligible for ADAP enrollees specifically. We identified ADAP enrollees using the Coordination of Benefits (COB)—Other Health Insurance (OHI) file—specifically the COB–OHI Supplemental Record file—using a Supplemental Type Code that flags enrollees that have supplemental ADAP coverage.[207] This analysis reaffirmed our preliminary findings that the Prescriber-Pharmacy Methodology identifies drugs used in the treatment of HIV/AIDS at a percentage close to the overall Part D average for all drug classes. However, when the analysis was isolated to ADAP enrollees only, we found that the Prescriber-Pharmacy Methodology identified drugs used in the treatment of HIV/AIDS as 340B-eligible at a significantly lower percentage than was identified for Part D beneficiaries overall. This finding is contrary to expectations given that ADAPs are eligible to be enrolled with the 340B Program as covered entities, and that HRSA has affirmed that any individual registered in an ADAP will be considered to meet the 340B patient definition (as described earlier in this section). Further, this under-identification of 340B units for ADAP enrollees could impact the completeness and accuracy of data used

[203] The authors of the study defined ''specialty drugs'' as those ''generally considered to be high value; high-touch—for example, medications that require temperature control or other special handling, and medications that require ongoing management by a physician or pharmacists specialized in the relevant condition; or complex—for example, biotechnology products or orphan drugs; or some combination of the above.''

[204] Clark BL, Hou J, Chou CH, Huang ES, Conti R. The 340B discount program: outpatient prescription dispensing patterns through contract pharmacies in 2012. Health Aff (Millwood). 2014 Nov;33(11):2012–7. doi: 10.1377/hlthaff.2014.0833. PMID: 25367997; PMCID: PMC4545491.

[205] CBO, Growth in the 340B Drug Pricing Program, September 9, 2025. *https://www.cbo.gov/publication/60661*.

[206] ''Notice Regarding Section 602 of the Veterans Health Care Act of 1992—Rebate Option.'' 63 FR 35239. See: *https://www.govinfo.gov/content/pkg/FR-1998-06-29/pdf/98-17142.pdf*.

[207] As explained in the Plan Communication User Guide for Medicare Advantage Prescription Drug Plans (February 27, 2026), the Supplemental Record file lists other health insurance that is supplemental to, that is, pays after, Part D. The Supplemental Type Code indicates the type of supplemental insurance contained in the record. *https://www.cms.gov/files/document/mapd-plan-communications-user-guide-v19-0-march-2026.pdf*.

for Part D inflation rebate calculations for certain drug classes such as antiretrovirals, if not sufficiently addressed.

The second part of the analysis examined how a modification to the Prescriber-Pharmacy Methodology would identify drugs used in the treatment of HIV/AIDS as 340B-eligible compared to the existing Prescriber-Pharmacy Methodology. We analyzed the impact on the overall percentage of identified Part D 340B units for both antiretrovirals and all other drug classes if CMS were to consider all Part D units for ADAP enrollees as 340B-eligible. This analysis of the modification to the Prescriber-Pharmacy Methodology to treat all ADAP units as 340B-eligible determined that: (1) for certain drug classes, specifically antiretroviral medications used in the treatment of HIV/AIDS, a modification to account for ADAP enrollees would result in a meaningful increase in the number of rebatable units identified as 340B-eligible, and (2) for all other drug classes, the modification would not have a substantial impact on the percentage of Part D units identified as 340B-eligible. Based on the additional evidence reviewed and subsequent analyses demonstrating the extent to which relevant PDE records for ADAP enrollees would be under-identified as 340B-eligible, we now concur with comments on the CY 2026 PFS proposed rule that we revisited. We agree with the commenters' assertion that a modification to the Prescriber-Pharmacy Methodology is needed to fully account for 340B-eligible units for ADAP enrollees. Where the ADAP acts as a payor of the Part D medication, we would consider all Part D units for ADAP enrollees as 340B-eligible. Such units would be removed from the total number of units and total rebate amount for a Part D rebatable drug as described in the Preliminary Rebate Report and Rebate Report detailed at § 428.401(b) and (c), respectively.

Specifically, we are proposing the following modification to the Prescriber-Pharmacy Methodology: CMS would identify PDE records for beneficiaries who have ADAP supplemental coverage as listed in the COB–OHI Supplemental Record file using the Supplemental Type Code that flags enrollees that have supplemental ADAP coverage. CMS would then exclude all units associated with those PDE records from Part D inflation rebate calculations.

If a beneficiary included in the COB–OHI Supplemental Record file is identified as having supplemental insurance from an ADAP at the time a Part D drug was dispensed to such beneficiary during the applicable period, we would designate the units as 340B-eligible and remove the associated units from the inflation rebate calculation. Because State ADAP formularies can vary, and because we will not have State-specific insight regarding an ADAP's formulary coverage for a specific beneficiary's claims dispensed in a specific State, we would treat all PDE records dispensed for a beneficiary identified as having ADAP supplemental insurance on the COB–OHI file as 340B-eligible and remove the units associated with these PDE records. Since some of the ADAP enrollees identified in the proposed modification to the Prescriber-Pharmacy Methodology may already have Part D units identified as 340B-eligible using the existing Prescriber-Pharmacy Methodology, counting all ADAP enrollees' units identified under the proposed modification as 340B-eligible could potentially double-count 340B-eligible units. To avoid double-counting, we would identify units that were already flagged as 340B-eligible using the existing Prescriber-Pharmacy Methodology and exclude those from the count of ADAP 340B-eligible units identified under the proposed modification.

CMS acknowledges that this approach may result in an overestimation of 340B-eligible units for ADAP enrollees. Notwithstanding this limitation, CMS has determined that treating all Part D drugs dispensed to ADAP enrollees as 340B-eligible is appropriate for the following reasons: (1) the manner in which 340B discounts are realized for 340B-eligible ADAP units varies among State ADAP programs, and (2) variability in drug coverage across State-specific drug formularies presents significant challenges in developing a single, uniformly applicable methodology capable of accurately identifying 340B eligibility on a drug-by-drug or program-by-program basis. Further, in CMS' analysis of the proposed modification to the Prescriber-Pharmacy Methodology, and the corresponding treatment of all ADAP enrollee units as 340B-eligible, CMS determined that: (1) for certain drug classes, specifically antiretroviral medications used in the treatment of HIV/AIDS, the proposed modification would result in a meaningful increase in the percentage of Part D rebatable units identified as 340B-eligible, and (2) for all other drug classes, the proposed modification would not have a substantial impact on the percentage of units identified as 340B-eligible if all ADAP enrollee units were treated as 340B-eligible. In other words, CMS' analysis indicates, for the majority of drug classes with exception of antiretroviral medications used in the treatment of HIV/AIDS, treating all ADAP enrollee units as 340B eligible is expected to have minimal or no impact on the identification of 340B-eligible units from the Prescriber-Pharmacy Methodology. These findings demonstrate that the modification to the Prescriber-Pharmacy Methodology is narrowly and appropriately targeted towards antiretroviral medications used in the treatment of HIV/AIDS, which aligns with the evidence described earlier in this section suggesting that the percentage of 340B units identified for antiretrovirals may be higher than the average percentage of 340B units identified overall. In light of these considerations, CMS has determined that a broad, programmatic approach to identifying 340B-eligible ADAP units is preferable to a more granular methodology that may yield inconsistent or inaccurate results. If adopted, the modification to the Prescriber-Pharmacy Methodology proposed herein would be effective for Rebate Reports issued for the applicable period that begins October 1, 2025, and subsequent applicable periods.

We solicit comments on this proposal.

(2) Medicare Part D Claims Data 340B Repository

In the Medicare Part D Drug Inflation Rebates Paid by Manufacturers: Initial Memorandum, Implementation of Section 1860D–14B of Social Security Act, and Solicitation of Comment (''initial Medicare Part D Drug Inflation Rebate Guidance''),[208] CMS solicited comments on the best mechanism to identify 340B units dispensed under Part D to exclude units from Part D inflation rebate calculations. Interested parties recommended that CMS create a mechanism through which covered entities would retrospectively submit data to CMS identifying 340B-purchased drugs dispensed under Part D and urged that this mechanism allow covered entities to submit these data directly to CMS, rather than through claims that dispensers submit via Part D plan sponsors. In response to these recommendations, we solicited comments in the CY 2025 PFS proposed rule (89 FR 61971 through 61972) on a 340B repository. As highlighted in the CY 2025 final rule (89 FR 98292), many commenters expressed strong support for a 340B repository. In the CY 2026

[208] See: *https://www.cms.gov/files/document/medicare-part-d-inflation-rebate-program-initial-guidance.pdf.*

PFS proposed rule (90 FR 32641 through 32644), we proposed to establish a 340B repository, and as described in the CY 2026 PFS final rule (90 FR 49749), many commenters supported this proposal to establish a 340B repository.

In the CY 2026 PFS final rule (90 FR 49750), we established a 340B repository to receive voluntary submissions from covered entities of certain data elements associated with Part D claims for which the covered entity dispensed (directly or indirectly, including via retrospective replenishment and contract pharmacy arrangements) units of a drug for which a manufacturer provides a discount under the 340B Program (''Part D 340B claims''). We established the 340B repository to allow for assessment of such data for potential use in identifying units of Part D rebatable drugs for which a manufacturer provided a discount under the 340B Program in a future applicable period. We established that covered entities will be allowed to submit data on units of Part D 340B claims beginning in 2026 to begin testing the usability of the 340B repository. We are currently working to operationalize the 340B repository to allow covered entities to begin submitting data on 340B units of Part D rebatable drugs and expect the 340B repository to launch in Fall 2026. Once the 340B repository launches in Fall 2026, we will begin testing the usability of data voluntarily submitted by covered entities, starting with claims with dates of service in 2026. Covered entities that voluntarily submit data to the 340B repository need to follow the processes and requirements that CMS has established for voluntary reporting starting in 2026 and the associated information collection currently approved under OMB control number 0938–1485.

In the CY 2026 PFS final rule (90 FR 49750), we strongly encouraged all covered entities to submit data elements to the 340B repository during the 2026 testing period, noting that this participation would allow for robust testing of data quality and completeness and provide an opportunity for covered entities to develop and test their data submission processes. We also noted that we would address the possibility of requiring covered entities to report data elements to the 340B repository in future years in future rulemaking and that we were actively considering proposing mandatory reporting to the 340B repository in the near future.

We are now proposing at § 428.203(c) to require providers and suppliers that are covered entities as defined under § 10.3 (hereinafter collectively ''340B providers'' unless otherwise noted) to submit Part D 340B data to the 340B repository beginning in 2027. Such reporting would fulfill a 340B provider's obligation to provide access to documentation relating to covered Part D drugs written or ordered by such 340B provider to maintain enrollment in Medicare, as we are proposing at § 424.516(f)(4). We describe these proposals in further detail in sections III.F.3.c.2.a. through III.F.3.c.2.c. of this proposed rule.

(a) Background: Requirement for Physicians, Other Suppliers, and Providers To Maintain and Provide Access to Documentation

Section 1866(j)(1)(A) of the Act requires the Secretary to establish a process for the enrollment of providers and suppliers into the Medicare program. The overarching purpose of the enrollment process is to help confirm that providers seeking to bill Medicare for services and items furnished to Medicare beneficiaries meet all applicable Federal and State requirements to do so. The process is, to an extent, a ''gatekeeper'' that prevents unqualified and potentially fraudulent individuals and entities from entering and inappropriately billing Medicare. Since 2006, we have undertaken rulemaking efforts to implement enrollment procedures. These regulations are generally codified in 42 CFR part 424, subpart P. They address, among other things, requirements that providers must meet to obtain and maintain Medicare billing privileges.

Section 6406(a) of the Patient Protection and Affordable Care Act (ACA) amended section 1842(h) of the Act by adding a new paragraph which establishes that the Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under Title XVIII of the Act, as specified by the Secretary.

In addition, section 6406(b)(3) of the ACA amended section 1866(a)(1) of the Act to require that providers maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider, as specified by the Secretary.

To implement section 6406 of the ACA, on May 5, 2010, CMS published an interim final rule titled ''Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements,'' (75 FR 24437) which amended § 424.516(f) to specify requirements for, among other things, documentation and access to documentation related to certain orders and referrals. We clarified in that rulemaking that the documentation includes both written and electronic documentation. CMS also amended § 424.535(a)(10) to establish that CMS may revoke enrollment, for a period of not more than one year for each act of noncompliance, for a provider or a supplier if such provider or supplier fails to meet the requirements of § 424.516(f). CMS finalized the interim final rule in an April 27, 2012 final rule titled ''Medicare and Medicaid Programs; Changes in Provider and Supplier Enrollment, Ordering and Referring, and Documentation Requirements; and Changes in Provider Agreements'' (77 FR 25284).

(b) Proposal To Require Providers and Suppliers That Are Covered Entities To Submit Documentation Relating to Part D 340B Claims (§§ 424.516(f)(4), 424.535(a)(1), and 428.203(c))

To inform policy development for this rulemaking, we reviewed and considered the comments received on the CY 2026 PFS proposed rule. In this feedback, many commenters suggested that we require covered entities and/or their contractors to report data to a 340B repository. We agree. To ensure robust data submissions in 2027 to determine if data submitted to the 340B repository could be used reliably in the future to remove 340B units from Part D inflation rebate calculations in accordance with section 1860D–14B(b)(1)(B) of the Act, we believe it necessary to transition from voluntary submission to requiring 340B provider participation in the 340B repository.

We are therefore proposing at § 424.516(f)(4) that a provider or supplier that is a covered entity as defined at § 10.3 would be required to maintain and provide access to documentation as set forth at proposed § 428.203(c). We are proposing this requirement in accordance with sections 1866(a)(1)(X) and 1842(h)(9) of the Act. We note that we are proposing to designate our proposal at § 424.516(f)(4) rather than § 424.516(f)(3) because we

are reserving § 424.516(f)(3) for use in separate CMS rulemaking. If this proposal is finalized, CMS would reserve the right to revoke, in accordance with existing § 424.535(a)(10), a currently enrolled provider or supplier's Medicare enrollment and any corresponding provider agreement or supplier agreement for failure to comply with the requirements for maintaining and providing access to documentation specified in proposed § 424.516(f)(4). Although we acknowledge that § 424.516(f) has historically set forth documentation requirements for providers and suppliers with respect to their Part A and Part B services, the statutory authorities underlying that provision, sections 1842(h)(9) and 1866(a)(1)(X) of the Act, do not expressly limit documentation requirements to services furnished under Part A and Part B. Sections 1842(h)(9) and 1866(a)(1)(X) of the Act collectively set forth that providers and suppliers must maintain and provide access to documentation relating to ''items or services written or ordered by the provider *under this title,* as specified by the Secretary'' (emphasis added). Both sections 1842(h)(9) and 1866(a)(1)(X) of the Act fall under Title XVIII (that is, the Medicare statute), which inherently includes Part D. As such, requiring providers and suppliers to maintain and provide access to documentation related to covered Part D drugs written or ordered by a provider or supplier is consistent with sections 1866(a)(1)(X) and 1842(h)(9) of the Act. By transitioning from voluntary submission to mandatory participation in the 340B repository, CMS would be able to ensure more complete and reliable data submissions, thereby improving its ability to accurately assess potential future use of the 340B repository to exclude 340B units from Part D rebate calculations, consistent with its obligations under section 1860D–14B(b)(1)(B) of the Act.

At § 428.203(c), we propose the documentation to which a 340B provider must provide access, as well as the timeframe within which such access must be provided, for the provider or supplier to fulfill their obligations set forth in the proposed § 424.516(f)(4). Proposed § 428.203(c)(1) would require that, beginning with claims with a date of service on or after January 1, 2027, a provider or supplier that is a covered entity as defined at § 10.3 must submit the data elements associated with each claim for a covered Part D drug billed to Medicare Part D for which such covered entity or its contractor(s) (such as contract pharmacies) dispensed units of a drug for which a manufacturer provides a discount under the 340B Program to such covered entity. This requirement would apply, for example, to claims for units of a drug covered under Part D and dispensed by contract pharmacies that the covered entity, its contractors, or its third-party administrators identify as 340B-eligible and for which the covered entity obtains a 340B discount, including through retrospective replenishment models. This requirement would also apply, for example, to claims for units of a drug covered under Part D and dispensed by the covered entity's in-house pharmacy.

Specifically, we are proposing to require that a provider or supplier that is a covered entity as defined at § 10.3 must submit the following data elements associated with each claim for units of a covered Part D drug billed to Medicare by such covered entity or its contractor(s) (such as contract pharmacies) for which a manufacturer provides a discount under the 340B Program to such covered entity: (1) Date of Service (that is, the date the prescription was filled by the pharmacy); (2) Prescription or Service Reference Number; (3) Fill Number (that is, the code indicating whether the prescription is an original or a refill; if a refill, the code indicates the refill number); (4) Dispensing Pharmacy NPI; and (5) NDC–11. Additionally, we are proposing at § 428.203(c)(2) that, in addition to submitting the data elements set forth in proposed § 428.203(c)(1), a provider or supplier that is a covered entity as defined at § 10.3 must submit its 340B ID and name as designated in the 340B OPAIS database.

We understand that reporting the data proposed at § 428.203(c) may impose new operational demands on 340B providers, potentially requiring the development of reporting processes where none currently exist and that 340B providers will need time to develop a process for collecting the 340B data elements to submit to the 340B repository and prepare the data in a form and manner prescribed by CMS. Additionally, given the variety in the scope of provider types and organizations that participate in the 340B Program, we recognize the amount of preparation time to submit data varies. We propose at § 428.203(c)(3) to require that 340B providers report data on a quarterly basis (though they may choose to submit more frequently) within 1 calendar quarter following the close of the relevant calendar quarter. For example, for claims with dates of service between October 1, 2027, through December 31, 2027, 340B providers would submit the data elements from Part D 340B claims to the 340B repository no later than March 31, 2028. Quarterly submissions are necessary so CMS has timely information to assess the reliability of the data for potential future use in removing 340B units from Part D inflation rebate calculations. In addition, quarterly submissions may minimize the burden on 340B providers by reducing the amount of data in each submission and the amount of quality assurance necessitated for each submission. We solicit comments on this proposal.

Specifically, at § 428.203(c)(3), we are proposing that the data elements and information set forth in § 428.203(c)(1) and (c)(2) must be submitted on a quarterly basis and in a form and manner specified by us in accordance with the following timelines: data elements and information associated with claims with dates of service during the first calendar quarter must be submitted by the close of the second calendar quarter; data elements and information associated with claims with dates of service during the second calendar quarter must be submitted by the close of the third calendar quarter; data elements and information associated with claims with dates of service during the third calendar quarter must be submitted by the close of the fourth calendar quarter; and data elements and information associated with claims with dates of service during the fourth calendar quarter must be submitted by the close of the first calendar quarter of the immediately following calendar year.

These are the same data elements, information, and timing requirements that are specified in the CY 2026 PFS final rule (90 FR 49750) establishing the 340B repository with voluntary submission.

We note that we are issuing a revised collection of information (0938–1485) titled ''Information Collection Request (ICR) for the Medicare Prescription Drug Inflation Rebate Program under sections 11101 and 11102 of the Inflation Reduction Act (IRA)'' (CMS–10930, OMB 0938–1485) alongside this proposed rule to reflect the burden associated with a mandatory submission to the 340B repository. We are working to operationalize the 340B repository in a way that minimizes burden on 340B providers and have engaged with a range of interested parties to consider the technical requirements that would facilitate lower burden for submission to the 340B repository. See section V.B.2. of this proposed rule for an updated estimate of burden associated with the

collection of data for the 340B repository. The ICR contains more details regarding how covered entities would submit data to the 340B repository.

Under this current proposal, the data submitted to the 340B repository would not be used to calculate inflation rebates. We will continue to use the Prescriber-Pharmacy Methodology to remove 340B units from Part D inflation rebate calculations. Any future proposal to use the data reported to the 340B repository to remove 340B units from Part D inflation rebate calculations would undergo notice-and-comment rulemaking. We intend to analyze the data submitted to the 340B repository under this proposal to determine if they could be used reliably in the future to remove 340B units from Part D inflation rebate calculations in accordance with section 1860D–14B(b)(1)(B) of the Act. We would match the stored data elements in the 340B repository to PDE transactions for each Part D rebatable drug dispensed during the applicable period and would evaluate 340B repository data for: (1) data integrity, and (2) submission frequency and completeness across covered entity types and geographies, including through comparison to claims identified under the claims-based methodology adopted in the CY 2026 PFS final rule to exclude 340B units starting on January 1, 2026, from Part D inflation rebates. Note, we understand the importance of maintaining the confidentiality of data submitted to the 340B repository, and this data would not be made available to external parties, including manufacturers and Part D plan sponsors.

We solicit comments on the proposal at § 424.516(f)(4) that a provider or supplier that is a covered entity as defined at § 10.3 would be required to submit to CMS the documentation set forth at proposed § 428.203(c)(1) and (2) relating to covered Part D drugs written or ordered by such provider or supplier and comply with the submission requirements set forth at § 428.203(c)(3) and (4). We also solicit comments on the documentation and timing requirements proposed at § 428.203(c) to which a provider or supplier that is a covered entity would be required to adhere to fulfill their obligation at proposed § 424.516(f)(4). We also solicit comments on the scope of Part D 340B claims for which a provider or supplier that is a covered entity as defined at § 10.3 must submit data elements under the proposed regulation text.

(c) Submitting Part D 340B Claims Data to the 340B Repository (§ 428.203(c))

We expect that the 340B repository will be operational by Fall 2026 for voluntary submissions from covered entities, as we adopted in the CY 2026 PFS final rule (90 FR 49748). As we stated earlier in this section, we are now proposing to require all 340B providers to submit certain data elements associated with Part D 340B claims beginning in 2027. We strongly encourage 340B providers to begin submitting data to the 340B repository voluntarily in 2026 to test operational processes, as we are proposing here to adopt the requirement that 340B providers submit data elements from their Part D 340B claims starting in 2027. The rest of this section proposes the form and manner by which, starting in 2027, pursuant to the proposed § 428.203(c), 340B providers would submit data to the 340B repository.

As stated in section III.F.3.c.b., under the 340B mandatory reporting proposal, the data elements and information set forth in paragraphs (c)(1) and (2) of § 428.203 would be submitted on a quarterly basis. We propose here that we would rely upon the completeness and accuracy of the data submitted by 340B providers to the 340B repository, consistent with the 340B provider requirement to certify the accuracy of such submissions described below, to consider all data elements received by the 340B repository to be associated with Part D 340B claims. That is, CMS would rely on the accuracy and completeness of the submitted, certified data to the 340B repository to verify the 340B status of a claim.

We solicit comments on this proposal.

We also propose, as part of every submission, to require 340B providers (or an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification) to certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, its submissions include all Part D 340B claims for the 340B provider at the time of submission for the relevant period. 340B providers or their authorized representative would be required to certify the completeness and accuracy of the data submitted and to certify that the submitter is authorized to submit on behalf of the 340B provider.

We solicit comments on this proposal.

In the CY 2026 PFS final rule (90 FR 49750), describing the proposal for voluntary data submission, we noted that we understand covered entities typically contract with vendors, such as 340B third-party administrators (TPAs), to determine 340B-eligibility of claims using data submitted by covered entities and their contract pharmacies. We continue to acknowledge these contracts and, therefore, we propose that 340B providers could arrange for TPAs or other vendors to submit the required data elements to the 340B repository on their behalf. 340B providers would ultimately be responsible for the accuracy of the data submitted to the 340B repository, even if a 340B provider has an arrangement with a vendor to submit on its behalf.

We solicit comments on this proposal.

In section III.F.3.c.b., we proposed to require that 340B providers report data on a quarterly basis. Here, we separately propose that 340B providers would have additional time to submit data to reflect a revision to the 340B determination of claims with dates of service throughout an applicable period. A revision could come in one of two forms: (1) resubmission of data for a claim that the 340B provider previously submitted to the 340B repository in error or with errors in the requested data fields, or (2) new submission of data for a claim for a drug that the 340B provider had previously determined was not purchased under the 340B Program, but later identified was purchased under such program. In instances where the 340B provider submits Part D 340B claims data to the repository that is either (1) incomplete or (2) contains invalid data, we may inform the 340B provider of such error and request that the 340B provider resolve and resubmit the Part D 340B claims data in order to process the submission successfully. As noted in the CY 2026 PFS final rule (90 FR 49754), we will provide details on the process and timing for covered entities to submit revised data to the 340B repository after the end of the reporting period in the future, and we anticipate that this same timing would apply in 2027 when 340B providers would be required to submit Part D 340B data to the 340B repository. Specifically, at § 428.203(c)(4), we are proposing that data elements and information submitted in accordance with paragraph (c)(3) of such section that is either incomplete or contains invalid data must be resubmitted at a later time in a form and manner specified by CMS.

We solicit comments on this proposal.

d. Clarification of Date of Receipt for Rebate Reports

As stated in the CY 2025 PFS final rule (89 FR 98305) which was effective on January 1, 2025 and appeared in the

December 8, 2024 **Federal Register**, § 428.400 defines the date of receipt as the calendar day following the day in which a report of a rebate amount (as set forth in § 428.401(b), (c), and (d) and § 428.402(b) and (c)) is made available to the manufacturer of a Part D rebatable drug by CMS. The date of receipt starts the clock for calculation of deadlines at multiple points in the rebate reporting process, including for manufacturer submission of a suggestion of error and for payment of rebate amounts owed. For example, as set forth in § 428.405(a)(1), a rebate amount owed is due no later than ''the 30th calendar day after the date of receipt of information regarding the rebate amount.''

For clarity and transparency, we are making technical corrections to the examples provided in CY 2025 PFS final rule of the calculation of due dates based on the ''date of receipt''. In the CY 2025 PFS final rule (89 FR 98306), we provided examples of the ''date of receipt'', including: (1) ''if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, will be the date of receipt and, therefore, day one of the 10-calendar-day period to submit a Suggestion of Error; the Suggestion of Error would be due by 11:59 p.m. PT on June 10, 2026 [ ]''; and (2) ''if the Rebate Report is provided on June 30, 2026, then July 1, 2026, would be the date of receipt and therefore day one of the 30-calendar-day payment period; payment would be due no later than 11:59 p.m. PT on July 30, 2026.'' We are correcting these examples to be consistent with the definition of ''date of receipt'' in § 428.400. Specifically, in each example provided, the ''date of receipt'' should be day 0 of the relevant calendar period, not day one. Therefore, if the Preliminary Rebate Report is provided on May 31, 2026, then June 1, 2026, will be the ''date of receipt'' and day zero of the 10-calendar-day period to submit a Suggestion of Error, such that Suggestions of Error would be due by 11:59 p.m. PT on June 11, 2026. Likewise, if a Rebate Report is provided on June 30, 2026, then July 1, 2026, will be the date of receipt and day zero of the 30-calendar-day payment period, such that payment would be due no later than 11:59 p.m. PT on July 31, 2026.

e. Enforcement of Manufacturer Payment of Rebate Amounts (§ 428.500)

In accordance with section 1860D–14B(a)(2) of the Act, the manufacturer of a Part D rebatable drug is required to provide a rebate equal to the rebate amount specified in section 1860D–14B(b) for the rebatable drug for the applicable period within 30 calendar days after receipt of the rebate amount from CMS. Section 1860D–14B(e) of the Act gives us the authority to impose a CMP equal to 125 percent of the rebate amount specified at section 1860D–14B(b) for each drug for each applicable period on a manufacturer that fails to pay the specified rebate amount. Subpart F implements this section of the Act and establishes the procedures for determining and collecting a CMP.

We are clarifying here that the imposition of CMPs under section 1860D–14B(e) of the Act, in accordance with § 428.500, is not the exclusive remedy for a manufacturer's failure to comply with its rebate payment obligations described in § 428.405(a), nor the exclusive remedy for other conduct that may impact obligations, such as rebate amounts owed, under the Part D Inflation Rebate Program. For example, whether imposing CMPs under section 1860D–14B(e) of the Act or not, when we deem it appropriate, we may refer manufacturers to the Department of Justice, the Department of the Treasury, and/or the Department of Health and Human Services Office of Inspector General for further review and investigation.

G. Medicare Shared Savings Program

1. Executive Summary and Background

a. Purpose

As of January 1, 2026, the Medicare Shared Savings Program (Shared Savings Program) has 511 accountable care organizations (ACOs) with over 700,000 healthcare providers and organizations providing care to over 12.6 million assigned beneficiaries.[209] Eligible groups of providers and suppliers, such as physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or joining an ACO and in so doing agree to become accountable for the total cost and quality of care provided to an assigned population of Medicare FFS beneficiaries [210] (herein also referred to as ''Original Medicare beneficiaries''). Under the Shared Savings Program, providers and suppliers that participate in an ACO continue to receive Original Medicare (OM) payments under Parts A and B,[211] and the ACO may be eligible to receive a shared savings payment if it meets specified quality and savings requirements, and in some instances may be required to share in losses if it increases healthcare spending.

As part of our effort to align spending and value in OM, we are focused on developing policies that would grow the number of health care providers and beneficiaries in accountable care relationships and grow savings to the Medicare Trust Funds. To achieve these goals, we are proposing changes to the Shared Savings Program and seeking comments on potential future policy developments in several requests for information, informed by the following strategic objectives:

- Strengthen financial incentives to participate and drive savings while minimizing ''gaming'' [212] opportunities in the Shared Savings Program.
- Grow participation in the Shared Savings Program through more meaningful participation and through beneficiary engagement, including beneficiary incentives.
- Simplify Shared Savings Program requirements and reduce participant burden in the Shared Savings Program, including through advancing ACO use of digital quality measures.

More specifically, our proposed changes to the Shared Savings Program's financial methodology would strengthen financial incentives for ACOs to participate in the program while mitigating selection issues and benchmark rebasing concerns. Our proposed changes to the Shared Savings Program's beneficiary assignment methodology would expand the population of Medicare FFS beneficiaries for which ACOs are accountable for quality and cost of care, while minimizing potential gaming opportunities in connection with the assignment methodology, and aligning Shared Savings Program policies. Under proposed changes to the Shared Savings Program quality performance standard and other quality reporting requirements, we would advance ACO use of digital quality measures and reduce participant burden. Our proposal to allow flexibility for all Shared Savings Program ACOs to reduce or eliminate Part B cost sharing for eligible beneficiaries, and therefore expand

[209] See ''Shared Savings Program Fast Facts—As of January 1, 2026'', available at *https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf*.

[210] ''Medicare fee-for-service beneficiary'' is defined under section 1899(h)(3) of the Act, and a related definition was codified at 42 CFR 425.20.

[211] Over time, in Shared Savings Program rulemaking, we have used various phrases to refer to payments under the original Medicare fee-for-service program. Herein, we sometimes refer to Medicare fee-for-service (FFS) payments under Parts A and B as ''Original Medicare payments.'' More generally, we use the terms ''Traditional Medicare'' and ''Original Medicare'' interchangeably and consider the terms to be synonymous.

[212] For instance, in section III.G.2.a of this proposed rule, we describe the potential for Shared Savings Program assignment policies to be exploited in a manner that results in differences in outcomes that could advantage the ACO's financial performance.

availability of this flexibility beyond ACOs participating in the prepaid shared savings payment option (which we propose to discontinue), is intended to increase beneficiary engagement. Our proposed changes to simplify the Shared Savings Program Certified Electronic Health Record Technology (CEHRT) use requirements and beneficiary information notice requirements would reduce burden for ACOs. Other modifications to the Shared Savings Program regulations addressed in this proposed rule include: proposed changes to the definition of primary care services for the purpose of determining beneficiary assignment, and proposed modifications to definitions of experienced and inexperienced with performance-based risk Medicare ACO initiatives used in determining an ACO's eligibility for participation options, and proposed changes the determining quarterly payment amounts received by eligible ACOs participating under the Advance Investment Payment (AIP) option. Further, through this proposed rule, we seek comment on specialty care in the Shared Savings Program. We provide a more detailed summary of the proposed changes to the Shared Savings Program and the topics on which we seek comment in a Request for Information (RFI) in section III.G.1.c. of this proposed rule.

b. Statutory and Regulatory Background on the Shared Savings Program

On March 23, 2010, the Patient Protection and Affordable Care Act (Pub. L. 111–148) was enacted, followed by enactment of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) on March 30, 2010, which amended certain provisions of the Patient Protection and Affordable Care Act (hereinafter collectively referred to as ''the Affordable Care Act''). Section 3022 of the Affordable Care Act amended title XVIII of the Act (42 U.S.C. 1395 *et seq.*) by adding section 1899 of the Act to establish the Medicare Shared Savings Program to facilitate coordination and cooperation among health care providers to improve the quality of care for Medicare FFS beneficiaries and reduce the rate of growth in expenditures under Medicare Parts A and B. (See 42 U.S.C. 1395jjj.)

Section 1899 of the Act has been amended through subsequent legislation. The requirements for assignment of Medicare FFS beneficiaries to ACOs participating under the program were amended by the 21st Century Cures Act (Pub. L. 114–255). The Bipartisan Budget Act of 2018 (Pub. L. 115–123), further amended section 1899 of the Act to provide for the following: expanded use of telehealth services by physicians or practitioners participating in an applicable ACO to furnish services to prospectively assigned beneficiaries; greater flexibility in the assignment of Medicare FFS beneficiaries to ACOs by allowing ACOs in tracks under retrospective beneficiary assignment a choice of prospective assignment for the agreement period; permitting Medicare FFS beneficiaries to voluntarily identify an ACO professional as their primary care provider and requiring that such beneficiaries be notified of the ability to make and change such identification, and mandating that any such voluntary identification will supersede claims-based assignment; and allowing ACOs under certain two-sided models to establish CMS-approved beneficiary incentive programs.

The Shared Savings Program regulations are codified at 42 CFR part 425. The final rule establishing the Shared Savings Program appeared in the November 2, 2011, **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations; final rule (76 FR 67802) (hereinafter referred to as the ''November 2011 final rule'')). A subsequent update to the program rules appeared in the June 9, 2015, **Federal Register** (Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations final rule (80 FR 32692) (hereinafter referred to as the ''June 2015 final rule'')). The final rule entitled ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations—Revised Benchmark Rebasing Methodology, Facilitating Transition to Performance-Based Risk, and Administrative Finality of Financial Calculations,'' which addressed changes related to the program's financial benchmark methodology, appeared in the June 10, 2016, **Federal Register** (81 FR 37950) (hereinafter referred to as the ''June 2016 final rule''). A final rule, ''Medicare Program: Medicare Shared Savings Program; Accountable Care Organizations—Pathways to Success and Extreme and Uncontrollable Circumstances Policies for Performance Year 2017,'' appeared in the December 31, 2018, **Federal Register** ((83 FR 67816) (hereinafter referred to as the ''December 2018 final rule'')).

In the interim final rule with comment period (IFC) entitled ''Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,'' which was effective on the March 31, 2020 date of display and appeared in the April 6, 2020, **Federal Register** (85 FR 19230) (hereinafter referred to as the ''March 31, 2020 COVID–19 IFC''), and the IFC entitled ''Medicare and Medicaid Programs; Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program,'' which was effective on May 8, 2020, and appeared in the May 8, 2020, **Federal Register** (85 FR 27550) (hereinafter referred to as the ''May 8, 2020 COVID–19 IFC''), we updated quality requirements, financial calculations, eligibility requirements, and assignment methodology due to the to the public health emergency (PHE) for coronavirus disease 2019 (COVID–19).

We have also made use of the annual CY PFS rules to address quality reporting for the Shared Savings Program and certain other issues. For summaries of certain policies finalized in prior PFS rules, refer to the CY 2019 PFS final rule (also referred to as the ''November 2018 final rule'') (83 FR 59452), CY 2020 PFS final rule (84 FR 62568), the CY 2021 PFS final rule (85 FR 84717), the CY 2022 PFS final rule (86 FR 65253 and 65254), the CY 2023 PFS final rule (87 FR 69779 and 69780), the CY 2024 PFS final rule (88 FR 79094 and 79095), the CY 2025 PFS final rule (89 FR 98082 and 98083), and the CY 2026 PFS final rule (90 FR 49757 through 49759). In the CY 2026 PFS final rule (90 FR 49757 through 49836), we finalized changes to Shared Savings Program policies, including to: limit participation in a one-sided model to an ACO's first agreement period under the BASIC track's glide path (if eligible), for a maximum of 5 PYs instead of 7 PYs; modify the Shared Savings Program eligibility and financial reconciliation requirements in connection with the statutory requirement that ACOs have at least 5,000 assigned Medicare FFS beneficiaries; make changes to the Shared Savings Program quality performance standard and other quality reporting requirements; expand the application of the Shared Savings Program quality and finance extreme and uncontrollable circumstances (EUC) policies to an ACO that is affected by an EUC due to a cyberattack, including ransomware/malware, as determined by the Quality Payment Program; and to make changes to other programmatic areas, including changes to Shared Savings Program eligibility requirements and change request

procedures, updates to the beneficiary assignment methodology to revise the definition of primary care services to align with payment policy changes, and to revise the Shared Savings Program's quality reporting monitoring policies.

Aside from CY PFS rulemaking, we also note that in a final rule entitled ''Medicare Program: Mitigating the Impact of Significant, Anomalous, and Highly Suspect Billing Activity on Medicare Shared Savings Program Financial Calculations in Calendar Year 2023,'' which was effective on October 15, 2024, and appeared in the September 27, 2024, **Federal Register** (89 FR 79152) (hereinafter referred to as the ''SAHS billing activity final rule''), we finalized an approach to address the SAHS billing activity CMS identified for CY 2023 to protect the accuracy, fairness, and integrity of Shared Savings Program financial calculations.

Policies applicable to Shared Savings Program ACOs for purposes of quality reporting for other programs have also continued to evolve based on changes in statute, such as the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), which established the Quality Payment Program. In the CY 2017 Quality Payment Program final rule with comment period (81 FR 77008), we established regulations for the MIPS and Advanced APMs and related policies applicable to eligible clinicians who participate in APMs, including the Shared Savings Program. We have also made updates to policies under the Quality Payment Program through the annual CY PFS rules.

c. Summary of Shared Savings Program Proposals

In sections III.G.2. through III.G.9. of this proposed rule, we propose modifications to the Shared Savings Program's policies. As a general summary, we are proposing the following changes to Shared Savings Program policies to:

- Revise policies for determining beneficiary assignment under the Shared Savings Program (section III.G.2. of this proposed rule):

++ Exclude from assignment calculations allowed charges for primary care services billed through a non-ACO Taxpayer Identification Number (TIN) by an ACO professional used in assignment (section III.G.2.a.(2)(a) of this proposed rule).

++ Modify assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status (section III.G.2.a.(2)(b) of this proposed rule).

++ Revise the definition of primary care services used in Shared Savings Program beneficiary assignment (section III.G.2.b. of this proposed rule).

- Revise the quality performance standard and other quality reporting requirements, including the following (section III.G.3. of this proposed rule):

++ Extend the availability of the MIPS CQMs collection type and the MIPS CQM reporting incentive for Shared Savings Program ACOs (section III.G.3.b. of this proposed rule).

++ Extend the scoring of Shared Savings Program ACOs reporting Medicare CQMs using flat benchmarks (section III.G.3.c. of this proposed rule).

++ Address Shared Savings Program ACOs' challenges with meeting the MIPS data completeness requirement (section III.G.3.d. of this proposed rule):

— Revise the Shared Savings Program quality reporting requirements beginning in PY 2026 (section III.G.3.d.(2) of this proposed rule).

— Establish the Medicare eCQMs collection type for Shared Savings Program ACOs (section III.G.3.d.(3) of this proposed rule).

— Revise the definition of a ''Beneficiary Eligible for Medicare CQMs'' (section III.G.3.d.(4) of this proposed rule).

++ Revise the Shared Savings Program scoring policy for excluded APP Plus measures and APP Plus measures that lack a benchmark (section III.G.3.e. of this proposed rule).

++ Update the APP Plus quality measure set (section III.G.3.f. of this proposed rule).

- Revise Shared Savings Program CEHRT use requirements (section III.G.4. of this proposed rule).

++ Simplify Shared Savings Program CEHRT use requirements (section III.G.4.b. of this proposed rule).

— Meet Shared Savings Program CEHRT use requirement by reporting at least one ACO-reported measure through the eCQMs or Medicare eCQMs collection types (section III.G.4.b.(1) of this proposed rule).

— Meet Shared Savings Program CEHRT use requirements by attesting to using FHIR capabilities in certified health IT to support reporting of at least one of the five ACO-reported measures (section III.G.4.b.(2) of this proposed rule).

— Meet Shared Savings Program CEHRT use requirements by attesting to one of the three ACO CEHRT use metrics (section III.G.4.b.(3) of this proposed rule).

— Revise public reporting requirements (section III.G.4.b.(4) of this proposed rule).

— Require compliance with Shared Savings Program CEHRT use requirements (section III.G.4.b.(5) of this proposed rule).

— Confirm no impact on current Shared Savings Program quality or MIPS scoring policies or process (section III.G.4.b.(6) of this proposed rule).

++ Request information on applying electronic prior authorization measures to Shared Savings Program ACOs (section III.G.4.c. of this proposed rule).

- Revise policies for the Shared Savings Program's financial methodology, including the following (section III.G.5. of this proposed rule):

++ Propose changes to the Shared Savings Program financial methodology to encourage additional savings in two-sided risk (section III.G.5.c. of this proposed rule):

— Increase the sharing rate under Level E of the BASIC track (section III.G.5.c.(1) of this proposed rule).

— Reduce the maximum weight on the regional adjustment for ACOs under the ENHANCED track (section III.G.5.c.(2) of this proposed rule) for ACOs that are lower spending compared to their regional service area.

++ Increase the prior savings adjustment by increasing the scaling factor (section III.G.5.d. of this proposed rule).

++ Risk adjust the 5 percent cap on upward adjustments to the historical benchmark (section III.G.5.e. of this proposed rule).

++ Incentivize new participation through a growth adjustment to the historical benchmark (section III.G.5.f. of this proposed rule).

++ Reform the Accountable Care Prospective Trend (ACPT) component of the benchmark update factor (section III.G.5.g. of this proposed rule).

- Increase beneficiary engagement by allowing ACOs to reduce or eliminate Part B cost sharing for beneficiaries (section III.G.6.a. of this proposed rule), and discontinue availability of the option for prepaid shared savings (section III.G.6.b. of this proposed rule).

- Modify the calculation methodology for setting quarterly advance investment payment amounts and revise the terminology on allowable uses of advance investment payments (section III.G.7. of this proposed rule).

- Revise the approach to determining whether an ACO is experienced or inexperienced with performance-based risk Medicare ACO initiatives (section III.G.8. of this proposed rule).

- Modify Shared Savings Program beneficiary notification requirements (section III.G.9. of this proposed rule):

++ Revise distribution timing of standardized written notices (section III.G.9.b.(1) of this proposed rule).

++ Remove the beneficiary follow-up notice (section III.G.9.b.(2) of this proposed rule).

Additionally, in section II.D. of this proposed rule there is a proposal to replace office/outpatient evaluation and management (O/O E/M) visit complexity add-on code, HCPCS code G2211 with modifiers that would allow for differential payment for ACO participants.

Finally, we are requesting information on potential future policy developments, including: (1) the transition to Fast Healthcare Interoperability Resources®-based quality measurement in the Shared Savings Program (section II.E. of this proposed rule); (2) potential approaches to more effectively integrate and meaningfully engage specialty care in the Shared Savings Program (section III.G.10. of this proposed rule); and (3) potential approaches to introducing primary care—focused capitated payment arrangements in the Shared Savings Program (section II.E. of this proposed rule).

Taken together, the Shared Savings Program proposals in this proposed rule are projected to reduce Trust Fund expenditures by $5.5 billion in total through the end of the 10-year period 2027 through 2036, ranging from approximately $8.9 billion lower spending at the 10th percentile to $2.3 billion lower spending at the 90th percentile, as described in the Regulatory Impact Analysis in section VII. of this proposed rule.

Certain policies, including both existing policies and proposed new policies described in this proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following proposals require the use of our authority under section 1899(i) of the Act: modifications to the ACPT component of the three-way blended benchmark update factor (described in section III.G.5.g. of this proposed rule); discontinuing availability of the option for prepaid shared savings (described in section III.G.6.b. of this proposed rule); and changes to the calculation methodology for quarterly advance investment payments (described in section III.G.7. of this proposed rule). As described in the Regulatory Impact Analysis in section VII. and elsewhere in this proposed rule, these proposed changes to the Shared Savings Program are expected to improve the quality and efficiency of care under the Medicare program and are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies we have adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

We will continue to reexamine this projection in the future to ensure that an alternative payment model does not result in additional program expenditures and so continues to satisfy the requirement under section 1899(i)(3)(B) of the Act. If we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we will undertake notice and comment rulemaking to adjust the payment model to ensure continued compliance with the statutory requirements.

d. PY 2027 Application Cycle Flexibility

Some of the proposed financial methodology changes described in section III.G. of this proposed rule, if finalized, may be consequential for ACOs' decisions to enter an agreement period under Level E of the BASIC track or the ENHANCED track. We anticipate a significant number of renewal applications for the January 1, 2027 agreement period start date. There are currently 96 ACOs that entered an agreement period beginning on January 1, 2022, that would need to apply to renew to continue their participation in the Shared Savings Program by entering an agreement period beginning on January 1, 2027. Considering the timing of CY PFS rulemaking and the Shared Savings Program application cycle for the January 1, 2027 start date (occurring in CY 2026), ACO applicants would have notice of the proposed changes after the deadline for submitting their applications to continue their participation. Additionally, under a previously established timeline for application actions and deadlines, the application cycle would require ACO applicants to finalize their selection of track/level of participation by early September 2026,[213] which is before the CY 2027 PFS final rule will likely be issued. ACO applicants will have to make their final selection between the BASIC track and ENHANCED track before the CY 2027 PFS rule is finalized. To mitigate the potential impact on ACO applicants in making their final selection of track/level of participation in the Shared Savings Program, we anticipate providing ACOs applying for an agreement start date of January 1, 2027, with a time limited opportunity to change their final selection between the BASIC track and ENHANCED track (if eligible). We also note that an ACO applicant that has not submitted an application for a January 1, 2027 agreement start date as of the date of display of this proposed rule that wishes to enter a new agreement in the Shared Savings Program, may apply to enter a new agreement period beginning on January 1, 2028 during the application cycle occurring in CY 2027.

2. Beneficiary Assignment Methodology

a. Proposed Modifications to the Shared Savings Program Assignment Methodology

(1) Background

Under section 1899(b)(2)(A) of the Act, an ACO must ''be willing to become accountable for the quality, cost, and overall care of the Medicare fee-for-service beneficiaries assigned to it.'' As defined in section 1899(h)(3) of the Act and in the Shared Savings Program's regulations at § 425.20, the term ''Medicare fee-for-service beneficiary'' means an individual who is enrolled in the original Medicare FFS program under Parts A and B and is not enrolled in a Medicare Advantage (MA) plan under Part C, an eligible organization under section 1876 of the Act, or a Program of All-Inclusive Care for the Elderly (PACE) program under section 1894 of the Act. Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act (Pub. L. 114–255) and the Bipartisan Budget Act of 2018 (Pub. L. 115–123), provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided by physicians in the ACO who are ACO professionals and, in the case of PYs beginning on or after January 1, 2019, services provided by a Federally Qualified Health Center (FQHC) or Rural Health Clinic (RHC). In the context of the Shared Savings Program, ''assignment'' (as defined in § 425.20) refers to an operational process by which we determine whether a beneficiary has chosen to receive a sufficient level of certain primary care services from physicians and other health care practitioners associated with a specific ACO so that the ACO may be

[213] See CMS, Medicare Shared Savings Program, ''Key Application Actions and Deadlines For Agreement Periods Beginning on February 1, 2027'', available at *https://www.cms.gov/files/document/*XEI*key-application-actions-deadlines.pdf.*

appropriately designated as exercising basic responsibility for that beneficiary's care during a given benchmark year or PY.[214] We refer to the process by which we determine assignment under section 1899(c)(1) of the Act as ''claims-based assignment''.

Further, under section 1899(c)(2)(B) of the Act, a non-claims-based process for voluntary alignment applies to all Shared Savings Program ACOs and is used to supplement claims-based assignment. In accordance with section 1899(c)(2)(B)(iii) of the Act, voluntary alignment supersedes claims-based assignment.

The regulations governing the assignment methodology under the Shared Savings Program, with provisions on claims-based assignment and voluntary alignment, are in 42 CFR part 425, subpart E. In the sections that follow we provide additional regulatory background about the Shared Savings Program's stepwise claims-based assignment methodology (section III.G.2.a.(1)(a) of this proposed rule) and criteria based on Medicare enrollment status that we use to determine a beneficiary's eligibility for assignment (section III.G.2.a.(1)(b) of this proposed rule), provide an overview of assignment-based program operations (section III.G.2.a.(1)(c) of this proposed rule), and describe beneficiaries excluded from the assigned population under the current assignment methodology (section III.G.2.a.(1)(d) of this proposed rule).

(a) Background on Step-wise Assignment Methodology

As we have described in the CY 2024 PFS final rule (88 FR 79136), under claims-based assignment, we determine a Medicare FFS beneficiary is assigned to an ACO if the beneficiary meets the criteria in § 425.401(a) to be eligible for assignment to an ACO, and the beneficiary's utilization of primary care services [215] meets the criteria established under the assignment methodology specified in § 425.402 (specifying the basic assignment methodology) and § 425.404 (specifying special assignment conditions for ACOs including FQHCs and RHCs). Section 425.402 specifies a step-wise assignment methodology for determining an ACO's assigned beneficiary population based on beneficiaries' use of primary care services. Section 425.402(b) of the Shared Savings Program regulations specifies the step-wise methodology we use to assign Medicare FFS beneficiaries to an ACO based on available claims information, for PY 2016 and subsequent PYs. In accordance with § 425.404(b), for PYs starting on January 1, 2019, and subsequent PYs, under the assignment methodology in § 425.402, we treat a service reported on an FQHC or RHC claim as a primary care service performed by a primary care physician.

The Shared Savings Program step-wise assignment process is offered in two similar, but distinct, claims-based assignment methodologies: prospective assignment as specified under § 425.400(a)(3); and preliminary prospective assignment with retrospective reconciliation as specified under § 425.400(a)(2). Consistent with the requirements of section 1899(c)(2)(A) of the Act, we offer all Shared Savings Program ACOs the opportunity to select their assignment methodology annually, starting with agreement periods beginning on July 1, 2019, in accordance with §§ 425.400(a)(4)(ii) and 425.226(a)(1). We use the same step-wise assignment methodology under § 425.402 to assign beneficiaries to ACOs under prospective assignment and ACOs under preliminary prospective assignment with retrospective reconciliation.

The step-wise assignment methodology was initially established with the November 2011 final rule and was modified through subsequent rulemaking. For a discussion of the relevant background and related considerations, we refer readers to the November 2011 final rule (76 FR 67853 through 67858), June 2015 final rule (see 80 FR 32699 through 32701, and 32748 through 32755), CY 2023 PFS final rule (87 FR 69825 through 69829), and the CY 2024 PFS final rule (88 FR 79136 through 79163). We have detailed how we perform claims-based assignment in programmatic material, including publicly available specifications documents. See, for example, Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (Section 2.3 Claims-Based Assignment).

In the discussion that follows, we first describe our use of the ACO participant list to identify primary care services billed by ACO professionals and CMS certification numbers (CCNs) used in the assignment methodology, and then we describe the steps of the claims-based assignment process.

(i) Use of ACO Participant List To Identify Primary Care Services Billed by ACO Professionals and CCNs Used in Assignment Calculations

As we described in the CY 2023 PFS final rule (87 FR 69825), under the Shared Savings Program, ACOs are accountable for the quality, cost, and overall care of the Medicare FFS beneficiaries that are assigned to the ACO (§ 425.100(a)). ACOs are formed by one or more ''ACO participants,'' which are responsible for managing and coordinating care for the assigned beneficiary population. The Shared Savings Program regulations define ''ACO participant'' at § 425.20 as an entity identified by a Medicare-enrolled billing Taxpayer Identification Number (TIN) through which one or more ''ACO providers/suppliers'' (as defined at § 425.20) bill Medicare, that alone or together with one or more other ACO participants compose an ACO, and that is included on the list of ACO participants that is required under § 425.118 (herein ''ACO participant list''). An ''ACO provider/supplier'' is an individual or entity that: (1) is a provider (as defined at § 400.202) or supplier (as defined at § 400.202); (2) is enrolled in Medicare; (3) bills for items and services furnished to Medicare FFS beneficiaries during the agreement period under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations; and (4) is included on the list of ACO providers/suppliers that is required under § 425.118 (herein ''ACO provider/supplier list'').[216] We require each ACO to execute contractual agreements with each of its ACO participants (''ACO participant agreements''), to ensure that the ACO participant and each ACO provider/supplier billing through the TIN of the ACO participant agree to the requirements of the Shared Savings Program (see 87 FR 69825, and see also § 425.116).

As we explained in the CY 2023 PFS final rule (87 FR 69825 through 69826),

[214] As we have explained in earlier rulemaking (see 88 FR 79136; see also 76 FR 67851, and 83 FR 67863), the term ''assignment'' for purposes of the Shared Savings Program in no way implies any limits, restrictions, or diminishment of the rights of Medicare FFS beneficiaries to exercise freedom of choice in the physicians and other health care practitioners from whom they receive covered services.

[215] As described in section III.G.2.b. of this proposed rule, we define primary care services for purposes of the Shared Savings Program in § 425.20 as a set of services identified by HCPCS codes and CPT codes, as specified under § 425.400(c).

[216] For additional background on development and maintenance of the ACO provider/supplier list, we refer readers to the CY 2023 PFS final rule at 87 FR 69826.

under § 425.118(a), an ACO must maintain, update, and submit to us an accurate and complete list identifying each ACO participant (including its Medicare-enrolled TIN) and each ACO provider/supplier (including its National Provider Identifier (NPI), CCN, or other identifier). More specifically, an ACO must submit a draft ACO participant list before the start of an agreement period and before each performance year thereafter. In accordance with § 425.118(a)(3), the ACO must certify the accuracy of its ACO participant list before the start of its agreement period and before each performance year thereafter. An ACO must maintain and periodically update its ACO participant list. For additional background on development and maintenance of the ACO participant list we refer readers to the CY 2023 PFS final rule at 87 FR 69826, and CY 2026 PFS final rule at 90 FR 49775 through 49778.

More generally, in accordance with § 425.102(a), an ACO may be formed from the following ACO participants or combinations of ACO participants: (1) ACO professionals in group practice arrangements; (2) networks of individual practices of ACO professionals; (3) partnerships or joint venture arrangements between hospitals and ACO professionals; (4) hospitals employing ACO professionals; (5) Critical Access Hospitals (CAHs) that bill under Method II (as described in § 413.70(b)(3)); (6) RHCs; (7) FQHCs; and (8) teaching hospitals that have elected under § 415.160 to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians (herein referred to as electing teaching amendment (ETA) hospitals).

Under § 425.20, ''ACO professional'' is defined to mean an individual who is Medicare-enrolled and bills for items and services furnished to Medicare FFS beneficiaries under a Medicare billing number assigned to the TIN of an ACO participant in accordance with applicable Medicare regulations and who is either of the following: (1) a physician legally authorized to practice medicine and surgery by the State in which he or she performs such function or action; or (2) a practitioner who is a physician assistant (PA), a nurse practitioner (NP), or a clinical nurse specialist (CNS).[217] As detailed in section III.G.2.a.(1)(ii) of this proposed rule, the stepwise assignment methodology considers primary care services furnished by the following ACO professionals: primary care physicians (as defined in § 425.20), physicians with specialty designations included in § 425.402(c), and non-physician ACO professionals (NPs, PAs, CNSs) (herein collectively referred to as ''ACO professionals used in assignment'' for brevity).

Under the claims-based assignment process we identify allowed charges for a beneficiary's primary care services received in an ACO (furnished by ACO professionals used in assignment billing through the TIN of an ACO participant or an FQHC, RHC, Method II CAH, or ETA hospital identified by a CCN enrolled under the TIN of an ACO participant), in any other ACO, or other individual practitioners, or groups of practitioners identified by Medicare-enrolled billing TINs or CCNs that are not participating in the Shared Savings Program. We use the ACO participant list certified by the ACO to identify ACO professionals used in assignment that are billing primary care services, and to identify CCNs enrolled under the TIN of an ACO participant, for purposes of performing claims-based assignment for the PY, and, if applicable, assignment for the ACO's benchmark years in the case of establishing or adjusting the ACO's historical benchmark under subpart G (see § 425.652(a)).

We use different approaches to identifying primary care services furnished by ACO professionals and CCNs enrolled under the TIN of an ACO participant. Because of the billing relationship between an ACO professional and an ACO participant, any claims for primary care services billed by an ACO professional through the TIN of an ACO participant would be used for assignment. We note that operationally we identify an ACO professional based on the physician's or non-physician practitioner's NPI. As we explained in the CY 2023 PFS final rule (87 FR 69826), for purposes of beneficiary assignment, we identify claims for services furnished by Method II CAHs, ETA hospitals, FQHCs, and RHCs using the CCN assigned to the facility. Section 425.402(f) includes provisions on how we identify services furnished by FQHCs, RHCs, Method II CAHs, and ETA hospitals, based on CCNs enrolled under the TIN of an ACO participant, for purposes for beneficiary assignment for PY 2023 and subsequent PYs. Under this approach, we use the Provider Enrollment, Chain, and Ownership System (PECOS) to determine the CCNs for all FQHCs, RHCs, Method II CAHs, and ETA hospitals enrolled under the TIN of an ACO participant prior to the start of performance year, and periodically during the performance year, and account for changes in CCN enrollment status during the PY.[218] We also note that the claims data used for assignment for FQHCs, RHCs, Method II CAHs, and ETA hospitals are limited to outpatient facility claims, and have specified in program specifications additional steps we use to identify data on outpatient facility claims for these four provider types.[219]

As specified in § 425.306, each ACO participant that submits claims for services used to determine the ACO's assigned population under subpart E of part 425 must be exclusive to one Shared Savings Program ACO. In initially establishing exclusivity requirements for ACO participants in the November 2011 final rule (76 FR 67811), we explained that individual NPIs are free to participate in multiple ACOs if they bill under several different TINs. We explained that when providers whose services are the basis of assignment bill under two or more TINs, each TIN would be exclusive to only one ACO, assuming both TINs have both joined as participants, but the provider billing under the TINs would not have to be exclusive to one ACO. In the February 2016 proposed rule (81 FR 5824, 5849), we recognized there may be cases where a beneficiary is receiving primary care services from ACO participants in multiple ACOs or from both ACO participants and non-ACO providers and suppliers. We explained that in such cases, the composition of each ACO is important in determining whether the beneficiary is assigned to an ACO at all, and in determining to which ACO (among several) the beneficiary may be assigned. As we explained in the CY 2023 PFS final rule (87 FR 69828), our policies for accounting for changes in CCN enrollment status, for identifying services furnished by FQHCs, RHCs, Method II CAHs, and ETA hospitals for purposes of beneficiary assignment, reflect our operational approach to treat CCNs in a similar fashion to ACO participant TINs and not allow a CCN to switch between ACOs during the performance year (see § 425.402(f)(3)(iii)). In earlier

[217] Sometimes we refer to NPs, PAs, and CNSs who are ACO professionals in the ACO as ''non-physician ACO professionals''.

[218] We refer readers to the discussion in the CY 2023 PFS final rule at 87 FR 69825 through 69829.

[219] See Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (Appendix D: Outpatient Facility Claims Used in Beneficiary Assignment).

rulemaking, we have not more generally sought to address the impact on assignment of an ACO professional used in assignment (NPI) billing primary care services for a beneficiary through an ACO participant TIN and non-ACO TIN, and related policy considerations.

(ii) Steps of the Claims-Based Assignment Process

In each step of the claims-based assignment process, we determine whether the allowed charges for a beneficiary's primary care services in an ACO are greater than allowed charges for the beneficiary's primary care services in any other ACO, or other individual practitioners, or groups of practitioners identified by Medicare-enrolled billing TINs or CCNs that are not participating in the Shared Savings Program (that is, a non-ACO individual or group TIN or non-ACO CCN). In doing so, we determine which ACO or non-ACO entity provided a beneficiary's plurality of allowed charges for primary care services for purposes of assignment. Herein, for brevity, we sometimes refer to this stage of the assignment process as ''plurality competition''.[220]

To follow is a summary of the steps used in the claims-based assignment methodology under § 425.402(b):

In accordance with § 425.402(b)(1), as a ''pre-step'' to the first and second step of the claims-based assignment process, CMS identifies all beneficiaries who had at least one primary care service during the applicable assignment window[221] with a physician who is an ACO professional in the ACO and who is a primary care physician as defined under § 425.20 or has one of the primary specialty designations specified in § 425.402(c). This pre-step is designed to satisfy the statutory requirement under section 1899(c)(1) of the Act that beneficiaries be assigned to an ACO based on their use of primary care services furnished by physicians participating in the ACO. Beneficiaries who meet the pre-step requirement are then assigned to an ACO through either the first or second step of the assignment methodology specified in § 425.402(b)(3) and (b)(4).

As described in § 425.402(b)(2), for beneficiaries who meet the pre-step requirement under § 425.402(b)(1), CMS identifies all primary care services furnished by ACO professionals of that ACO who are primary care physicians as defined under § 425.20, non-physician ACO professionals, and physicians with specialty designations included in § 425.402(c) during the applicable assignment window. This provision reflects an operational step necessary to identify the sum of allowed charges for primary care services for a beneficiary received in an ACO (furnished by ACO professionals used in assignment billing through the TIN of an ACO participant or CCNs enrolled under the TIN of an ACO participant), as compared to any other ACO, non-ACO CCN, or non-ACO individual or group TIN, for determining the outcome of the plurality competition under step 1 and step 2 of the assignment methodology.

Under the first step of the assignment process, specified at § 425.402(b)(3), a beneficiary who is eligible for assignment and meets the pre-step requirement is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for primary care services furnished during the assignment window by primary care physicians, NPs, PAs, or CNSs who are ACO professionals in any other ACO, or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN (that is, a non-ACO CCN, or non-ACO individual or group TIN).

The second step of the assignment methodology, specified at § 425.402(b)(4), applies to the remainder of the beneficiaries who are eligible for assignment and meet the pre-step requirement, who have not had a primary care service rendered during the assignment window by any primary care physician, NP, PA, or CNS, either inside or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary during the assignment window by physicians who are ACO professionals with specialty designations specified in § 425.402(c) are greater than the allowed charges for primary care services furnished during the assignment window by physicians with such specialty designations who are ACO professionals in any other ACO, or who are unaffiliated with an ACO and are identified by a Medicare-enrolled billing TIN (that is, a non-ACO CCN, or non-ACO individual or group TIN).

For PY 2025 and subsequent PYs, as specified in § 425.402(b)(5), we employ a third step to assign eligible Medicare FFS beneficiaries who are not identified by the ''pre-step'' criterion specified under § 425.402(b)(1). In this step, we identify all beneficiaries who had at least one primary care service with a non-physician ACO professional in the ACO during the applicable assignment window, and had at least one primary care service with a physician who is an ACO professional in the ACO and who is a primary care physician or who has one of the primary specialty designations included in § 425.402(c) during the applicable expanded window for assignment (see § 425.402(b)(5)(i) through (ii)).[222] As described in § 425.402(b)(5)(iii), for a beneficiary meeting the aforementioned criteria in § 425.402(b)(5)(ii), we identify all primary care services furnished by ACO professionals in the ACO who are primary care physicians, non-physician ACO professionals, and physicians with specialty designations included in § 425.402(c) during the applicable expanded window for assignment. The identification of primary care services described in § 425.402(b)(5)(iii) serves as an operational step which is similar to the step described in § 425.402(b)(2). This operational step is necessary to identify the sum of allowed charges for primary care services for a beneficiary received in an ACO (furnished by ACO professionals used in assignment billing through the TIN of an ACO participant or CCNs enrolled under the TIN of an ACO participant), as compared to any other ACO, non-ACO CCN, or non-ACO individual or group TIN, for determining the outcome of the plurality competition under step 3.

In accordance with § 425.402(b)(5)(iv), a beneficiary identified in § 425.402(b)(5)(ii) who is eligible for assignment is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, physicians with specialty designations included in

[220] We have infrequently made references to ''competition'' in claims-based assignment in earlier rulemaking. See, for example, 85 FR 84790 (in describing observations based on internal analysis of the rate at which beneficiaries are assigned to an ACO and subsequently not assigned to that ACO), and 89 FR 98197 through 98198 (in generally referring to the ACOs included in the claims-based assignment competition).

[221] As defined in § 425.20, ''assignment window'' means the 12-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both. As we explained in the CY 2024 PFS final rule (88 FR 79137, see also 83 FR 67860), the assignment window for ACOs under prospective assignment is a 12-month period offset from the calendar year (for example, October through September preceding the calendar year), while for ACOs under preliminary prospective assignment with retrospective reconciliation, the assignment window is the 12-month period based on the calendar year.

[222] As defined in § 425.20, ''expanded window for assignment'' means the 24-month period used to assign beneficiaries to an ACO, or to identify assignable beneficiaries, or both that includes the applicable 12-month assignment window and the preceding 12 months.

§ 425.402(c), or non-physician ACO professionals during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations included in § 425.402(c), NPs, PAs, and CNSs who are ACO professionals in any other ACO, or not affiliated with any ACO and identified by a Medicare-enrolled billing TIN (that is, a non-ACO CCN, or non-ACO individual or group TIN).

As previously described, under § 425.402(b)(3), (b)(4), (b)(5)(iv), the plurality competition which occurs in each step of assignment compares allowed charges for primary care services furnished to a beneficiary by certain ACO professionals in an ACO with allowed charges for primary care services furnished by the same type of health care providers who are either (1) ACO professionals in any other ACO, or (2) not affiliated with any ACO and identified by a Medicare-enrolled billing TIN. Under the existing provisions, for purposes of plurality competition, we attribute to a non-ACO TIN the allowed charges for primary care services for a beneficiary furnished by an ACO professional that are billed through the non-ACO TIN. In determining the outcome of plurality competition for a beneficiary we consider both: (1) allowed charges for primary care services for the beneficiary received inside the ACO (furnished by an ACO professional or FQHC, RHC, Method II CAH or ETA hospital that has enrolled under the TIN of an ACO participant), and (2) allowed charges for primary care services for the same beneficiary being billed by the same ACO professional outside the ACO to a non-ACO TIN. As a result, a beneficiary may be identified as receiving the plurality of their primary care services outside an ACO based on a difference in the TIN to which the services are being billed by their health care provider who is an ACO professional used in assignment. Under these circumstances, when the plurality of allowed charges for primary care services is attributed to a non-ACO TIN, the ACO whose ACO professionals are furnishing services to the beneficiary would not be held accountable for the beneficiary's quality and cost of care.

(b) Background on Criteria Based on Medicare Enrollment Status Use To Identify Beneficiaries Eligible for Assignment and the Assignable Beneficiary Population

With the June 2015 final rule (see 80 FR 32743 through 32746, 32774 through 32775, and 32840 through 32841), we added § 425.401, establishing criteria for a beneficiary to be assigned to an ACO, which included assignment eligibility criteria under § 425.401(a), and exclusion criteria for prospectively assigned beneficiaries under § 425.401(b).[223] These criteria included requirements based on a beneficiary's Medicare enrollment status. Additional background on considerations in establishing the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status is provided in section III.G.2.a.(2)(b) of this proposed rule.

In subsequent rulemaking, we finalized amendments to § 425.401(b) introductory text, to apply the prospective assignment exclusion criteria in determining beneficiaries that would remain prospectively assigned at the end of CY 2019 to an ACO participating in a 6-month PY or performance period during 2019. Refer to the CY 2019 PFS final rule at 83 FR 59946 through 59947, and 60093; and the December 2018 final rule at 83 FR 67951, and 68069. We note that the criteria for determining a beneficiary's eligibility for assignment under § 425.401(a), and the prospective assignment exclusion criteria specified under § 425.401(b)(1) through (3), have remained unchanged since being finalized with the June 2015 final rule.

Currently, in accordance with § 425.401(a), a beneficiary may be assigned to an ACO under the assignment methodology in §§ 425.402 and 425.404, for a performance or benchmark year, if the beneficiary meets all of the following criteria during the assignment window:

(1) Has at least 1 month of Part A and Part B enrollment, and does not have any months of Part A only or Part B only enrollment.

(2) Does not have any months of Medicare group (private) health plan enrollment.

(3) Is not assigned to any other Medicare shared savings initiative.

(4) Lives in the United States (U.S.) or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

If a beneficiary meets the above criteria, and then is assigned to an ACO that is participating under prospective assignment, the beneficiary may be later excluded from the ACO's prospective assignment list if they no longer meet these eligibility criteria. In accordance with § 425.401(b), a beneficiary is excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each PY consistent with § 425.400(a)(3)(ii), if the beneficiary meets any of the following criteria during the performance or benchmark year: [224]

(1) Does not have at least 1 month of Part A and Part B enrollment, and has any months of Part A only or Part B only enrollment.

(2) Has any months of Medicare group (private) health plan enrollment.

(3) Did not live in the U.S. or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residency at the end of the year.

We have also applied the eligibility criteria established at § 425.401(a) and the prospective assignment exclusion criteria at § 425.401(b) in determining whether a beneficiary is eligible to be assigned to an ACO through voluntary alignment. We refer readers to discussions in earlier rulemaking (see 81 FR 80501 through 80510, 83 FR 59959 through 59964, and 89 FR 98097 through 98101), on the establishment of and modifications to these policies. With the CY 2025 PFS final rule (89 FR 98097 through 98101), we finalized the voluntary alignment policies applicable for PY 2025 and subsequent PYs under § 425.402(e)(2)(iii).

In accordance with § 425.402(e)(2)(iii)(A), among other conditions that must be satisfied for a beneficiary to be prospectively assigned to an ACO through voluntary alignment for PY 2025 and subsequent PYs, the beneficiary must meet the eligibility criteria established at § 425.401(a), and must not be excluded by the criteria at § 425.401(b). Further, as specified under § 425.402(e)(2)(iii)(A), the exclusion criteria at § 425.401(b) apply for purposes of determining beneficiary eligibility for voluntary alignment to an ACO based on the beneficiary's designation of an ACO professional as responsible for coordinating their overall care under § 425.402(e), regardless of the ACO's assignment methodology selection under § 425.226(a)(1).

[223] We also refer readers to the related discussion in the proposed rule entitled ''Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations'', which appeared in the December 8, 2014 **Federal Register** (79 FR 72760, 72790 through 72792, and 72811).

[224] We note the introductory text of § 425.401(b) includes a reference to applicability of the prospective assignment exclusion criteria for determining assignment to ACOs participating under a 6-month performance year or performance period during CY 2019, under § 425.609(b)(1)(ii) and (c)(1)(ii).

There is currently asymmetry in the requirements used to identify the ACO assigned population under criteria in § 425.401 based on Medicare enrollment status, and the broader ''assignable beneficiary'' population (as defined in § 425.20), used in determining factors based on national and regional Medicare FFS expenditures.[225] As we have explained in earlier rulemaking, the assignable population is a subset of the larger population of Medicare FFS beneficiaries (see, for example, 88 FR 79138). Under our operational approach to identifying the assignable beneficiary population, we require that the beneficiary have at least 1 month of Part A and Part B enrollment and no Medicare group health plan enrollment (including MA) during that same month during the applicable 12-month assignment window. In comparison, for a beneficiary to be eligible to be assigned to an ACO under the criteria in § 425.401(a)(1) through (2) the beneficiary must: (1) have at least 1 month of Part A and Part B enrollment, and not have any months of Part A only or Part B only enrollment during the assignment window; and (2) not have any months of Medicare group (private) health plan enrollment during the assignment window. As a result, beneficiaries with one or more month of Part A only or Part B only enrollment, or Medicare group health plan enrollment during the assignment window could be included in the assignable beneficiary population, while beneficiaries with such Medicare enrollment status are ineligible for assignment to an ACO.

With the June 2016 final rule (see 81 FR 37985 through 37989), we established the use of the assignable population, rather than the broader Medicare FFS population in certain financial calculations based on national and regional FFS expenditures. In the June 2016 final rule (81 FR 37961), we explained that this approach to use the assignable population ensured these calculations were based on beneficiaries that have some chance of being assigned to the ACO. We also clarified that some beneficiaries who meet the definition of ''assignable beneficiary'' will ultimately be excluded from assignment to an ACO for purposes of determining the ACO's benchmark year or PY expenditures because they fail to meet the assignment criteria specified under § 425.401(a). In subsequent rulemaking we have established policies to ensure alignment between the assigned and assignable populations [226] or calculations based on these populations.[227] However, we did not previously seek to address the differences in Medicare enrollment status of beneficiaries in the assignable population and the assigned population.

(c) Overview of Assignment-Based Program Operations

Various Shared Savings Program operations are based on the ACO's assigned population, or consider the size of the ACO's assigned population, as described in prior rulemaking (see, for example, 88 FR 79137 through 79138). To follow is a summary of these policies, including references to proposed changes to Shared Savings Program policies elsewhere in section III.G. of this proposed rule.

Various aspects of the Shared Savings Program's financial methodology under subpart G depend on the size or composition of the ACO's assigned population, including calculating the ACO's benchmark and performance year expenditures, and adjusting and updating the ACO's benchmark. For each performance year, we determine whether the estimated average per capita Medicare Parts A and B FFS expenditures for Medicare FFS beneficiaries assigned to the ACO are above or below the ACO's updated benchmark, to determine whether the ACO qualifies for a shared savings payment or is responsible for sharing losses with CMS (as applicable) (§§ 425.605(a) and 425.610(a)). In computing an ACO's historical benchmark, we determine the per capita Parts A and B FFS expenditures for beneficiaries that would have been assigned to the ACO in any of the 3 most recent years prior to the start of the ACO's agreement period, in accordance with § 425.652(a) and (c). In benchmark calculations, the assigned population is the basis for determining the ACO's regional service area used in calculating the two-way blend of national and regional growth rates applied in trending and updating the ACO's benchmark (§ 425.652(a)(5)(iv)–(v), and (b)(2)), and the regional adjustment to the benchmark (§ 425.656). The assigned population is also used in calculating a proration factor applied in the prior savings adjustment (§ 425.658(b)(3)), and in determining an ACO's eligibility for and the amount of the population adjustment to the historical benchmark (§ 425.662(b)). The average prospective HCC risk scores for the ACO's assigned beneficiaries are used to risk adjust the ACO's benchmark expenditures (§§ 425.652(a)(3) and (10); 425.605(a)(1); 425.610(a)(2)), and other benchmark calculations (see, for example, § 425.656(b)(3) and (4) on calculating the regional adjustment, and § 425.660(b)(4) on calculating the ACPT component of the three-way blended benchmark update factor). As another example, as described in section III.G.5.e of this proposed rule, we are proposing to risk adjust the 5 percent cap on upward adjustments to the benchmark, based on average CMS–HCC risk scores for the ACO's assigned beneficiary population. In addition, we use the size of the ACO's assigned population in other financial calculations, including: determining the MSR/MLR threshold based on the ACO's number of assigned beneficiaries (§§ 425.605(b)(2)(i)(C) and 425.610(b)(1)(iii)); determining the eligibility of a low revenue ACO participating in the BASIC track for an opportunity to share in savings even if it does not meet the MSR (§ 425.605(h)); and determining the applicability of an alternative performance payment limit or loss recoupment limit for an ACO with fewer than 5,000 assigned beneficiaries in any benchmark year (§§ 425.605(i) and 425.610(l)).

The size of the ACO's assigned population is the basis for our determinations related to participation requirements and payment methodologies. For instance, we evaluate whether an ACO meets the requirement to have at least 5,000 assigned beneficiaries to be eligible to participate in the Shared Savings Program (§§ 425.110 and 425.600(h)(3)). We also use the ACO's number of assigned beneficiaries in repayment mechanism amount calculations (§ 425.204(f)), and in determining expenditures based on the ACO's assigned population when identifying if the ACO is a high revenue or low revenue ACO (as defined under § 425.20) for purposes of determining an ACO's eligibility for the Advance Investment Payment option (§ 425.630(b)(4)).

The ACO's assigned population informs the amount of quarterly

[225] With the June 2016 final rule (see, for example, 81 FR 37985 through 37989, and 38013), we finalized the definition for ''assignable beneficiary'' under § 425.20, which we subsequently amended with the CY 2024 PFS final rule (88 FR 79143 through 79144, and 79162 through 79163).

[226] We refer readers to the CY 2024 PFS final rule (88 FR 79136 through 79163), in which we finalized use of an expanded window for assignment in both step 3 of the assignment methodology, and the definition of an assignable beneficiary, which we explained was necessary to maintain symmetry between the two approaches (see, for example, 88 FR 79158).

[227] We refer readers the CY 2023 PFS final rule (87 FR 69929 through 69932), in which we finalized modifications to our methodology for calculating county FFS expenditures to provide for the use of separate assignment windows for ACOs depending on their selected assignment methodology, to address and protect against bias in the calculations.

advance investment payments (§ 425.630(b) and (f)) and prepaid shared savings (§ 425.640(f) and (h)) for eligible ACOs. Elsewhere in this proposed rule we are proposing to amend the quarterly advance investment payment calculation methodology (section III.G.7.) and discontinue availability of the option for prepaid shared savings (section III.G.6.b.).

The assigned population is central to other programmatic areas, including quality and financial extreme and uncontrollable circumstances policies (see § 425.512(c)(1)(i); see also §§ 425.605(f)(1)–(2) and 425.610(i)(1)–(2)), and CMS's provision of beneficiary-identifiable data and aggregate reports to ACOs under subpart H.

(d) Beneficiaries Excluded From the Assigned Population Under the Current Assignment Methodology Based on the Assignment Calculations and Medicare Enrollment Status

As previously noted in the background discussion in section III.G.2.a.(1) of this proposed rule, current policies exclude beneficiaries from assignment when, for example, a non-ACO TIN is determined to provide the plurality of a beneficiary's primary care services as a result of ACO professionals billing primary care services for the beneficiary inside and outside the ACO, or when we determine a beneficiary is ineligible for assignment based on Medicare enrollment status. Our estimates, based on simulations using PY 2024 data, suggest the former leads to approximately 97,800 beneficiary person years not being assigned to an ACO due to non-ACO TIN being identified as providing the plurality of the beneficiary's primary care services, and the latter leads to approximately 248,000 beneficiary person years not being assigned due only to their Medicare enrollment status.[228]

We are currently seeking approaches to expand the population of Medicare FFS beneficiaries for which ACOs are accountable for quality and cost of care. ACOs provide high-quality care to people with Medicare, and they are a critical tool to help Make America Healthy Again by supporting whole person care that addresses prevention, chronic illness and the root causes of disease, and achieving savings for the Medicare Trust Funds.[229] As described in section III.G.1.a. of this proposed rule, as part of our effort to align spending and value in OM, we are focused on developing policies that would grow the number of Medicare FFS beneficiaries in accountable care relationships and grow savings to the Medicare Trust Funds.

Since PY 2024, we have seen the number of beneficiaries assigned to Shared Savings Program ACOs steadily increase.[230] As of January 1, 2024, 10.8 million beneficiaries were initially assigned to 480 ACOs. As of January 1, 2025, 11.2 million beneficiaries were initially assigned to 477 Shared Savings Program ACOs. As of January 1, 2026, Shared Savings Program ACOs are serving 12.6 million beneficiaries that were initially assigned to 511 ACOs, a 12.3 percent increase from 2025, and the largest number ever served by the Shared Savings Program.[231] However, the number of beneficiaries assigned to Shared Savings Program ACOs remains a fraction of the larger OM population. Based on an internal analysis, for PY 2024, about one-third (10.3 million) of the OM population (30.8 million) was assigned to an ACO participating under the Shared Savings Program.[232] [233]

Our proposals to modify the Shared Savings Program assignment policies on plurality competition and assignment eligibility criteria based on Medicare enrollment status represent an opportunity to make meaningful steps toward achieving our stated goals around growing the number of Medicare FFS beneficiaries involved in accountable care relationships and also to further strengthen Shared Savings Program policies. Regarding the latter, as described further in section III.G.2.a.(2)(a) of this proposed rule, our proposed changes to assignment calculations would reduce the potential for ACO professionals' billing patterns inside and outside the ACO for the care of the same beneficiaries to result in differences in assignment outcomes that advantage the ACO's financial performance. As described in section III.G.2.a.(2)(b) of this proposed rule, our proposed changes to the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status to align with the approach to identifying the assignable population would allow for greater symmetry between the ACO assigned population and the assignable population, and help ensure consistency between Shared Savings Program calculations used in determining ACO financial performance.

(2) Proposed Revisions

(a) Proposal To Exclude From Assignment Calculations Allowed Charges for Primary Care Services Billed Through a Non-ACO TIN by an ACO Professional Used in Assignment

As described in section III.G.2.a.(1)(a)(ii) of this proposed rule, in claims-based assignment calculations for a beneficiary we consider allowed charges for primary care services furnished by an ACO professional billed through an ACO participant TIN (that is, inside the ACO), and allowed charges for primary care services furnished by the same ACO professional billed through a non-ACO TIN (that is, outside the ACO). Under current assignment polices, it is possible that a beneficiary may not be assigned to an ACO, despite choosing to receive care from the same physician or non-physician practitioner, only because of a difference in the TIN through which the services are being billed.

We propose to amend the Shared Savings Program assignment methodology to address the circumstance under which ACO professionals used in assignment bill primary care services for a beneficiary through an ACO participant TIN and non-ACO TIN. More specifically, we propose to remove from assignment

[228] Person years represents the sum of fractions of the year during which beneficiaries were enrolled in one of four Medicare enrollment types (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries). In section III.G.2.a.(2)(b) of this proposed rule, we describe in greater detail our consideration of Shared Savings Program-eligible months in identifying beneficiaries eligible for assignment.

[229] See CMS, Fact Sheet, ''2026 Medicare Accountable Care Organization Initiatives Participation Highlights'' (February 4, 2026), available at *https://www.cms.gov/newsroom/fact-sheets/2026-medicare-accountable-care-organization-initiatives-participation-highlights*.

[230] See ''Shared Savings Program Fast Facts—As of January 1, 2026'', available at *https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf* (specifying the count of beneficiaries initially assigned to ACOs for each performance year). Performance year specific ''Fast Facts'' are available through the Medicare Shared Savings Program website, Program Data web page at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/data*. See also the ''Fast Facts Archives'' (zip file), available at *https://www.cms.gov/files/zip/fast-facts-archives.zip*.

[231] CMS, Fact Sheet, ''2026 Medicare Accountable Care Organization Initiatives Participation Highlights'' (February 4, 2026), available at *https://www.cms.gov/newsroom/fact-sheets/2026-medicare-accountable-care-organization-initiatives-participation-highlights*.

[232] See, for example, Medicare Shared Savings Program, Performance Year Financial and Quality Results, Public Use File for PY 2024, available at *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results* (including a variable ''Total Assigned Beneficiaries'', specifying number of assigned beneficiaries for PY 2024, which summed across ACOs reconciled for PY 2024 totals 10,326,340).

[233] For purposes of this analysis, the total population of 30.8 million includes all beneficiaries with at least 1 month of Part A and Part B enrollment and no Medicare group (private) health plan enrollment (including MA) in that same month during the year.

calculations for purposes of plurality competition in step 1 under § 425.402(b)(3), step 2 under § 425.402(b)(4), and step 3 under § 425.402(b)(5)(iv), allowed charges for primary care services billed through a non-ACO TIN by an ACO professional used in assignment.

This proposed change would only impact the determination of assignment under the Shared Savings Program, and would not change how assigned beneficiary expenditures are calculated under the Shared Savings Program's financial methodology, for a benchmark year (in accordance with § 425.652(a)) or performance year (in accordance with §§ 425.605(a) and 425.610(a)). Under this proposal, assigned beneficiary expenditures for purposes of Shared Savings Program financial calculations would continue to include payment amounts for primary care services furnished to an assigned beneficiary billed through an ACO participant or non-ACO TIN, among other payment amounts.

We also note that under this proposed approach, ACO professionals may continue to bill under several different TINs, such as ACO participants in multiple ACOs or both ACO participants and non-ACO providers and suppliers. This proposed change would not impact an ACO professional's ability to receive FFS payment for primary care services billed through an ACO participant or non-ACO TIN.

We provide the following hypothetical examples to illustrate the outcome of plurality competition under the current approach and the proposed revised approach. In these illustrations, for simplicity, we assume the beneficiary meets the assignment eligibility criteria and therefore could be assigned to an ACO based on the outcome of plurality competition.

As one example, consider a beneficiary for which ACO professionals used in assignment billed primary care services through an ACO participant in ACO A and a non-ACO TIN, and the sum of allowed charges for this beneficiary for these services is greater for the billings through the non-ACO TIN than through the ACO. For instance, ACO professionals billed primary care services through an ACO participant in ACO A, resulting in allowed charges of $100 for each of three services, totaling $300. For this same beneficiary, ACO professionals in ACO A also billed primary care services to a non-ACO TIN, resulting in allowed charges of $100 for each of four services, totaling $400. Under our existing policy, we would determine that the non-ACO TIN provided the plurality of the beneficiary's primary care services, because it provided the greatest amount of allowed charges for the beneficiary, and as a result the beneficiary would not be assigned to ACO A. Under the proposed approach, we would exclude from plurality competition the allowed charges of $400 which the ACO professionals in ACO A billed through the non-ACO TIN. As a result, under the proposed approach, ACO A would be determined to have provided the plurality of allowed charges for primary care services for the beneficiary, and we would assign the beneficiary to ACO A.

As a second example, consider a beneficiary for which ACO professionals used in assignment billed primary care services through ACO participants in two different ACOs (ACO A and ACO B), and a non-ACO TIN, and the sum of allowed charges for this beneficiary for these services is greater for the billings through the non-ACO TIN than through either ACO. For instance, ACO professionals billed primary care services for the beneficiary through an ACO participant in ACO A, resulting in allowed charges of $100 for each of three services, totaling $300. These ACO professionals also billed primary care services for the beneficiary through an ACO participant in ACO B, resulting in allowed charges of $100 for each of two services, totaling $200. These same ACO professionals billed primary care services for the beneficiary to a non-ACO TIN, resulting in allowed charges of $100 for each of four services, totaling $400. Under our existing policy, we would determine that the non-ACO TIN provided the plurality of the beneficiary's primary care services, and as a result the beneficiary would not be assigned to an ACO. Under the proposed approach, we would exclude from plurality competition the allowed charges of $400 which the ACO professionals in ACO A and ACO B billed through the non-ACO TIN. As a result, we would decide the outcome of plurality competition between ACO A ($300 in allowed charges) and ACO B ($200 in allowed charges), and determine that ACO A provided the plurality of allowed charges for primary care services for the beneficiary, and we would assign the beneficiary to ACO A.

As a third example, consider a beneficiary for which an ACO professional used in assignment billed primary care services through an ACO participant in ACO A and a non-ACO TIN, and for which other health care providers unaffiliated with an ACO are also billing primary care services for the beneficiary through a non-ACO TIN, and the sum of allowed charges for this beneficiary for these services is greater for the billings through the non-ACO TIN than the ACO. For instance, an ACO professional billed primary care services through an ACO participant in ACO A, resulting in allowed charges of $100 for each of three services, totaling $300. For this same beneficiary, an ACO professional in ACO A also billed primary care services to a non-ACO TIN, resulting in allowed charges of $100 for one service. Additionally, allowed charges of $100 for each of five services, totaling $500, were billed through the non-ACO TIN by a primary care physician who is unaffiliated with any ACO. Under our existing policy, we would determine that the non-ACO TIN provided the plurality of allowed charges for primary care services for the beneficiary, and as a result the beneficiary would not be assigned to ACO A. Under the proposed approach, we would exclude from plurality competition the allowed charges of $100 which the ACO professional billed through the non-ACO TIN. In this hypothetical example, the outcome of plurality competition would not change under the proposed approach, as we would still determine that the non-ACO TIN provided the plurality of allowed charges for primary care services for the beneficiary, and the beneficiary would not be assigned to ACO A.

We note that if an ACO professional bills under ACO participants in multiple ACOs, but not to a non-ACO TIN, we do not anticipate the proposed change would impact the outcome of the plurality competition (compared to our current approach).

As illustrated in the examples above, this proposed approach would reduce the likelihood that we would determine the beneficiary's plurality of allowed charges for primary care services to be attributed to a non-ACO TIN or non-ACO CCN and increase the likelihood that a beneficiary is assigned to an ACO. Based on our simulations of this proposed approach described in section III.G.2.a.(2)(c) of this proposed rule, we observed that nearly all ACOs (462 of 476 ACOs or 97 percent) would experience a relatively small increase in their assigned population (less than 1 percent growth). We observed the remaining 3 percent of ACOs would experience growth in their assigned population ranging from 4 percent to 12 percent. We also observed that on average the beneficiaries added to assignment with this proposed change have higher cost and higher risk scores. This latter point highlights that the existing assignment methodology includes vulnerabilities that could lead ACOs, ACO participants or their ACO professionals to avoid at-risk

beneficiaries (as defined in § 425.20). We explore related considerations in the discussion that follows.

Shared Savings Program policies include certain safeguards against ACO avoidance of at-risk beneficiaries. Specifically, section 1899(d)(3) of the Act, and related regulations under § 425.316(b), authorize us to monitor for ACO avoidance of at-risk beneficiaries. If we discover that an ACO has engaged in the avoidance of at-risk beneficiaries, we can impose remedial action or terminate the ACO, in accordance with § 425.316(b)(2).

There may be multiple possible pathways for an ACO to engage in strategic patient risk selection.[234] In recent years, we have engaged in monitoring to identify potential patient risk selection behavior by ACOs. Our monitoring and compliance processes for identifying and addressing ACO avoidance of at-risk beneficiaries can be resource intensive. We believe that the proposed change to determining the outcome of plurality competition within the assignment methodology would allow for a more efficient solution to mitigate a mechanism for ACOs, ACO participants, or their ACO professionals to avoid accountability for the quality and cost of care for high-cost at-risk beneficiaries. A pattern of billing by ACO professionals used in assignment resulting in a population of relatively higher costs beneficiaries not being assigned to the ACO could provide a mechanism for the ACO to achieve lower PY expenditures as compared to its historical benchmark, thereby potentially increasing its savings or decreasing its losses. An ACO avoiding assignment of high-cost beneficiaries under the Shared Savings Program reduces the cost effectiveness of coordinated care and shared savings initiatives, limiting savings for the Trust Funds, and potentially limiting improvements in quality of care and outcomes that could result for the patient. We are concerned that the provisions addressing avoidance of at-risk beneficiaries under section 1899(d)(3) of the Act and § 425.316(b), entail an ACO-specific analysis which may not serve as an adequate deterrent against the aforementioned concerns about ACO professionals billing patterns for the care of the same beneficiaries resulting in differences in assignment outcomes that advantage the ACO's financial performance. In comparison, the proposed approach to modifying plurality competition would result in a program-wide change which would be implemented with each assignment run, which we believe will largely resolve our concerns.

We believe the proposal to exclude from assignment calculations allowed charges for primary care services furnished by an ACO professional used in assignment billed through a non-ACO TIN offers a tailored approach to reduce the potential for ACO professionals' billing patterns, inside and outside the ACO for care of the same beneficiaries, to result in differences in assignment outcomes that advantage the ACO's financial performance. We recognize that the proposed approach could result in assignment of beneficiaries for which ACO professionals may be billing a greater amount of primary care services through non-ACO TINs, compared to ACO participant TINs. We recognize there could be appropriate billings by ACO professionals through multiple different TINs (inside and outside the ACO) for services furnished to a beneficiary, such as a result of the physician or non-physician practitioner working in more than one practice location, or reflective of multiple employment arrangements. Nonetheless, we believe it is appropriate to assign the beneficiary to an ACO under such circumstances. We believe that beneficiaries added to ACOs' assigned populations under the proposed changes in assignment would benefit from better care coordination and quality improvement activities through ACOs participating under Shared Savings Program requirements, and the proposed changes to assignment are estimated to result in higher net Federal savings (as described in section III.G.2.a.(2)(c) of this proposed rule). These potential benefits outweigh potential concerns that this approach minimizes our consideration of billing arrangements of ACO professionals through non-ACO TINs.

We acknowledge a possibility that ACOs, ACO participants, or their ACO professionals, and non-ACO TINs may have relied on the existing program policy to structure arrangements in which ACO professionals bill inside and outside the ACO for the care of the same beneficiary. However, we do not believe any such reliance interests outweigh our concerns about the potential for ACOs and other providers/suppliers to exploit a vulnerability with the existing Shared Savings Program assignment methodology, and the potential benefits for beneficiaries and the Trust Funds of the proposed modifications to the plurality competition, as we describe elsewhere in section III.G.2.a. of this proposed rule.

We propose to apply this revised approach to determining assignment for the PY starting on January 1, 2028, and subsequent PYs. We discuss the proposed timing of applicability further in section III.G.2.a.(2)(d) of this proposed rule, including use of the same assignment rules in determining beneficiary assignment for purposes of benchmark calculations as would apply in the PY.

We propose to revise and republish § 425.402(b)(3), (b)(4), and (b)(5)(iv), with new provisions added to steps 1, 2, and 3 of the claims-based assignment methodology (respectively). As proposed, these provisions would continue to specify the existing approach to comparing allowed charges for primary care services furnished to a beneficiary by certain ACO professionals in an ACO with allowed charges for primary care services furnished by the same type of health care providers who are either (1) ACO professionals in any other ACO, or (2) not affiliated with any ACO and identified by a Medicare-enrolled billing TIN. We propose to revise these paragraphs to add provisions, applicable for performance year 2028 and subsequent performance years, specifying how we identify and exclude from assignment allowed charges for primary care services billed by an ACO professional used in assignment under a Medicare-enrolled billing TIN unaffiliated with any ACO (for brevity referred to in the proposed regulation as a ''non-ACO TIN'') during the applicable assignment window. To follow is a summary of the proposed amendments to § 425.402(b)(3), (b)(4), and (b)(5)(iv).

We propose to revise § 425.402(b)(3), specifying assignment step 1 as follows:

- We propose to specify the existing provisions of assignment step 1 under paragraph (b)(3) in new paragraph (b)(3)(i), and also redesignate existing paragraphs (b)(3)(i) and (ii) as paragraphs (b)(3)(i)(A) and (B) (respectively).
- Under new paragraph (b)(3)(ii), we propose to specify that for performance year 2028 and subsequent performance years, if an ACO professional for which we identify a primary care service under § 425.402(b)(2) also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then we would exclude from consideration in assignment under proposed new § 425.402(b)(3)(i) the allowed charges for primary care services billed by the ACO professional

[234] See, for example, McWilliams JM, et al. ''Savings or Selection? Initial Spending Reductions in the Medicare Shared Savings Program and Considerations for Reform.'' *Milbank Q.* 2020 Sep;98(3):847–907, available at *https://onlinelibrary.wiley.com/doi/10.1111/1468-0009.12468.*

under the non-ACO TIN during the applicable assignment window.

We propose to revise § 425.402(b)(4), specifying *assignment* step 2 as follows:

- We propose to specify the existing provisions of assignment step 2 under paragraph (b)(4) in new paragraph (b)(4)(i), and also redesignate existing paragraphs (b)(4)(i) and (ii) as paragraphs (b)(4)(i)(A) and (B) (respectively).
- Under new paragraph (b)(4)(ii), we propose to specify that for performance year 2028 and subsequent performance years, if an ACO professional for which we identify a primary care service under § 425.402(b)(2) also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then we would exclude from consideration in assignment under proposed new § 425.402(b)(4)(i) the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable assignment window.

We propose to revise § 425.402(b)(5)(iv), the provision of assignment step 3 in which we determine which ACO or non-ACO entity provided a beneficiary's plurality of allowed charges for primary care services, as follows:

- We propose to specify the existing provisions of under paragraph (b)(5)(iv) in new paragraph (b)(5)(iv)(A), and also redesignate existing paragraphs (b)(5)(iv)(A) and (B) as paragraphs (b)(5)(iv)(A)(*1*) and (*2*) (respectively).
- Under new paragraph (b)(5)(iv)(B), we propose to specify that for performance year 2028 and subsequent performance years, if an ACO professional for which we identify a primary care service under § 425.402(b)(5)(iii) also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then we would exclude from consideration in assignment under proposed new § 425.402(b)(5)(iv)(A) the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable expanded window for assignment.

As we have described in section III.G.2.a.(1) of this proposed rule, in determining claims-based assignment, we consider allowed charges for primary care services billed through physicians and non-physician practitioners, as well as FQHCs, RHCs, Method II CAHs, and ETA hospitals (as identified by CCN). The more general language of the proposed new provisions of the regulations in § 425.402(b)(3), (b)(4), and (b)(5)(iv) describing exclusion from assignment calculations of allowed charges for primary care services billed by an ACO professional (physicians and non-physician practitioners) used in assignment through a non-ACO TIN is inclusive of primary care services billed through a non-ACO CCN enrolled under the non-ACO TIN. To the extent the ACO professional is billing primary care services through an ACO participant TIN and a non-ACO CCN, this proposed approach would also exclude from plurality competition the allowed charges billed through the non-ACO CCN.

We seek comment on the proposed change to the step-wise assignment methodology under which we would exclude allowed charges for primary care services billed through a non-ACO TIN by an ACO professional used in assignment, and related proposed changes to the Shared Savings Program regulations at § 425.402(b)(3) (applicable to step 1), (b)(4) (applicable to step 2), and (b)(5)(iv) (applicable to step 3), as revised and republished. We seek comment on the proposal to apply this approach in determining Shared Savings Program assignment for the PY starting on January 1, 2028, and subsequent PYs.

(b) Proposal To Modify Assignment Eligibility Criteria and Prospective Assignment Exclusion Criteria Based on Medicare Enrollment Status

In this section, we provide additional background on the development of the Shared Savings Program's assignment eligibility criteria and prospective assignment exclusion criteria; revisit key considerations informing the development of our existing policies, and discuss factors informing our proposal to modify these policies; and describe our proposal to modify the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status.

As we explained in the December 2014 proposed rule (79 FR 72790 through 72791) and June 2015 final rule (80 FR 32743 through 32744), the assignment eligibility criteria we proposed and finalized were consistent with criteria we established to operationalize the Shared Savings Program's assignment methodology finalized with the November 2011 final rule. We referenced a detailed specifications document, which included information regarding the beneficiary assignment process, that we made available to the public on the CMS website.[235] [236]

In the December 2014 proposed rule (79 FR 72791), we explained that to determine whether a beneficiary is eligible to be assigned to an ACO, we must have information about the beneficiary's Medicare enrollment status. We explained that as required by section 1899(h)(3) of the Act, and consistent with the definition of Medicare FFS beneficiary in § 425.20, only beneficiaries enrolled in traditional Medicare FFS under Parts A and B are eligible to be assigned to an ACO participating in the Shared Savings Program. In the December 2014 proposed rule (79 FR 72791), we proposed that beneficiaries who have coverage under only one of these parts (Part A or Part B) would not be eligible to be assigned to an ACO, because of the statutory definition for Medicare FFS beneficiary and because an important objective of the Shared Savings Program is to help align incentives between Part A and Part B.

Further, in the December 2014 proposed rule (79 FR 72791), we explained that beneficiaries enrolled in a group health plan including beneficiaries enrolled in MA plans under Part C, eligible organizations under section 1876 of the Act, and Programs of All-Inclusive Care for the Elderly (PACE) under section 1894 of the Act are also not eligible to be

[235] Between May 2012 and December 2014, CMS issued and updated the initial versions of the Shared Savings Program's ''Shared Savings and Losses and Assignment Methodology Specifications'', which included specifications for beneficiary assignment and the shared savings and losses calculations under the program. The specifications, and the CMS web page where the document has been posted, have been updated over time. The earlier versions of the document are maintained in the ACO Management System (ACO–MS) Knowledge Library (accessible to ACOs) at *https://acoms.cms.gov/knowledge-management/view/8320*. The ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' documents for current years are available on ''Program Guidance & Specifications'' web page of the Shared Savings Program's website at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations*.

[236] The Physician Group Practice (PGP) demonstration, authorized under section 1866A of the Act, was implemented by CMS from April 2005 through March 2010, and served as a model for many aspects of the Shared Savings Program (see, for example, 76 FR 67833). Although not expressly stated in earlier rulemaking, the assignment eligibility criteria initially established under the Shared Savings Program closely tracked the parameters for the assignment methodology under the PGP demonstration. See for example, Kautter, J. et al. (RTI International), ''Physician Group Practice Demonstration Bonus Methodology Specifications'' (December 20, 2004), available at *https://www.cms.gov/priorities/innovation/files/x/pgp-payment.pdf* (Section 3.1 Assignment Criteria, pages 9–10).

assigned. In the June 2015 final rule (80 FR 32745), we summarized and responded to comments suggesting that the criterion that a beneficiary not have any months of Medicare group (private) health plan enrollment during the assignment window be revised to not more than 3 to 6 months, to account for certain situations where beneficiaries, such as dual eligible beneficiaries, might change, enroll in or disenroll from plans more frequently. The comments explained that this would allow such beneficiaries to remain attributed to the ACO. In our response we explained that section 1899(c) of the Act requires the Secretary to determine an appropriate method to assign Medicare FFS beneficiaries to an ACO. We then explained that as required by section 1899(c) of the Act, and consistent with the definition of Medicare FFS beneficiary under section 1899(h)(3) of the Act and § 425.20 of the Shared Savings Program regulations, our policy provided that only beneficiaries enrolled in traditional Medicare FFS under Parts A and B are eligible to be assigned to an ACO participating in the Shared Savings Program. We explained our belief that such policy was consistent with these requirements because under such approach only beneficiaries enrolled in traditional Medicare FFS under Parts A and B ''throughout the full performance year'' would be eligible to be assigned to an ACO. At the time, we declined to revise our policy in response to the commenters' concerns, but specified our plan to consider this issue further, and potentially address the issue in future rulemaking. We have not revisited these topics in subsequent rulemaking.

We have continued to consider our approach to determining the eligibility of Medicare FFS beneficiaries for assignment. In considering whether to propose revising our approach, we revisited key considerations informing the development of these policies.

The first consideration informing the development of our eligibility criteria was consistency with the definition of a Medicare FFS beneficiary under section 1899(h)(3) of the Act. While we maintain that our existing policies for determining eligibility for assignment are consistent with such definition, we acknowledge that these eligibility criteria potentially operate to exclude from eligibility for assignment beneficiaries that may satisfy this definition.

Section 1899(h)(3) of the Act defines a ''Medicare fee-for-service beneficiary'' as an individual who is enrolled in the original Medicare FFS program under Parts A and B and is not enrolled in an MA plan under Part C, an eligible organization under section 1876 of the Act, or a PACE program under section 1894 of the Act. In the prior rulemaking discussed previously in this section, we adopted restrictive eligibility criteria under the assignment methodology we established under section 1899(c) of the Act. Under this approach, a beneficiary is eligible for assignment only if, during the 12-month assignment window (as defined under § 425.20, and described in section III.G.2.a.(1) of this proposed rule), the beneficiary has at least 1 month of Part A and Part B enrollment, but no month of Part A only or Part B only enrollment, and no month of Medicare group health plan enrollment. The requirements excluding from eligibility for assignment Medicare FFS beneficiaries that have a month of Part A only or Part B only enrollment, or Medicare group health plan enrollment during the assignment window are consistent with, but not required by, section 1899(h)(3) of the Act. In our response to comments included in the June 2015 final rule (80 FR 32745), we did not disagree that it could be permissible under section 1899(h)(3) of the Act for beneficiaries with some months of Medicare group health plan enrollment to be eligible for assignment by noting our intention to potentially address this issue in future rulemaking. Moreover, in earlier rulemaking, we did not specify that the more restrictive view we took towards identifying beneficiaries eligible to be assigned based on Medicare enrollment status was the only possible approach to operationalizing identification of a Medicare FFS beneficiary under the definition of section 1899(h)(3) of the Act for assignment under section 1899(c) of the Act.

The second consideration was that an objective of the Shared Savings Program is to help align incentives between Part A and Part B. The Shared Savings Program's financial methodology similarly reflects the alignment of Part A and Part B incentives and the composition of the ACO's assigned population, in that we only consider expenditures for months during which the beneficiary was enrolled under both Parts A and B [237] in determining benchmark year and performance year expenditures. We acknowledge that the existing assignment eligibility criteria based on Medicare enrollment status, in which we require a beneficiary to have at least 1 month of Part A and Part B enrollment, but no month of Part A only or Part B only enrollment, and no month of Medicare group health plan enrollment during the assignment window, is not the only way to further the objective to align incentives between Parts A and B. For instance, this alignment would be achieved under an approach that allows for beneficiaries to be eligible for assignment if they have at least 1 month of Part A and B enrollment during the assignment window in combination with the existing approach to determining the beneficiary's expenditures for the same month(s) the beneficiary was enrolled in Part A and B.

Based on this reconsideration and to increase the number of Medicare FFS beneficiaries in accountable care relationships, we are proposing to expand the criteria for assignment eligibility to permit assignment of a Medicare FFS beneficiary with at least 1 month of Part A and Part B enrollment during the assignment window and no Medicare group health plan enrollment during that same month. We believe this proposed approach would retain consistency with section 1899(h)(3) of the Act and further the Shared Savings Program's stated objective of aligning incentives between Part A and Part B. This proposed modification to the assignment eligibility criteria and prospective assignment exclusion criteria would incrementally increase the assigned population and be aligned with our goal of growing the number of Medicare FFS beneficiaries involved in accountable care relationships (described in section III.G.2.a.(1)(d) of this proposed rule). Additionally, as we address in the following discussion, this proposed approach to identifying beneficiaries eligible for assignment based on Medicare enrollment status would align with our use of Shared Savings Program-eligible months in identifying beneficiaries eligible for assignment and calculation of assigned beneficiary expenditures using months of Part A and B enrollment, and bring greater symmetry to program calculations based on the assigned and assignable populations.

In determining assignment, we identify a beneficiary's Shared Savings Program-eligible months, in which the beneficiary is alive on the first of the month, enrolled in both Parts A and B, and not enrolled in a Medicare group

[237] For a description of how CMS annualizes the assigned beneficiary's expenditures, refer to Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (Section 3.1.2 Annualizing Assigned Beneficiary Expenditures).

health plan.[238] This results in assignment of beneficiaries with between 1 and 12 months of Parts A and B enrollment, so long as the remaining criteria under § 425.401(a) are met. There are various reasons for beneficiaries currently eligible for assignment to have fewer than 12 months of Parts A and B enrollment, including the timing of when the beneficiary becomes eligible for Medicare, and if a beneficiary dies during the period. We also use Shared Savings Program-eligible months for assigned beneficiaries in other Shared Savings Program operations, including to assign a monthly enrollment status to the beneficiary according to four Medicare enrollment types (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) and to calculate beneficiary person years.[239] [240] The proposed approach to identifying beneficiaries as eligible for assignment if they have at least 1 month of Part A and Part B enrollment and no Medicare group health plan enrollment during that same month during the assignment window, would effectively expand the population of assigned beneficiaries who have fewer than 12 months of Parts A and B enrollment.

Under our existing approach we determine, based on the point in time assignment is run, whether a beneficiary meets the assignment eligibility criteria or must be excluded from the assigned population based on the criteria specified under § 425.401. In doing so we consider the beneficiary's eligibility throughout the applicable assignment window for the assignment run, using the relevant data available on Medicare enrollment status, overlap in assignment with other Medicare shared savings initiatives, and other factors.[241] We would maintain this approach, based on the point in time assignment is run, in implementing the proposed revised assignment eligibility criteria and prospective assignment exclusion criteria.

We also note that for beneficiaries assigned under the proposed eligibility criteria based on Medicare enrollment status, we would apply the existing approach to determine expenditures used in benchmark year and performance year expenditure calculations in which we only consider expenditures for months during which the beneficiary was enrolled under both Parts A and B. That is, we would not consider expenditures for months in which the beneficiary was enrolled under Part A only or Part B only. We also note that the Shared Savings Program financial calculations do not consider Part C claims data. We believe this modified approach would remain consistent with the program's objective to hold ACOs accountable for the total cost of the beneficiary's care as based in Parts A and B expenditures.

As described in section III.G.2.a.(1)(b) of this proposed rule, the assignable beneficiary population (as defined in § 425.20) is a subset of the larger population of Medicare FFS beneficiaries, as defined under section 1899(h)(3) of the Act and § 425.20. Operationally, this population includes beneficiaries that have at least 1 month of Part A and Part B enrollment and no Medicare group health plan enrollment during that same month during the applicable 12-month assignment window. This approach to identifying Medicare FFS beneficiaries who meet the criteria for inclusion in the assignable population is less restrictive compared to the existing assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status. Applying a similar approach to identifying Medicare FFS beneficiaries eligible for assignment could bring greater symmetry to the composition of the assignable beneficiary population and the assigned population and thereby allow for more comparable calculations between factors based on assignable beneficiary expenditures used in establishing, adjusting and updating the ACO's historical benchmark and factors based on the ACO's assigned population (including benchmark year and performance year expenditures).

As described in the Regulatory Impact Analysis, in section VII of this proposed rule, as enrollment in MA has grown over recent years,[242] so has the number of beneficiaries switching back to OM from MA.[243] Our current eligibility criteria based on Medicare enrollment status restricts and delays the eligibility of such beneficiaries for assignment to ACOs. Allowing beneficiaries with at least one month of Part A and Part B enrollment and no Medicare group health plan enrollment during that same month during the assignment window to be eligible for assignment would allow us to more accurately account for when this population qualifies as Medicare FFS beneficiaries and, in turn, is included in ACO assignment, and encompass various circumstances around the timing of a beneficiary's enrollment in Medicare and changes in enrollment that result in a beneficiary having one or more months of Part A only or Part B only enrollment, or Medicare group health plan enrollment.[244] We also note that the population of beneficiaries transitioning between MA and OM are captured in the assignable beneficiary population. In this respect, the proposed approach to align the assignment eligibility criteria and prospective assignment exclusion

[238] In the June 2015 final rule (80 FR 32745), we specified that only beneficiaries enrolled in traditional Medicare FFS under Parts A and B ''throughout the full performance year'' are eligible to be assigned to an ACO. However, this statement from earlier rulemaking does not always accurately reflect the Shared Savings Program's assignment operations in which we allow for an eligible beneficiary who has fewer than 12 months of enrollment in Parts A and B to be assigned to an ACO.

[239] To calculate person years: We sum the number of Shared Savings Program-eligible months for each assigned beneficiary for each Medicare enrollment type; we then divide this number by 12 (the number of months in a calendar year).

[240] See Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (Section 3.1. Calculating ACO-Assigned Beneficiary Expenditures).

[241] The Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), includes among other information, selected characteristics of Shared Savings Program ACO reports for ACOs under preliminary prospective assignment with retrospective reconciliation and for ACOs under prospective assignment (see Appendix F, Tables 14 and 15.)

[242] See, for example, *Data.CMS.gov*, Medicare Enrollment Dashboard, Medicare Enrollment for March 2026, available at *https://data.cms.gov/tools/medicare-enrollment-dashboard* (showing yearly trend data for MA, FFS, and Total, from 2013 through 2025).

[243] See Xu L, et al. ''Medicare Switching: Patterns Of Enrollment Growth In Medicare Advantage, 2006–22''. *Health Affairs* (September 5, 2023), available at *https://doi.org/10.1377/hlthaff.2023.00224* (finding only slightly increasing number of switchers from MA to OM over 2020 to 2023 compared to earlier years, and includes Exhibit 3 indicating higher rates of switching from MA to FFS for disabled beneficiaries, full dual eligible beneficiaries, and beneficiaries with >3 HCC diagnostic codes in 2022). See also, Mackleby G, Liu A, and Trish E. ''Switching Medicare Plans Outside Open Enrollment Was Increasingly Common, Especially Among Sicker Enrollees, 2015–22''. *Health Affairs* (February 2, 2026), available at *https://www.healthaffairs.org/doi/10.1377/hlthaff.2025.00915* (among MA enrollees, finding compared with Medicare open enrollment period switchers, alternative enrollment period switchers tended to have higher risk scores and hospitalization rates before switching).

[244] We note that there are a multitude of factors impacting the timing for when a beneficiary enrolls in OM or a MA plan, and the timing of when a beneficiary may change to a different MA plan or switch back to OM. Information on initial enrollment in OM and timing for when a beneficiary can join, switch, drop or make changes in their MA plan, is included in the Medicare & You Handbook (2026), available at *https://www.medicare.gov/publications/10050-medicare-and-you.pdf*.

criteria with the approach we use to identify the assignable beneficiary population based on Medicare enrollment status serves an important purpose in resolving the asymmetry between the assigned and assignable populations which has grown over time in light of changes to Medicare enrollment trends.

ACOs may rely on programmatic data included in program reports and data files we deliver to ACOs (described in section III.G.2.a.(2)(d) of this proposed rule) to understand their assigned population, and the reason for beneficiaries' ineligibility for assignment, among other factors. Additionally, ACOs may be accustomed to coordinating care, reporting quality measures, and considering approaches to lowering growth in expenditures for Medicare beneficiaries eligible for assignment, which presently includes beneficiaries with at least 1 month of Part A and Part B enrollment, but no month of Part A only or Part B only enrollment, and no month of Medicare group health plan enrollment during the assignment. As described in section III.G.2.a.(2)(d) of this proposed rule, we anticipate updating the Shared Savings Program's publicly available specification documents, programmatic resources, and program reports to include information that would help ACOs understand their assigned population and the population of beneficiaries eligible to be assigned under the proposed revised assignment methodology (if finalized). Although we recognize it may take ACOs time to update their data systems and models for analysis of Shared Savings Program data, we do not believe this potential concern outweighs the reasons for proposing this change described elsewhere in section III.G.2.a of this proposed rule. We note that the proposal to apply the changes to the beneficiary assignment methodology for the PY starting on January 1, 2028, and subsequent PYs, provides time for ACOs to prepare for any related changes.

We propose to revise the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status under § 425.401, and to apply the revised criteria in determining assignment for the PY starting on January 1, 2028, and subsequent PYs. We discuss the proposed timing of applicability further in section III.G.2.a.(2)(d) of this proposed rule, including use of the same assignment rules in determining beneficiary assignment for purposes of benchmark calculations as would apply in the PY. The following is a description of the proposed criteria for a beneficiary to be assigned to an ACO for a PY or benchmark year which would apply for the PY starting on January 1, 2028, and subsequent PYs. Later in this section of this proposed rule, we detail our proposal to revise and republish § 425.401, including to incorporate the following new provisions.

Under new § 425.401(a)(2), we propose to specify the beneficiary assignment eligibility criteria applicable for the PY starting on January 1, 2028, and subsequent PYs. Accordingly, we propose a beneficiary may be assigned to an ACO under the assignment methodology in §§ 425.402 and 425.404, for a performance or benchmark year, if the beneficiary meets all of the following criteria during the assignment window:

- Has at least 1 month of Part A and Part B enrollment and does not have Medicare group (private) health plan enrollment during that same month during the assignment window.
- Is not assigned to any other Medicare shared savings initiative.
- Lives in the U.S. or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

We note that under the proposed approach to revising the assignment eligibility criteria based on Medicare enrollment status, we would continue to apply the existing criteria which ensure that a beneficiary is not assigned to any other Medicare shared savings initiative (consistent with § 425.401(a)(3)), and lives in the U.S. or U.S. territories and possessions (consistent with § 425.401(a)(4)).

Under new § 425.401(b)(2), we propose to specify the prospective assignment exclusion criteria applicable for the PY starting on January 1, 2028, and subsequent PYs. Accordingly, we propose a beneficiary would be excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each PY consistent with § 425.400(a)(3)(ii) if the beneficiary meets any of the following criteria during the performance or benchmark year: [245]

- Does not have at least 1 month of Part A and Part B enrollment without Medicare group (private) health plan enrollment during that same month during the assignment window.
- Did not live in the U.S. or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residency at the end of the year.

We note that under the proposed approach to revising the prospective assignment exclusion criteria, we would continue to apply the existing criterion to exclude from prospective assignment a beneficiary that did not live in the U.S. or U.S. territories and possessions (consistent with § 425.401(b)(3)).

More generally, we note that the assignment eligibility criteria and prospective assignment exclusion criteria under § 425.401 apply in determining beneficiaries assigned under claims-based assignment and voluntary alignment. We anticipate the proposed changes in criteria based on Medicare enrollment status would increase the population assigned under both methods.

We propose to revise and republish § 425.401, to specify the existing criteria for a beneficiary to be assigned to an ACO for a performance or benchmark year apply to PYs starting prior to January 1, 2028 (as applicable), and to specify the proposed criteria applicable for the performance year starting on January 1, 2028, and subsequent performance years. The following list summarizes the proposed amendments to § 425.401:

- We propose to add subject headings to the introductory text of paragraphs (a) and (b) of § 425.401 to specify the following: paragraph (a) includes provisions with ''Assignment eligibility criteria''; and paragraph (b) includes provisions with ''Prospective assignment exclusion criteria''.
- We propose to revise § 425.401(a)(1) to specify the provisions with assignment eligibility criteria applicable for PYs starting prior to January 1, 2028 (as applicable), by making the following amendments:

++ Redesignating paragraphs (a)(1)(i) and (ii) as paragraphs (a)(1)(i)(A) and (B) (respectively), and redesignating paragraphs (a)(2) through (a)(4) as paragraphs (a)(1)(ii) through (a)(1)(iv) (respectively).

++ Adding the following heading to introductory text of paragraph (a)(1), specifying the timing of applicability for the provisions: ''For performance years starting prior to January 1, 2028 (as applicable)''.

[245] We omitted from this description the reference to applicability of the prospective assignment exclusion criteria for determining assignment to ACOs participating under a 6-month PY or performance period during CY 2019, under § 425.609(b)(1)(ii) and (c)(1)(ii) which is otherwise retained for completeness in the introductory text of § 425.401(b) (under the proposed amendments).

• We propose to add new paragraph (a)(2) with the assignment eligibility criteria applicable for the performance year starting on January 1, 2028, and subsequent performance years (previously described in this section of this proposed rule).

• We propose to revise § 425.401(b)(1) to specify the provisions with prospective assignment exclusion criteria applicable for performance years starting prior to January 1, 2028 (as applicable), by making the following amendments:

++ Redesignating paragraphs (b)(1)(i) and (ii) as paragraphs (b)(1)(i)(A) and (B) (respectively), and redesignating paragraphs (b)(2) and (b)(3) as paragraphs (b)(1)(ii) and (b)(1)(iii) (respectively).

++ Adding the following heading to introductory text of paragraph (b)(1), specifying the timing of applicability for the provisions: ''For performance years starting prior to January 1, 2028 (as applicable)''.

• We propose to add new paragraph (b)(2) with the prospective assignment exclusion criteria applicable for the PY starting on January 1, 2028, and subsequent PYs (previously described in this section of this proposed rule).

We also propose a technical and conforming change to cross-references to provisions of § 425.401 within § 425.612(a)(1)(iv)(A)(*2*), which describes certain conditions under which we make payments for SNF services furnished to a beneficiary preliminarily prospectively assigned to an ACO for which a waiver of the SNF 3-day rule was approved.

We seek comment on the proposed changes under which we would apply modified assignment eligibility criteria and prospective assignment exclusion criteria based on a beneficiary's Medicare enrollment status in determining assignment to an ACO for the performance year starting on January 1, 2028, and subsequent PYs. Under the proposed approach more beneficiaries would be eligible for assignment, and remain prospectively assigned to ACOs, under both claims-based assignment and voluntary alignment, than under current program policies. We seek comment on the proposed amendments to § 425.401 (as revised and republished), specifying the assignment eligibility criteria and prospective assignment exclusion criteria that would apply by PY, and the proposed technical and conforming change to cross-references to provisions of § 425.401 within § 425.612(a)(1)(iv)(A)(2).

(c) Simulations To Understand the Potential Effect of Proposed Changes

We performed separate simulations to understand the potential effect for each of the proposed changes to the assignment methodology.

Using PY 2024 data we simulated the impact of the proposed approach to excluding from assignment calculations allowed charges for primary care services billed through a non-ACO TIN by an ACO professional used in assignment (described in section III.G.2.a.(2)(a) of this proposed rule). The simulation was performed using data for all 476 ACOs reconciled for PY 2024. For purposes of the simulation, we made multiple simplifying assumptions. This included treating all ACOs as if they were under preliminary prospective assignment with retrospective reconciliation for purposes of identifying the impact on assignment and simplicity of simulating benchmark assignment. Since the proposed change is to plurality competition we would anticipate a comparable impact if we performed the simulation using the off-set assignment window. For simulating financial impacts, we assumed all ACOs to be starting their first agreement period on January 1, 2024, to have benchmark years of BY 2021, 2022 and 2023, and applied an equal weight to each BY in benchmark calculations. In approximating the benchmark calculations under the simulations we applied the benchmarking methodology applicable for ACOs entering an agreement period beginning on January 1, 2024 under §§ 425.652 through 425.660, with several exceptions. In adjusting the benchmark to account for changes in severity and case mix of the assigned beneficiary between BY3 and PY 2024 under § 425.652(a)(10), we applied the approach to capping positive adjustments at 3 percent in accordance with §§ 425.605(a)(1)(i) and 425.610(a)(2)(i) rather than the demographic plus 3 percent cap specified under §§ 425.605(a)(1)(ii) and 425.610(a)(2)(ii). We also simulated the updated benchmark using a one-third weight for the ACPT component of the three-way blended update factor, although a one-sixth weight was applied in determining financial reconciliation for PY 2024, as described in section III.G.5.g of this proposed rule. In simulating the updated benchmark calculations we did not apply the existing guardrail policy specified in § 425.652(b)(5), which ensures that the use of the three-way blended update factor will not result in lower benchmarks than the two-way national-regional blended update factor in a way that poses higher financial risk for ACOs under two-sided models, or that could jeopardize an ACO's continued participation in the Shared Savings Program under the financial performance monitoring policy described in § 425.316(d), or both.[246]

Under these simulations, we observed that the proposed change to the plurality competition would add over 97,800 assigned beneficiary person years to Shared Savings Program assignment (nearly 1 percent growth). In simulations, we found that 462 of 476 ACOs (or 97 percent) observed less than 1 percent growth, while the remaining 14 out of 476 ACOs (3 percent) experienced growth greater than 4 percent, including one ACO that observed growth as large as 12 percent.

Under simulations of the financial impacts, using PY 2024 data, we calculated ACOs' updated benchmark expenditures minus PY expenditures, to estimate impacts on gross savings/losses; with a resulting reduction in this amount indicating potentially lower shared savings, and greater liability for shared losses. We found that ACOs observed an average 3.90 percent decrease in per capita gross savings/losses ($355 per capita) and an average 3.92 percent decrease in aggregate gross savings/losses. Average reductions in gross savings/losses were driven by two factors: (1) the simulated assignment method tended to add relatively more beneficiaries in the PY (2024) than they added in the benchmark years (2021, 2022, 2023); and (2) the added beneficiaries were substantially higher cost and had higher risk scores than beneficiaries assigned to ACOs under the existing assignment methodology. These two factors combined mean that ACOs' average benchmark expenditures increased by a relatively smaller degree than their PY expenditures increased, resulting in lower gross savings/losses.

Using PY 2024 data, we simulated the impact of the proposed approach to revising the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status (described in section III.G.2.a.(2)(b) of this proposed rule). For purposes of simulating the proposed changes to the prospective assignment exclusion criteria based on Medicare enrollment status, it was important to recognize the ACO's selection of assignment methodology, to be able to accurately observe the impact of the proposed change. Therefore, we performed separate simulations for ACOs based on their selection of assignment methodology. For ACOs

[246] See 87 FR 69885.

under preliminary prospective assignment with retrospective reconciliation, we simulated the proposed change to assignment eligibility criteria using a 12-month assignment window that aligned with PY 2024. For ACOs under prospective assignment, we simulated the proposed change to assignment eligibility criteria using an offset assignment window from October 2022 through September 2023. In both cases, we identified beneficiaries with at least 1 month of Part A and Part B enrollment and no Medicare group health plan enrollment (including MA) during that same month during the applicable assignment window as being eligible for assignment. For ACOs under prospective assignment we further simulated application of the modified exclusion criteria applied at the end of PY 2024 based on CY 2024 data (making certain simplifying assumptions). To remain prospectively assigned under the simulated modified Medicare enrollment status criteria, the beneficiary had at least 1 month of Part A and Part B enrollment and no Medicare group health plan enrollment during the same month, during CY 2024. For simulating financial impacts, we made the same assumptions as previously described in this discussion used to simulate the impact of the proposed changes to plurality competition, with respect to identifying benchmark years and related weights for ACOs, as well as the benchmarking methodology that was applied including the approach to adjusting and updating the historical benchmark.

Based on our simulations, across all ACOs for PY 2024, we observe an increase of approximately 248,000 (2.45 percent) assigned beneficiary person years resulting from the proposed modifications to the assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status. We observed differing impacts on the assigned population for ACOs under prospective assignment versus preliminary prospective assignment with retrospective reconciliation, with the assigned population (in terms of assigned beneficiary person years) increasing with final assignment by 2.25 percent versus 2.57 percent respectively. This difference is explained by the type of beneficiaries that are being added with use of modified assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status. We observed that a larger share of beneficiaries that are initially prospectively assigned were removed from final assignment because they transition to and remain in a Medicare group health plan during the PY.

Under simulations of the financial impacts of modifying assignment criteria based on Medicare enrollment status, using PY 2024 data, we calculated ACOs' updated benchmark expenditures minus PY expenditures, to estimate impacts on gross savings/losses; with a resulting reduction in this amount indicating potentially lower shared savings, and greater liability for shared losses. We found that on average ACOs' PY per capita expenditures increased slightly more (by 0.60 percent) than benchmark per capita expenditures increased (by 0.43 percent), resulting in $20 lower average per capita gross savings/losses (−6.62 percent). Overall impacts on aggregate gross savings/losses were also negative but relatively smaller, decreasing average ACO gross savings/losses and program-wide gross savings/losses by 3.20 percent.

We observed differences in average expenditures and risk scores by Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) among the beneficiary population added with the simulated changes in assignment compared to the population already assigned. Related findings are summarized in Table B–G1. Within the ESRD enrollment type, we observed a disproportionately higher number of additional beneficiaries compared to the other enrollment types. The added population of ESRD beneficiaries had, on average, largely similar per capita expenditures and lower average risk scores than already assigned ESRD beneficiaries. Within the disabled and aged/dual eligible enrollment types, the added populations of beneficiaries had, on average, higher per capita expenditures and higher average risk scores than the corresponding populations of already assigned beneficiaries. Within the aged/non-dual eligible enrollment type, the added population of beneficiaries had, on average, slightly lower per capita expenditures and lower average risk scores than already assigned aged/non-dual eligible beneficiaries.

TABLE B-G1: SIMULATION OF PROPOSED CHANGES TO ASSIGNMENT ELIGIBILITY CRITERIA - NUMBER AND CHARACTERISTICS OF BENEFICIARIES ADDED FOR PY 2024

	Assigned Population under Existing Eligibility Criteria	Assigned Population Added with Proposed Medicare Enrollment Status Criteria	Percent Difference
Mean Assigned Person Years	**21,241.8**	**531.8**	**2.50%**
ESRD	75.6	6.1	8.03%
Disabled	1,448.2	85.9	5.93%
Aged/Dual	1,143.7	88.1	7.70%
Aged/Non-Dual	18,574.3	351.7	1.89%
Mean Per Capita Expenditures	**$13,256**	**$15,433**	**16.42%**
ESRD	$95,405	$92,714	-2.82%
Disabled	$12,657	$16,797	32.71%
Aged/Dual	$19,287	$23,435	21.51%
Aged/Non-Dual	$12,594	$12,570	-0.19%
Mean CMS-HCC Risk Score	**0.993**	**0.899**	**-9.47%**
ESRD	0.969	0.955	-1.38%
Disabled	0.966	1.122	16.15%
Aged/Dual	0.962	1.005	4.50%
Aged/Non-Dual	1.003	0.852	-15.08%

Note: The reported "Percent Difference" may slightly differ from manual recalculation using other values reported in the table due to rounding.

For additional analysis on estimated impacts, we also refer readers to the Regulatory Impact Analysis in section VII. of this proposed rule. In the Regulatory Impact Analysis of this proposed rule, we describe the estimated financial impact of the proposed change to exclude from assignment calculations allowed charges for primary care services billed through a non-ACO TIN by an ACO professional used in assignment (described in section III.G.2.a.(2)(a) of this proposed rule), and the proposed changes to assignment eligibility criteria and prospective assignment exclusion criteria (described in section III.G.2.a.(2)(b) of this proposed rule). We explain that in combination the proposed changes to assignment would be estimated to result in higher net Federal savings, although the policies may also marginally decrease the number of ACOs participating in the Shared Savings Program as a result of assignment of higher cost beneficiaries to ACOs and reduced gross savings, while also increasing overall the number of beneficiaries assigned to Shared Savings Program ACOs. The collective proposed changes represent an opportunity to grow the number of Medicare FFS beneficiaries involved in accountable care relationships, and drive savings, which would advance us towards our goal to align spending and value in OM, and related strategic objectives (described in section III.G.1.a. of this proposed rule). The proposed change to assignment calculations (described in section III.G.2.a.(2)(a) of this proposed rule) would reduce the potential for differences in billing patterns by ACO professionals (inside and outside the ACO), for care of the same beneficiaries, to result in differences in assignment outcomes that advantage the ACO's financial performance, in particular billing that results in non-assignment of higher cost and higher risk beneficiaries. The proposed changes to assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status (described in section III.G.2.a.(2)(b) of this proposed rule), would allow for greater symmetry between the ACO assigned population and the assignable population, and help ensure consistency between Shared Savings Program calculations used in determining ACO financial performance. At this juncture, we believe the considerations outweigh the concern about the potential for attrition from the Shared Savings Program by ACOs unwilling to be held accountable for the quality and cost of care of this population of Medicare beneficiaries.

We also note that we did not simulate the potential impact of the proposed changes to the assignment methodology on ACO quality performance. We refer readers to section III.G.3. of this proposed rule for a discussion of proposed changes to the Shared Savings Program quality performance standard and other quality reporting requirements. Given the relatively small increases in ACOs' assigned populations that are likely to result under the proposed changes to the assignment methodology, we anticipate there would be minimal impact on ACOs' reporting of quality measures for the expanded population of beneficiaries.

We seek comment on the potential effects of the proposed changes to the assignment methodology on the composition of ACOs' assigned populations and ACOs' financial and quality performance. We also seek comment on the potential for these proposed changes to have unintended consequences for participation by ACOs, ACO participants, and ACO professionals, including with respect to their ability to meet Shared Savings Program goals for an expanded population of assigned beneficiaries which would result under the proposed changes to the Shared Savings Program assignment methodology.

(d) Implementation of Proposed Revisions to the Beneficiary Assignment Methodology

As described in sections III.G.2.a.(2)(a) and (b) of this proposed rule, we are proposing changes to the Shared Savings Program beneficiary assignment methodology that would be applicable to all ACOs for the PY starting on January 1, 2028, and subsequent PYs. In this section of this proposed rule, we discuss impacts on certain program operations in additional detail, specifically: (1) the timing of applicability for the proposed approach in connection with the timing of the annual application cycle for ACOs to enter a new agreement period under the Shared Savings Program; (2)

applicability of the proposed approach to determining benchmark assignment and relatedly adjustments to historical benchmark calculations for ACOs participating in an existing agreement period; and (3) considerations specific to program reports and data which we make available to ACOs.

Consistent with how we have implemented previous changes to the Shared Savings Program assignment methodology, we would use the revised methodology each time assignment is determined for a given benchmark year or PY and, as applicable, to determine the eligibility of ACOs applying to enter into or renew participation in the Shared Savings Program. Regarding the latter, applicant eligibility for PY 2027 will be determined during CY 2026. We would not be able to review public comments and decide whether to finalize the proposed changes in sufficient time to apply the revised criteria for PY 2027 applications. We use estimates for the ACO's benchmark year assignment in multiple determinations during Phase 1 of the application cycle, which concludes in mid-October 2026, before the CY 2027 PFS final rule will likely be issued.[247] This includes, determining whether an ACO applicant meets the requirement for having at least 5,000 assigned beneficiaries (refer to § 425.110(a)(1) and (a)(3)), determining whether an ACO meets the definition of a low revenue ACO for purposes of eligibility for the Advance Investment Payment option (refer to § 425.630(b)(4)), and calculating the ACO's repayment mechanism amount (refer to § 425.204(f)). Additionally, we anticipate that the proposed revised approach to determining beneficiary assignment described in section III.G.2.a. of this proposed rule, if finalized, would require significant operational changes to the Shared Savings Program assignment methodology, which would take time to prepare in advance of initial use of the approach during the application process. For these reasons, we would not be able to apply the revised beneficiary assignment methodology for the PY starting on January 1, 2027, and we are proposing to apply this change beginning with the PY starting on January 1, 2028.

Additionally, we would apply the proposed revised approach (if finalized) to determining beneficiary assignment in establishing, adjusting, updating, and resetting historical benchmarks for ACOs entering new agreement periods beginning on January 1, 2028, and in subsequent years. Also consistent with how we have implemented previous changes to the assignment methodology, we would adjust benchmarks at the start of PY 2028 for all ACOs in agreement periods for which PY 2028 is a second or subsequent PY. Accordingly, the ACOs' benchmarks would reflect the use of the same assignment rules as would apply in the PY (refer to § 425.652(a)(9)).

In accordance with the Shared Savings Program regulations under subpart H, we provide ACOs with certain aggregate reports and beneficiary-identifiable claims data on the ACO's assigned beneficiary population, to conduct health care operations work. We are committed to maintaining transparency of Shared Savings Program by providing ACOs with data related to the determination of their assigned population, and providing ACOs with data on their assigned population to aid in their operations under the Shared Savings Program. Under § 425.704, we provide ACOs with monthly claim and claim line feed (CCLF) files with beneficiary-identifiable data, which include Parts A, B, and D data.[248] Further, in accordance with § 425.702, we provide ACOs with Shared Savings Program reports which include aggregate and beneficiary-identifiable information on their assigned population near the start of each PY, during each quarter, and in conjunction with annual financial reconciliation.[249] [250] We anticipate updating the Shared Savings Program's publicly available specification documents, programmatic resources, and program reports to include information that would help ACOs understand their assigned population and the population of beneficiaries eligible to be assigned under the revised assignment methodology (if finalized).

b. Proposed Revisions to the Definition of Primary Care Services Used in Shared Savings Program Beneficiary Assignment

(1) Background

Section 1899(c)(1) of the Act, as amended by the 21st Century Cures Act and the Bipartisan Budget Act of 2018, provides that the Secretary shall determine an appropriate method to assign Medicare FFS beneficiaries to an ACO based on their utilization of primary care services provided by physicians in the ACO who are ACO professionals and, in the case of PYs beginning on or after January 1, 2019, services provided by a FQHC or RHC. However, the statute does not specify a list of services considered to be primary care services for purposes of beneficiary assignment.

In the November 2011 final rule (76 FR 67853), we established the initial list of services, identified by Current Procedural Terminology (CPT) and Healthcare Common Procedure Coding System (HCPCS) codes, that we considered to be primary care services. In that final rule, we indicated that we intended to monitor CPT and HCPCS codes and would consider making changes to the definition of primary care services to add or delete codes used to identify primary care services if there were sufficient evidence that revisions were warranted. We have updated the list of primary care service codes in subsequent rulemaking (refer to 80 FR 32746 through 32748; 80 FR 71270 through 71273; 82 FR 53212 and 53213; 83 FR 59964 through 59968; 85 FR 27582 through 27586; 85 FR 84747 through 84756; 85 FR 84785 through 84793; 86 FR 65273 through 65279; 87 FR 69821 through 69825; 88 FR 79163 through 79174; 89 FR 98087 through 98101; 90 FR 49794 through 49797) to reflect additions or modifications to the codes that have been recognized for payment under the PFS and to incorporate other changes to the definition of primary care services for purposes of the Shared Savings Program. For the PY starting on January 1, 2025, and subsequent PYs, we defined primary care services for purposes of assigning beneficiaries to ACOs under § 425.402 at § 425.400(c)(1)(ix).

(2) Proposed Revisions

Based on continued review of the HCPCS and CPT codes that are currently used for payment under the PFS or that we are proposing to use for payment

[247] See Medicare Shared Savings Program, Key Application Actions and Deadlines For Agreement Periods Beginning on January 1, 2027, available at *https://www.cms.gov/files/document/key-application-actions-deadlines.pdf*.

[248] See for example, CMS, ''Accountable Care Organization—Operational System (ACO–OS), Claim and Claim Line Feed (CCLF) Information Packet (IP)'' (version 43.0, 5/13/2026), available at *https://www.cms.gov/files/document/cclf-information-packet.pdf*.

[249] See, for example, Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (Appendix F: Report Descriptions).

[250] CMS has made publicly available the PY 2026 Shared Savings Program Report templates through the ''Program Guidance & Specifications'' web page of the Shared Savings Program website, at *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations*.

under the PFS starting in CY 2027, we have determined it would be appropriate to propose to amend the definition of primary care services used in the Shared Savings Program assignment methodology to include certain additional codes for the PY starting on January 1, 2027, and subsequent PYs, to remain consistent with billing and coding under the PFS.

We propose to specify a revised definition of primary care services used for assignment for the PY starting on January 1, 2027, and subsequent PYs in a new provision of the Shared Savings Program at § 425.400(c)(1)(xi) to include the list of HCPCS and CPT codes specified at § 425.400(c)(1)(x), as well as the following additions: Screening, Brief Intervention, and Referral to Treatment (SBIRT) (HCPCS codes G2011, G0396, and G0397), Vaccine Adverse Effects Management (HCPCS code GADV1), Advance Care Planning (HCPCS codes GACP1 and GACP2), if finalized under OM payment policy.

We propose to use the new provision at § 425.400(c)(1)(xi) for determining beneficiary assignment for the PY starting on January 1, 2027, and in subsequent PYs.

The following provides additional information about the CPT and HCPCS codes that we are proposing to add to the definition of primary care services used for purposes of beneficiary assignment:

- *Screening, Brief Intervention, and Referral to Treatment (HCPCS G2011, G0396, and G0397):* The purpose of the SBIRT program is to implement the screening, brief intervention, and referral to treatment public health model for children, adolescents, and/or adults in primary care and community health settings (for example, health centers, hospital systems, health maintenance organizations (HMOs), preferred-provider organizations (PPOs) health plans, Federally Qualified Health Centers (FQHC), behavioral health centers, pediatric health care providers, children's hospitals, etc.) and schools with a focus on screening for underage drinking, opioid use, and other substance use.[251] SBIRT [252] has three major components:

(1) *Screening:* Screen or assess a patient for risky substance use behaviors with standardized assessment tools (known as Medicare Structured Assessment) to identify the appropriate level of care. Screening quickly assesses a patient's substance use severity and identifies the appropriate treatment level;

(2) *Brief Intervention:* Brief intervention increases substance use insight and awareness and motivates behavioral change. Engage the patient in a short conversation to increase their awareness of risky substance use behaviors and provide feedback, motivation, and advice; and

(3) *Referral to Treatment:* Refer patients whose assessment or screening shows a need for additional services to specialty care treatment using specific tools such as Alcohol Use Disorders Identification Test (AUDIT) Manual or Drug Abuse Screening Test (DAST).

These three codes include screening and counseling services similar to counseling and other evaluation and management services already included in the definition of primary care services used for purposes of assignment. In the CY 2019 PFS final rule (83 FR 59965 through 59969), we finalized the addition of HCPCS G0442 (*Annual alcohol misuse screening, 15 minutes*) and G0443 (*Alcohol misuse counseling*) to the definition of primary care services used for purposes of assignment. In the CY 2024 PFS final rule (88 FR 79163 through 79175) we finalized the addition of CPT codes 99406 and 99407 for smoking and tobacco-use cessation counseling services. We also finalized the inclusion of G2086, G2087, and G2088 for office-based opioid use disorder services in the definition of primary care services used for purposes of assignment. Since HCPCS codes G2011, G0396, and G0397 include screening and documentation related to alcohol misuse, similar to G0442 and G0443, we believe this supports the inclusion of these HCPCS codes in the definition of primary care services.

- *Vaccine Adverse Effects Management* (HCPCS code GADV1): In section II.E. of this proposed rule, we are proposing an add-on payment for diagnosis and management of a suspected vaccine adverse reaction for services going above and beyond those captured in an E/M visit. These services entail listening to patient concerns, answering questions, and building trust; selecting diagnosis strategies and conveying information in a manner specific to the clinical situation and individual patient needs; providing patients with appropriate resources; and planning with patients the treatment of symptoms of vaccine adverse effects. We propose that this add-on code, HCPCS code GADV1 (Office or other outpatient evaluation and management service(s) for the diagnosis and treatment of vaccine adverse effects, new or established patient; each 15 minutes personally performed by the physician or qualified healthcare professional (list separately in addition to CPT codes 99202, 99203, 99204, 99205, 99211, 99212, 99213, 99214, 99215, 99341, 99342, 99344, 99345, 99347, 99348, 99349, 99350)), would be payable when a physician or NPP: (1) establishes and documents a temporal relationship to vaccination, and (2) performs a medically appropriate assessment to rule out alternative causes. Since, as proposed, this service is an add-on payment for diagnosis and management of a suspected vaccine adverse reaction for services going above and beyond those captured in an evaluation and management (E/M) visit we believe these services will likely be provided by the clinician that is responsible for the overall care of the beneficiary and should, therefore, be included in the definition of primary care services used for purposes of assignment.

We have, over time, proposed separate payment and coding in instances where E/M codes may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries which were then incorporated into the definition of primary care services used for purposes of assignment (see, for example: Transitional Care Management (77 FR 68978 through 68994), Chronic Care Management (78 FR 43337 through 43343), Advance Care Planning (80 FR 70955 through 70959)). Similarly, we believe that the inclusion of GADV1 for the assessment and treatment of vaccine adverse effects represents services and resources supportive of the furnishing of comprehensive, coordinated care management that are not reflected in E/M codes and therefore should be included in the definition of primary care services used for purposes of assignment. Further, the valuation of this service is crosswalked to HCPCS code G2212, which is included in the definition of primary care services used for purposes of assignment.

- *Advance Care Planning* (HCPCS codes GACP1 and GACP2): As discussed in section II.G. of this proposed rule, we are proposing to create two new HCPCS codes to describe advance care planning services furnished by clinical staff under the direct supervision of the billing physician or other practitioner: HCPCS G-code GACP1 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of*

[251] *https://www.samhsa.gov/substance-use/treatment/sbirt.*

[252] *https://www.cms.gov/outreach-and-education/medicare-learning-network-mln/mlnproducts/downloads/sbirt_factsheet_icn904084.pdf.*

such forms, when performed), first 20 minutes of clinical staff time with the patient, family member(s), directed by a treating physician or other treating qualified health care professional) and GACP2 (*Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), each additional 20 minutes with the patient, family member(s), directed by a treating physician or other treating qualified health care professional (List separately in addition to code for primary procedure)*) and proposing that the existing CPT codes 99497 and 99498 would only be used to report time personally spent by the billing practitioner. We believe that this new coding would more accurately distinguish and value the work of the billing practitioners, from time that is spent by their clinical staff in the provision of advance care planning services. As discussed in section II.G of this proposed rule, CMS emphasizes that clinicians must not, under any circumstances, attempt to influence their patients' decisions with respect to ACP.

In the CY 2019 PFS final rule (83 FR 59965 through 59968), we finalized the inclusion of advance care planning CPT codes 99497 and 99498 in the definition of primary care services under the Shared Savings Program because the services provided as part of advance care planning include counseling and other E/M codes similar to the services included in Annual Wellness Visits and other E/M codes that are already included in the list of primary care services used for purposes of assignment. We continue to believe that the care billed under advance care planning CPT and HCPCS codes would be considered primary care, and as such, believe that the new proposed HCPCS that represent clinical time provided under direct supervision should be included in the definition of primary care services used for purposes of assignment.

As part of this revised definition of primary care services used for assigning beneficiaries at § 425.402, we propose to incorporate a provision at § 425.400(c)(1)(xi)(C), specifying that the primary care service codes for purposes of assigning beneficiaries include a CPT code identified by CMS that directly replaces a CPT code specified at § 425.400(c)(1)(xi)(A) or a HCPCS code specified at § 425.400(c)(1)(xi)(B), when the assignment window or expanded window for assignment (as defined at § 425.20) for a benchmark year or PY includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

We also propose a technical modification to the introductory text in § 425.400(c)(1)(x), to limit the applicability of that provision to the PY starting on January 1, 2026. This change is necessary so that we can effectuate § 425.400(c)(1)(xi) as explained in this section of this proposed rule to apply for the PY starting on January 1, 2027, and subsequent PYs.

We seek comments on these proposed changes to the definition of primary care services used for assigning beneficiaries at § 425.400(c)(1)(xi) to Shared Savings Program ACOs for the PY starting on January 1, 2027, and subsequent PYs, and related technical change. We also seek comments on any other existing or new HCPCS or CPT codes proposed elsewhere in this proposed rule that we should consider adding to the definition of primary care services for purposes of assignment in future rulemaking.

3. Quality Performance Standard and Other Quality Reporting Requirements

a. Overview

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by Shared Savings Program ACOs and seek to improve the quality of care furnished by Shared Savings Program ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. As we stated in the November 2011 final rule establishing the Shared Savings Program (76 FR 67872), our principal goal in selecting quality measures for Shared Savings Program ACOs has been to identify measures of success in the delivery of high-quality healthcare at the individual and population levels. In the November 2011 final rule, we established a quality measure set spanning four domains: patient experience of care, and wherever practicable, caregiver experience of care; care coordination/patient safety; preventative health; and at-risk population (76 FR 67872 through 67891). We have subsequently updated the measures that comprise the quality measure set for the Shared Savings Program through rulemaking in the CY 2015, 2016, 2017, 2019, 2021, 2023, 2024, 2025, and 2026 PFS final rules (79 FR 67907 through 67921, 80 FR 71263 through 71269, 81 FR 80484 through 80489, 83 FR 59708 through 59715, 85 FR 84733 through 84734, 87 FR 69860 through 69863, 88 FR 79112 through 79114, 89 FR 98124 through 98132, and 90 FR 49797 through 90 FR 49822, respectively).

b. Proposal To Extend the Availability of the MIPS CQMs Collection Type and the MIPS CQM Reporting Incentive for Shared Savings Program ACOs

(1) Background

In the CY 2025 PFS proposed rule, we proposed to streamline the collection types available for Shared Savings Program ACOs reporting the APM Performance Pathway (APP) Plus quality measure set to the eCQMs and Medicare CQMs collection types for PY 2025 and subsequent PYs (89 FR 61856 and 61857). We also stated that our proposal to establish the APP Plus quality measure set to align with the Adult Universal Foundation measure set should aim to prioritize the eCQMs collection type—the gold standard collection type that underlies the Digital Quality Measurement Strategic Roadmap (available at *https://ecqi.healthit.gov/sites/default/files/CMSdQMStrategicRoadmap_032822.pdf*)—and use Medicare CQMs as the transition step on our building-block approach for Shared Savings Program ACOs' progress to adopt digital quality measurement (89 FR 61838). As stated in the CY 2025 PFS final rule (89 FR 98107), many commenters expressed concern with the proposal to eliminate the MIPS CQMs collection type for Shared Savings Program ACOs beginning in PY 2025. These commenters stated that eliminating the MIPS CQMs collection type would cause administrative burden due to Shared Savings Program ACOs having disparate electronic health records (EHRs) and experiencing reporting challenges with the submission of the eCQMs collection type. Several commenters noted that their efforts and resources would need to focus on determining the best reporting approaches at the expense of innovations that support patients. Some commenters stressed the challenges related to prior investments made in MIPS CQM reporting infrastructure that would be wasted following the elimination of the MIPS CQM collection type. Several of these commenters stated that having limited notice from CMS that the MIPS CQMs collection type would not be available to Shared Savings Program ACOs reporting the APP Plus quality measure set provides Shared Savings Program ACOs with only a few months to pivot to another option if the proposal not to include MIPS CQMs in the APP Plus quality measure set was finalized. One commenter objected to the exclusion of

the MIPS CQMs collection type from the APP Plus quality measure set and stated MIPS CQMs allow Shared Savings Program ACOs to leverage multiple data sources beyond just electronic medical record (EMR) data, including claims data, as an important component to ensuring the accuracy and completeness of data reported. Lastly, many commenters encouraged us to consider extending the availability of the MIPS CQMs collection type for Shared Savings Program ACOs and requested that the collection type remain available for an additional 1 to 3 years (89 FR 98107).

In response to these comments, we stated in the CY 2025 PFS final rule (89 FR 98107) that we acknowledged commenters' feedback regarding the challenges associated with not having MIPS CQM available to Shared Savings Program ACOs as a collection type for reporting the APP Plus quality measure set. We agreed with commenters that additional time was needed for Shared Savings Program ACOs that have invested in MIPS CQMs to transition to eCQMs and that having MIPS CQMs as a reporting option would allow Shared Savings Program ACOs to gain experience with all payer quality measure data collection and reporting before MIPS CQMs are phased out as a collection type for Shared Savings Program ACOs. We also stated that we were aware that some Shared Savings Program ACOs had already contracted with vendors for the MIPS CQMs collection type at their own expense, and that for these Shared Savings Program ACOs, additional time to transition to the eCQMs collection type was desirable. In addition, we expressed our understanding that the MIPS CQMs collection type allows Shared Savings Program ACOs to leverage multiple data sources beyond just EMR data, thereby allowing for improved accuracy and completeness of data submitted with this collection type. For these reasons, we finalized in the CY 2025 PFS final rule that we would provide Shared Savings Program ACOs with the option to use the MIPS CQMs collection type for 2 additional PYs (that is, PYs 2025 and 2026) when reporting the APP Plus quality measure set. We stated that we believed making the MIPS CQMs collection type available for Shared Savings Program ACOs for 2 additional PYs would fairly balance investments Shared Savings Program ACOs have already made with the MIPS CQMs collection type and CMS' long-term goals of adopting digital quality measurement. As finalized in the CY 2025 PFS final rule, the collection types available to Shared Savings Program ACOs reporting the APP Plus quality measure set for PY 2025 and subsequent years recognized the need for some Shared Savings Program ACOs to build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient measures while incentivizing Shared Savings Program ACOs to transition to eCQMs (89 FR 98107). We also stated that MIPS CQMs would no longer be available starting in PY 2027 and that we would continue to monitor the uptake of collection types by Shared Savings Program ACOs in the coming years (89 FR 98107).

In the CY 2023 PFS final rule, we extended the incentive for reporting eCQMs/MIPS CQMs through PY 2024 to align with the timeline for sunsetting of the CMS Web Interface reporting option and to allow Shared Savings Program ACOs an additional year to gauge their performance on the eCQMs/MIPS CQMs before full reporting of the measures were required beginning in PY 2025 (87 FR 69836 through 69838 and 89 FR 98121). We originally adopted this incentive in the CY 2022 PFS final rule to encourage Shared Savings Program ACOs to begin the transition to eCQM/MIPS CQM reporting in PYs 2022 and 2023 (86 FR 65269).

To continue to align the reporting incentive with the MIPS CQMs collection type, in the CY 2025 PFS final rule (89 FR 98123 and 98124), we extended the reporting incentive to Shared Savings Program ACOs reporting MIPS CQMs in PYs 2025 and 2026 to further support Shared Savings Program ACOs in meeting the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track.

Specifically, we finalized that for PYs 2025 and 2026, a Shared Savings Program ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the Shared Savings Program ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a PY, meeting the data completeness requirement at § 414.1340 for all eCQMs/MIPS CQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set, and; of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

Over the past 2 years, we have developed a greater understanding of the challenges Shared Savings Program ACOs face in reporting eCQMs and transitioning to digital quality measurement. Comments stated in the CY 2025 PFS final rule (89 FR 98107), responses to the RFI on deregulation and other forums, and feedback from Shared Savings Program ACOs and other interested parties expressed concerns about increased administrative burden and Shared Savings ACO's prior investments in MIPS CQM reporting infrastructure that would be wasted if the MIPS CQMs collection type was eliminated and encouraged CMS to preserve the MIPS CQMs collection type and the corresponding MIPS CQM reporting incentive during the transition to digital quality measurement. By extending the MIPS CQMs collection type and the corresponding MIPS CQM reporting incentive, Shared Savings Program ACOs could continue to utilize investments already made in MIPS CQM reporting infrastructure while taking steps towards making the full transition to digital quality measurement. After considering the feedback we received, we believe that the widespread adoption of the all payer/all patient collection types will require further time and support.

In the CY 2025 PFS final rule, we stated that we intend to fully transition to digital quality measurement in CMS quality reporting and value-based purchasing programs (89 FR 98106). We also reiterated the numerous benefits to using eCQMs, including their use of electronic standards that reduce the burden of manual extraction and reporting for measured entities, their use of clinical data to assess the outcomes of treatment by measured entities, and their fostering of access to real-time data for point of care quality improvement and decision support (89 FR 98106).

We refer readers to the Fast Healthcare Interoperability Resources® (FHIR®)-Based Digital Quality Measurement in the Quality Payment Program and other CMS Quality Programs—RFI in section IV.A.4.c. of this proposed rule. In that section, we state that we are advancing quality measurement by transitioning existing quality measures and reporting processes to FHIR-based digital approaches and requesting public comment on the timeline for transitioning to FHIR-based quality measurement. We also state that we request input from interested parties, ahead of future policy decisions, on developing a phased transition to FHIR-based digital quality reporting for applicable measures (that is, the 5 eCQMs and Medicare eCQMs in the

APP Plus quality measure set as proposed in section IV.A.4.b.(2) of this proposed rule) under which we would introduce a 2-year transition period beginning with PY 2028. During the transition period, existing quality reporting options for Shared Savings Program ACOs (that is, eCQMs, MIPS CQMs, Medicare CQMs, and the proposed Medicare eCQMs), would continue to be available while FHIR-based digital quality measure (dQM) options are introduced for selected measures. For Shared Savings Program ACOs, the transition to FHIR-based dQMs builds upon the existing eCQM reporting infrastructure used for the APP Plus quality measure set (including APP/APP Plus measure alignment and current electronic reporting approaches) while introducing FHIR-based specifications for dQMs and related software tools, such as the Measure Authoring Development Integrated Environment (MADiE), so that Shared Savings Program ACOs would have a feasible pathway to adopt FHIR-based quality measurement. Following this transition period, beginning with PY 2030, FHIR-based reporting would be required for those applicable measures that were available as FHIR-based dQM reporting options during the transition period. As discussed in section IV.A.4.c. of this proposed rule, by PY 2030, Shared Savings Program ACOs would need to be prepared to report each applicable APP Plus measure via FHIR-based digital quality reporting where a FHIR-based dQM specification exists for that measure. For APP Plus measures that do not have FHIR-based dQM specifications following the transition period, Shared Savings Program ACOs would continue to use applicable existing reporting mechanisms (for example, MIPS CQMs, Medicare CQMs, eCQM reporting via QRDA files, and proposed Medicare eCQMs) until FHIR-based dQM options are developed and adopted through future rulemaking.

Table B–G2 illustrates the timeline for the transition to FHIR-based quality reporting for Shared Savings Program ACOs, as described in section IV.A.4.c. of this proposed rule, as well as potential future quality performance scoring considerations subject to future notice and comment rulemaking. We note that between January 21, 2026, and February 23, 2026, CMS posted and sought public comment on draft FHIR-based digital specifications for 49 eligible clinician dQMs. This posting of draft specifications included specifications for the 5 measures in the APP Plus quality measure set that currently are available under the eCQMs, MIPS CQMs, and Medicare CQMs collection types (*https://ecqi.healthit.gov/sites/default/files/FHIR-Public-Comment-Webinar-CMS-20260121.pdf*).

TABLE B-G2: IMPLEMENTATION TIMELINE AND MILESTONES FOR TRANSITION TO FHIR-BASED DIGITAL QUALITY MEASUREMENT FOR SHARED SAVINGS PROGRAM ACOS

Phase	Timeframe	Collection Types Available for Quality Reporting	Potential Future Scoring Considerations
Transition Period with FHIR-Based Reporting Options (Year 1)	PY 2028	**FHIR-based dQM reporting options:** • dQMs • Medicare dQMs **Non-FHIR-based reporting options:** • eCQMs • MIPS CQMs • Medicare CQMs • Medicare eCQMs (proposed)	**FHIR-based dQM reporting options:** Benchmarking policies and reporting incentives would be established through future notice and comment rulemaking **Medicare CQMs and Medicare eCQMs:** Flat benchmarks (proposed) **All other non-FHIR-based reporting options:** Consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii) Anticipate sunsetting the current MIPS CQM reporting incentives
Transition Period with FHIR-Based Reporting Options (Year 2)	PY 2029	**FHIR-based dQM reporting options:** • dQMs • Medicare dQMs **Non-FHIR-based reporting options:** • eCQMs • MIPS CQMs • Medicare CQMs Medicare eCQMs (proposed)	**FHIR-based dQM reporting options:** Benchmarking policies and reporting incentives would be established through future notice and comment rulemaking **Medicare CQMs and Medicare eCQMs:** Flat benchmarks (proposed) **All other non-FHIR-based reporting options:** Consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii)
Mandatory FHIR-Based Reporting	PY 2030 and subsequent PYs	**FHIR-based dQM reporting options:** • dQMs • Medicare dQMs	Benchmarking policies would be established through future notice and comment rulemaking

(2) Proposed Revisions

In light of the concerns raised by Shared Savings Program ACOs and other interested parties, and our commitment to supporting Shared Savings Program ACOs in the transition to dQM reporting, we propose to extend the availability of the MIPS CQMs collection type for Shared Savings

Program ACOs reporting the APP Plus quality measure set for PY 2027 and subsequent PYs. We believe that the removal of the MIPS CQMs collection type for ACOs during this transition would be disruptive considering there was a significant increase in the number of Shared Savings Program ACOs that reported MIPS CQMs in PY 2025 compared to PYs 2023 and 2024. Based on initial PY 2025 MIPS quality submission data, Shared Savings Program ACOs are continuing to report the APP Plus quality measure set using the MIPS CQMs collection type, where 140 out of 472 financially reconciled ACOs reported at least one MIPS CQM; whereas 33 out of 453 financially reconciled Shared Savings Program ACOs in PY 2023 and 36 out of 476 financially reconciled Shared Savings Program ACOs in PY 2024 reported at least one MIPS CQM.

Maintaining the availability of the MIPS CQMs collection type for PY 2027 and subsequent PYs would eliminate the administrative burden associated with Shared Savings Program ACOs changing their current quality reporting collection type to another collection type after PY 2026 when the MIPS CQMs collection type would no longer be available under the policy finalized in the CY 2025 PFS final rule (89 FR 98123) and would also allow Shared Savings Program ACOs to focus their resources and efforts on the transition to dQM reporting instead.

Subject to future notice and comment rulemaking, we anticipate sunsetting the MIPS CQMs collection type beginning in PY 2030, when FHIR-based reporting becomes mandatory for all the eCQMs and the proposed Medicare eCQMs in the APP Plus quality measure set. As discussed in the FHIR-Based Digital Quality Measurement in the Quality Payment Program and Other CMS Quality Programs—RFI in section IV.A.4.c. of this proposed rule, we are requesting feedback on the phased timeline for FHIR-based reporting which starts with a 2-year transition period followed by required FHIR-based reporting for applicable measures.

To continue to align the reporting incentive with the MIPS CQMs collection type, we propose to extend the reporting incentive to Shared Savings Program ACOs reporting MIPS CQMs for PY 2027 and subsequent PYs to further support Shared Savings Program ACOs in meeting the Shared Savings Program quality performance standard for sharing in savings at the maximum rate under its track. Specifically, we propose that for PY 2027 and subsequent PYs, a Shared Savings Program ACO will meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses, if applicable:

- If the Shared Savings Program ACO reports all of the eCQMs/MIPS CQMs in the APP Plus quality measure set applicable for a PY, meeting the data completeness requirement at § 414.1340 for all eCQMs/MIPS CQMs, and;
- Achieves a quality performance score equivalent to or higher than the 10th percentile of the performance benchmark on at least one of the outcome measures in the APP Plus quality measure set, and;
- Achieves a quality performance score equivalent to or higher than the 40th percentile of the performance benchmark on at least one of the remaining measures in the APP Plus quality measure set.

Based on a CMS analysis of PY 2024 Shared Savings Program ACO quality results, 26 Shared Savings Program ACOs reported MIPS CQMs and met the Shared Savings Program quality performance standard by meeting the criteria for the MIPS CQM reporting incentive, through which they were eligible to receive maximum shared savings and avoid maximum shared losses (if applicable) for their track regardless of their quality score. These 26 Shared Savings Program ACOs did not achieve a quality score at or above the 40th percentile MIPS quality performance category score value, which is one of the pathways for meeting the quality performance standard, and therefore, would not have met the quality performance standard without the MIPS CQM reporting incentive.

We will continue to assess the appropriateness of having the MIPS CQMs collection type being an available collection type for Shared Savings Program ACOs along with the associated MIPS CQM reporting incentive. Subject to future notice and comment rulemaking, we anticipate sunsetting the MIPS CQM reporting incentive when we introduce the 2-year transition period beginning with PY 2028 during which the existing quality reporting options for Shared Savings Program ACOs (that is, eCQMs, MIPS CQMs, Medicare CQMs, and the proposed Medicare eCQMs) would continue to be available while FHIR-based dQM reporting options are introduced for selected measures (that is, the 5 eCQMs and the proposed Medicare eCQMs in the APP Plus quality measure set as proposed in section IV.A.4.b.(2) of this proposed rule).

We note that, in section III.G.3.d.(3) of this proposed rule, we are proposing to create the Medicare eCQMs collection type, which would be a new collection type for PY 2027 and subsequent PYs. As part of our proposal to extend the availability of the MIPS CQMs collection type and the MIPS CQM reporting incentive for PY 2027 and subsequent PYs, § 425.512(a) would contain the following information:

- Under paragraph (a)(2)(iv), we would specify that the paragraph applies to eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs.
- Under paragraph (a)(5)(i)(B), we would specify that the paragraph applies to PY 2025 and subsequent PYs.
- We would remove paragraph (a)(5)(i)(C).
- We would revise paragraph (a)(5)(iii)(C) to specify that it applies to eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs.

We are seeking public comments on our proposals to extend the availability of the MIPS CQMs collection type for Shared Savings Program ACOs and the MIPS CQM reporting incentive for PY 2027 and subsequent PYs.

c. Proposal To Extend the Scoring of Shared Savings Program ACOs Reporting Medicare CQMs Using Flat Benchmarks

(1) Background

In the CY 2024 PFS final rule (88 FR 79110), we finalized our proposal to establish Medicare CQMs and new benchmarks for scoring Shared Savings Program ACOs on the Medicare CQMs under MIPS in alignment with MIPS benchmarking policies. Because historical Medicare CQM data would not be available, we finalized that for PYs 2024 and 2025, we would score Medicare CQMs using performance period benchmarks. We also finalized that, for PY 2026 and subsequent PYs, when baseline period data became available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii), we would score Medicare CQMs using historical benchmarks.

As stated in the CY 2024 PFS final rule (88 FR 79109 and 79110), a few commenters expressed concern about Shared Savings Program ACOs being compared only to other Shared Savings Program ACOs that report Medicare CQMs. As part of their concern, they referenced that Medicare CQMs would be available only to Shared Savings Program ACOs. One commenter stated their preference to have their quality performance compared to all other participants on these measures, while another commenter stated that CMS

should stop measuring Shared Savings Program ACOs against each other and instead measure Shared Savings Program ACOs on a national standard so that all ACOs can pass and do not lose out on savings due to arbitrary quality decile cut points. In our response to these comments, we stated that given that benchmarks are specific to each collection type and that since we proposed to establish Medicare CQMs as a new collection type for only Shared Savings Program ACOs, only Shared Savings Program ACO data will be available to benchmark Medicare CQMs. For these reasons, we stated that it was appropriate to establish benchmarks for Medicare CQMs that were consistent with MIPS benchmarking policies (88 FR 79110). We also stated that Shared Savings Program ACOs that prefer to be compared to clinicians at large could do so by reporting eCQMs or MIPS CQMs, for which CMS calculates a benchmark using data reported by MIPS eligible clinicians reporting under the chosen collection type.

In the CY 2025 PFS final rule (89 FR 98117), we stated that in PY 2022, Shared Savings Program ACOs had a higher average performance on quality measures they were required to report to share in savings compared to other similarly sized clinician groups not in the Shared Savings Program. This included statistically significant higher performance for quality measures related to diabetes and blood pressure control; breast cancer and colorectal cancer screening; tobacco screening and smoking cessation; and depression screening and follow-up. We further stated that in shifting to Medicare CQMs, Shared Savings Program ACOs' quality performance would be benchmarked against other Shared Savings Program ACOs only reporting Medicare CQMs. We explained that since Shared Savings Program ACOs are high performers relative to comparably sized MIPS groups, benchmarking Medicare CQMs using only Shared Savings Program ACO data would lower some Shared Savings Program ACOs' MIPS measure achievement points on those measures. In other words, high-performing Shared Savings Program ACOs could earn lower measure achievement points relative to comparable MIPS groups because the Medicare CQM benchmarking pool is comprised of higher-than-average performance data. This would, in effect, create a ''tournament approach'' to scoring Medicare CQMs wherein Shared Savings Program ACOs must compete with other Shared Savings Program ACOs to earn measure achievement points.

In the CY 2025 PFS final rule, we finalized our proposal to add § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQMs collection type would be scored using flat benchmarks for their first 2 performance periods in MIPS (89 FR 98120). We further stated that the use of flat benchmarks would allow Shared Savings Program ACOs with high scores to earn maximum or near maximum achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years (89 FR 98118). Use of flat benchmarks also helps to ensure that Shared Savings Program ACOs with high quality performance on a measure are not penalized as low performers (89 FR 98118).

As stated in the CY 2025 PFS final rule, many commenters supported the proposal to score Shared Savings Program ACOs reporting Medicare CQMs using flat benchmarks (89 FR 98119). One commenter stated that it will be a difficult transition for ACOs to progress from the CMS Web Interface attestation method to CQM/eCQM reporting and that Medicare CQM flat benchmarking will remove uncertainty from Shared Savings Program ACO attestation to Medicare CQMs as they will no longer have to rely on benchmarking based upon the PY (89 FR 98119). Additionally, many commenters recommended that flat benchmarks for Medicare CQM be made permanent rather than for 2 years and noted that flat benchmarks make Medicare CQM scoring more predictable (89 FR 98120). One commenter recommended that CMS consider extending the flat benchmark scoring policies for Medicare CQMs beyond each measure's first 2 performance periods and some commenters recommended that CMS retroactively apply the flat benchmark policy for the 2024 performance period (89 FR 98120).

In response to comments on the proposals in the CY 2026 PFS final rule (90 FR 49812) related to removing the population and income adjustment applied to a Shared Savings Program ACO's quality score beginning in PY 2025, one commenter stated that flat benchmarks are temporary and are not a lasting offset to the unique challenges faced by Shared Savings Program ACOs that serve high Area Deprivation Index (ADI), Medicare Part D Low Income Subsidy (LIS), and dual eligible populations. We stated that should we consider extending flat benchmarks for Medicare CQMs, we would do so through notice and comment rulemaking (90 FR 49813).

(2) Proposed Revisions

Through responses to the RFI on deregulation and other forums, Shared Savings Program ACOs and other interested parties expressed support for policies that promote continuity while Shared Savings Program ACOs transition to digital quality measurement. In response to ACOs' concerns and to support Shared Savings Program ACOs in the transition to dQM reporting, for PY 2027 and subsequent years, in section IV.B.1.c.(1) of this proposed rule, we are proposing that all measures of the Medicare CQMs collection type would be scored using flat benchmarks. We are also proposing that for PY 2026, the following measures reported via the Medicare CQMs collection type for PY 2026 are scored using flat benchmarks instead of using historical benchmarks as finalized in the CY 2025 PFS final rule (89 FR 98120): Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001), Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134), and Controlling High Blood Pressure (Quality ID: 236). These three Medicare CQMs, under the policy finalized in the CY 2025 PFS final rule (89 FR 98120), would have historical benchmarks for PY 2026, consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii), because these measures would be in their third performance period in MIPS. We propose that Quality IDs: 001, 134, and 236, if reported via the Medicare CQMs collection type for PY 2026 (and subsequent years), would be scored using flat benchmarks. As discussed more fully later in this section, failure to apply this change retroactively would be contrary to the public interest. We note that Breast Cancer Screening (Quality ID: 112) and Colorectal Cancer Screening (Quality ID: 113) reported via the Medicare CQMs collection type would be scored using flat benchmarks for PY 2026 under the policy finalized in the CY 2025 PFS final rule (89 FR 98120), which is consistent with CMS' intent to score all measures reported via Medicare CQMs collection type using flat benchmarks.

In response to commenters who requested that we make Medicare CQMs a permanent collection type in the CY 2025 PFS final rule (89 FR 98108), we stated that from the inception of the Medicare CQMs collection type beginning in PY 2024, that we intended for the Medicare CQMs collection type to serve as a transition collection type

to help ACOs build the infrastructure, skills, knowledge, and expertise necessary to report all payer/all patient measures (88 FR 79097 and 79098). In addition, as we stated in the CY 2025 PFS proposed rule, we believed that our policy to establish the APP Plus quality measure set to align with the Adult Universal Foundation measure set should also aim to prioritize the eCQMs collection type and the use of the Medicare CQMs collection type is a transition step on our building-block approach for ACOs' to adopt digital quality measurement (89 FR 61838). We noted in the CY 2025 PFS final rule that the sunsetting of Medicare CQMs would take place no sooner than 5 years from the time the rule was written, when we anticipated there would be widespread uptake of FHIR API technology (89 FR 98108). While FHIR technology is employed in other components of digital health information, we noted that we would assess the uptake of FHIR API technology for quality reporting in alignment with the CMS Digital Quality Measurement Strategic Roadmap, specifically, Domain 3: Optimize Data Aggregation. In particular, we would assess whether Shared Savings Program ACOs broadly have developed capabilities to efficiently leverage FHIR API technology to aggregate quality reporting data and patient-centered measurement and are reporting eCQMs.

As of PY 2026, FHIR-based reporting of quality measures to CMS is not yet available to Shared Savings Program ACOs. As discussed in section IV.A.4.c. of this proposed rule, we intend to introduce a 2-year transition period to FHIR-based reporting beginning with PY 2028. During the transition period, existing quality reporting options for Shared Savings Program ACOs (that is, eCQMs, MIPS CQMs, Medicare CQMs, and the proposed Medicare eCQMs) would continue to be available while FHIR-based dQM options are introduced for selected measures (that is, the 5 eCQMs and the proposed Medicare eCQMs in the APP Plus quality measure set as proposed in section IV.A.4.b.(2) of this proposed rule). Following this transition period, beginning with PY 2030, FHIR-based reporting would be required for those applicable measures that were available as FHIR-based dQM reporting options during the transition period. The timing of this transition would influence our proposals related to the collection types available to Shared Savings Program ACOs and the associated scoring policies. We anticipate sunsetting the Medicare CQMs collection type and the use of flat benchmarks to score Medicare CQMs beginning in PY 2030, when FHIR-based reporting becomes mandatory for all the eCQMs and proposed Medicare eCQMs in the APP Plus quality measure set. As discussed in section IV.A.4.c. of this proposed rule, we are requesting feedback on the phased timeline for FHIR-based reporting which starts with a 2-year transition period followed by required FHIR-based reporting for applicable measures.

We expect that policies associated with this timeline would be proposed through future rulemaking.

In response to commenters who requested that we extend or make permanent flat benchmarks for Medicare CQMs, we stated in the CY 2025 PFS final rule (89 FR 98120) that we believed that the baseline period data, which would be available to establish historical benchmarks is consistent with MIPS benchmarking policies at § 414.1380(b)(1)(ii). As we stated in the CY 2025 PFS proposed rule (89 FR 61860), the use of historical benchmarks, when data are available, allows Shared Savings Program ACOs to know benchmarks prior to start of the PY and create opportunities for improvement. Also, as discussed in the CY 2024 PFS final rule, since Medicare CQMs would be subject to MIPS scoring policies, the application of MIPS benchmarking policies to Medicare CQMs is both logical and necessary for implementation of the new collection type (88 FR 79180). We believe it is no longer logical to apply this benchmark methodology to Medicare CQMs due to Shared Savings Program ACOs' concerns that quality-related changes are disruptive to the transition to digital quality measurement as well as due to the sunsetting of the population and income adjustment as finalized in the CY 2026 PFS final rule, each described in further detail later in this section.

In 2025, we conducted interviews with a sample of Shared Savings Program ACOs who reported Medicare CQMs for PY 2024, the first year of the Medicare CQMs collection type.[253] Interviewed Shared Savings Program ACOs reported continued challenges with the transition to digital quality measurement. Some Shared Savings Program ACOs shared that uncertainty regarding digital reporting standards have led them to restrict or pause adding new practices to their organization. These new restrictions limit practice access to the Shared Savings Program and beneficiary access to value-based care. To support the transition to digital quality measurement, Shared Savings Program ACOs and other interested parties that responded to the RFI on deregulation demonstrated support for policies that promote continuity and recommended against further alignment of Shared Savings Program quality reporting policies with MIPS. Given the challenges and concerns that Shared Savings Program ACOs have shared regarding navigating additional Shared Savings Program policy changes in a time of larger quality reporting transition, coupled with Shared Savings Program ACO patient data privacy concerns and lack of capability to report other measure collection types such as eCQMs, as discussed in section IV.B.1.c.(1) of this proposed rule, we propose to extend the use of flat benchmarks to score all Medicare CQMs for PY 2027 and subsequent PYs, and for Quality IDs 001, 134, and 236 for PY 2026. This proposal would continue to support Shared Savings Program ACOs that choose to report via that collection type during the transition to reporting and would be consistent with the goals of the deregulatory RFI (90 FR 15481 and 15482).

Under current policy, flat benchmarks for Medicare CQMs are only used in a measure's first two years in MIPS. Thus, the number of Medicare CQMs in the APP Plus quality measure set that will use flat benchmarks will decline over time. For PY 2025, all four Medicare CQMs (Quality IDs 001, 112, 134, and 236) in the APP Plus quality measure set were scored using flat benchmarks; however, this number decreased to two (Quality IDs 112 and 113) of five Medicare CQMs for PY 2026.

In the CY 2026 PFS final rule (90 FR 49807), we stated that we conducted an internal analysis of the PY 2024 Shared Savings Program ACO quality results to better understand the potential impact of the proposed removal of the population and income adjustment on 13 ACOs that earned the population and income adjustment bonus points and reported only Medicare CQMs. Specifically, we simulated the application of flat benchmarks for Medicare CQMs (as described at § 414.1380(b)(1)(ii)(F)), which was in effect starting in PY 2025. Had flat benchmarks been applied to the three Medicare CQMs in the APP quality measure set in PY 2024, the average MIPS quality performance category score earned by these 13 Shared Savings Program ACOs would have been on average 14 percentage points higher compared to an average increase of 4 percentage points that these Shared Savings Program ACOs earned from the

[253] Findings are based on internal analysis of interviews with ACOs that reported Medicare CQMs for PY 2024.

population and income adjustment in PY 2024, a difference of 10 percentage points. This would thus increase the likelihood that these Shared Savings Program ACOs would meet the quality performance standard by achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring or the alternative quality performance standard. We also stated that, while we anticipate that Shared Savings Program ACOs that choose to report Medicare CQMs would not be eligible for the eCQM/MIPS CQM reporting incentive or the Complex Organization Adjustment, these Shared Savings Program ACOs would likely sufficiently benefit from our policy to score Medicare CQMs using flat benchmarks as described at § 414.1380(b)(1)(ii)(F). Specifically, we anticipated that these Shared Savings Program ACOs would receive a positive scoring impact under flat benchmarks for Medicare CQMs, that would be greater than the current positive scoring impact these Shared Savings Program ACOs received under the population and income adjustment. This analysis further reflected the substantial impact of flat benchmarks on Shared Savings Program ACOs' quality scores. Since the population and income adjustment is no longer applicable beginning in PY 2026, as finalized in the CY 2026 PFS final rule (90 FR 49815), using flat benchmarks to score Quality IDs 001, 134, and 236 if reported via the Medicare CQMs collection type for PY 2026, and scoring all Medicare CQMs using flat benchmarks in PY 2027 and subsequent PYs, would further support Shared Savings Program ACOs that will no longer have access to the population and income adjustment and help ensure that Shared Savings Program ACOs with high quality performance on a measure are not penalized as low performers. Additionally, Shared Savings Program ACOs that report quality measures using the eCQMs or MIPS CQMs collection type may qualify for the collection type's respective reporting incentive or may be eligible to receive the Complex Organization Adjustment (if reporting using the eCQMs collection type). This proposed policy would also support Shared Savings Program ACOs that do not yet report or cannot report eCQMs or MIPS CQMs.

Section 1871(e)(1)(A) of the Act prohibits the Secretary from applying substantive changes in regulations retroactively before the effective date of the change except where the Secretary determines, as relevant here, that failure to apply the change retroactively would be contrary to the public interest. It is in the public interest to apply our proposed change to score Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001), Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134), and Controlling High Blood Pressure (Quality ID: 236) when reported via the Medicare CQMs collection type for PY 2026 using flat benchmarks. The evaluation of Shared Savings Program ACOs' PY 2026 quality performance, including the use of measure benchmarks to calculate quality scores, will occur in PY 2027. Retroactive application of flat benchmarks for Medicare CQMs for PY 2026 would enable the Shared Savings Program to better recognize the quality of care provided in PY 2026 and incentivize future improvements based on the evaluation of that care. We analyzed PY 2024 data on Shared Savings Program ACOs that reported all three Medicare CQMs in the APP quality measure set, which had performance-based benchmarks, and compared PY 2024 quality scores to simulated quality scores using flat benchmarks for the three Medicare CQMs. Flat benchmarks were estimated to increase average quality scores by 11 percentage points in this analysis.[254] Higher percentage points would increase the likelihood that these Shared Savings Program ACOs would meet the quality performance standard for sharing in savings at the maximum rate under its track by achieving a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring or the alternative quality performance standard to be eligible to share in savings at a lower rate that is scaled based on the ACO's quality performance. The quality performance standard helps hold Shared Savings Program ACOs accountable for the quality of care their providers furnish to their beneficiaries and further encourages ACOs to demonstrate consistently that they are providing high quality of care to their beneficiary populations year over year (90 FR 49836). This analysis also illustrated that the use of performance-based benchmarks could lead to Shared Savings Program ACOs forgoing shared savings that might otherwise have been available for reinvestment. Based on the Shared Savings Program ACO public reporting requirements § 425.308(b)(4)(ii), Shared Savings Program ACOs that generate shared savings must publicly report the total proportion of shared savings invested in infrastructure, redesigned care processes, and other resources required to support the triple aim of better health for populations, better care for individuals, and lower growth in expenditures, including the proportion distributed among Share Savings Program ACO participants. As such, the proposed change would afford the Shared Savings Program ACOs with increased shared savings the opportunity to devote greater resources to providing better quality of care to Medicare beneficiaries over time and improving care coordination that benefits the Medicare beneficiaries served by the Shared Savings Program ACOs.

Additionally, Shared Savings Program ACOs that participated in the interviews discussed earlier in this section also shared that some practices have closed due to financial challenges associated with the transition to digital quality measurement. Furthermore, some Shared Savings Program ACOs have begun to remove practices that cannot meet digital reporting requirements from their organization.[255] For practices experiencing financial and organizational instability, the loss of shared savings would compound these challenges and may cause them to close or negatively affect their ability to provide continuity of care, coordination of care, preventive care initiatives, and quality improvement initiatives for Medicare beneficiaries they serve. As a result, beneficiaries may experience challenges with accessing care, ineffective utilization of services, fragmented care, or duplicative tests or services, and ACOs may be slower to adopt digital quality measurement as a result.

As discussed in section III.G.3.f.(2) of this proposed rule, our proposal to remove Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) and Adult Immunization Status (Quality ID: 493) from the APP Plus quality measure set beginning in PY 2027, would result in the APP Plus quality measure set to have five Medicare CQMs for PY 2027 and subsequent PYs. These are the same Medicare CQMs that are in the APP Plus quality measure set for PY 2026. Under the proposals described in this section and as described in section IV.B.1.c.(1),

[254] Percent is based on internal analysis of ACOs' quality performance scores for PY 2024.

[255] Findings are based on internal analysis of interviews with ACOs that reported Medicare CQMs for PY 2024.

all Medicare CQMs in the APP Plus measure set (Quality IDs: 001, 112, 113, 134, and 236) would be scored using flat benchmarks for PY 2026 and subsequent PYs. The proposed APP Plus quality measure set for PY 2027 and subsequent PYs is displayed in Table B–G4 of this proposed rule. The APP Plus quality measure set for PY 2026 is displayed in Table 40 of the CY 2025 PFS final rule (89 FR 98129).

As discussed in the CY 2025 PFS final rule, a quality performance benchmark is the performance rate a Shared Savings Program ACO must achieve to earn the corresponding quality points for each measure (89 FR 98118). Flat benchmarks assign a performance rate range to each decile. In flat benchmarks for non-inverse measures, any performance rate at or above 90 percent is treated as the top decile; any performance rate between 80 percent and 89.99 percent would be treated as the second highest decile, and so on. For inverse measures, this would be reversed—any performance rate at or below 10 percent would be treated as the top decile; any performance rate between 10.01 percent and 20 percent would be treated as the second highest decile, and so on. The number of measure achievement points received for each measure is determined based on where a Shared Savings Program ACO's performance rate is within the benchmark decile categories.

For non-inverse measures, better quality performance is indicated by a higher performance rate. For example, Controlling High Blood Pressure (Quality ID: 236) is a non-inverse measure that measures the percentage of patients 18 to 85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period. Better quality performance on this measure is demonstrated by having a higher percentage of patients whose blood pressure was adequately controlled. Table B–G3 lists the flat benchmarks for a non-inverse Medicare CQM under our proposals discussed in this section of the proposed rule. For example, if a Shared Savings Program ACO reports a non-inverse Medicare CQM in PY 2026 or a subsequent PY and earns a performance rate of 55.25 percent, then the Shared Savings Program ACO would score in the 6th decile on that measure.

TABLE B-G3: FLAT BENCHMARKS FOR A NON-INVERSE MEDICARE CQM IN PY 2026 AND SUBSEQUENT PYs

Decile	Performance Rate Range
1	< 10.00
2	10.00 – 19.99
3	20.00 – 29.99
4	30.00 – 39.99
5	40.00 – 49.99
6	50.00 – 59.99
7	60.00 – 69.99
8	70.00 – 79.99
9	80.00 – 89.99
10	>= 90.00

For inverse measures, better quality performance is indicated by a lower performance rate. This is reflected in flat benchmark such that lower quality performance rates are found in higher deciles. For example, Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001) is an inverse quality measure that measures the percentage of patients 18–75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) greater than 9.0 percent during the measurement period. Better quality performance on this measure is demonstrated by having a lower percentage of patients whose glycemic status assessment was greater than 9.0 percent. Table B–G4 lists the flat benchmarks for an inverse Medicare CQM under our proposals discussed in this section of the proposed rule. For example, if a Shared Savings Program ACO reports an inverse Medicare CQM in PY 2026 or subsequent year and earns a performance rate of 12.25 percent, then the Shared Savings Program ACO would score in the 9th decile on that measure. Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001) is the only inverse Medicare CQM in the APP Plus quality measure set.

TABLE B-G4: FLAT BENCHMARKS FOR AN INVERSE MEDICARE CQM IN PY 2026 AND SUBSEQUENT PYs

Decile	Performance Rate Range
1	99.00 – 90.01
2	90.00 – 80.01
3	80.00 – 70.01
4	70.00 – 60.01
5	60.00 – 50.01
6	50.00 – 40.01
7	40.00 – 30.01
8	30.00 – 20.01
9	20.00 – 10.01
10	<= 10.00

There are scoring scenarios in which Shared Savings Program ACOs would earn higher measure achievement points under flat benchmarks compared to those they would earn under performance period benchmarks. Most notable are scenarios in which Shared Savings Program ACOs have a tight distribution of performance rates on a measure. For example, a non-inverse measure for which a performance rate of 90.00 percent is in the 8th decile. In this example, a Shared Savings Program ACO that reported a performance rate of 90.00 percent would be scored in the 8th decile when the hypothetical performance period benchmark is applied. Using the flat benchmarks described in Table B–G3 of this proposed rule, a Shared Savings Program ACO that reported a performance rate of 90.00 percent would be scored in the 10th decile, resulting in greater measure achievement points than under the hypothetical performance period benchmarks described in this example. For more details on the calculation of measure achievement points, we refer readers to the ''APM Performance Pathway (APP) Toolkit'' which is updated for each PY and posted in the QPP Resource Library.

As described in section IV.B.1.c.(1) of this proposed rule and in § 414.1380(b)(1)(ii)(F)(2), we are proposing that beginning with the CY 2026 performance period/2028 MIPS payment year, measures of the Medicare CQMs collection type would use flat benchmarks.

We seek public comment on our proposals to score Shared Savings Program ACOs reporting Medicare CQMs using flat benchmarks for PY 2027 and subsequent years and to retroactively apply the flat benchmarks for Quality IDs: 001, 134, and 236 when reported via the Medicare CQMs collection type for PY 2026.

d. Proposals To Address Shared Savings Program ACOs' Challenges With Meeting the MIPS Data Completeness Requirement

(1) Background

Requirements for data completeness are essential to ensure that data submitted on quality measures are sufficiently complete to accurately assess each Shared Savings Program ACO's quality performance. The data completeness requirement means that a Shared Savings Program ACO participant submitting measure data on a quality measure must submit data on at least a specific percentage of their patients that meet the measure's denominator criteria. Meeting the data completeness requirement ensures that the measure represents an appropriate percentage of the patient population applicable for a given quality measure. Robust data completeness requirements ensure the most accurate assessment of the performance of Shared Savings Program ACO participants.

In the CY 2017 Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (81 FR 77125), we established a data completeness threshold to ensure that data submitted on quality measures are complete enough to accurately assess each MIPS eligible clinician's quality performance. Additionally, in the CY 2020 PFS final rule (84 FR 62568, 62953), we added a requirement at § 414.1340 that quality data would not be considered true, complete, or accurate if such data are submitted selectively such that the data are unrepresentative of a MIPS eligible clinician or group's performance. In the CY 2024 PFS final rule, we finalized that we would maintain the data completeness criteria threshold of 75 percent (88 FR 79337). Specifically, as finalized, the data completeness criteria for the quality performance category (§ 414.1340) state that MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities submitting quality measure data on QCDR measures, MIPS CQMs, or eCQMs must submit data on at least 75 percent of the MIPS eligible clinician, group, virtual group, subgroup, and APM Entity's patients that meet the measure's denominator criteria, regardless of payer for MIPS payment years 2026 through 2030. In the CY 2024 PFS final rule, for APM Entities, specifically Shared Savings Program ACOs, we likewise established the data completeness criteria threshold of at least 75 percent for the Medicare CQMs aligned with the data completeness criteria threshold established for the eCQMs and MIPS CQMs collection types (88 FR 79337).

In the CY 2021 PFS final rule, we finalized modifications to the Shared Savings Program quality reporting requirements and quality performance standard for PY 2021 and subsequent PYs (85 FR 84720 through 84743) requiring Shared Savings Program ACOs to report quality data via the APP codified at § 414.1367. In the CY 2025 PFS final rule, we finalized that for PYs beginning on or after January 1, 2025, Shared Savings Program ACOs must submit quality data via the APP on the quality measures contained in the APP Plus quality measure set to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of a Shared Savings Program ACO participant for purposes of the MIPS quality performance category of the Quality Payment Program (89 FR 98568).

For data completeness criteria pertaining to the quality performance category, we finalized in the CY 2025 PFS final rule that an APM Entity, specifically a Shared Savings Program

ACO that meets reporting requirements under the APP, must meet the data completeness requirements established at § 414.1340(d)(1). Shared Savings Program ACOs reporting quality data on the APP Plus quality measure set meet the quality performance standard if they achieve a quality score that is equivalent to or higher than the 40th percentile across all MIPS quality performance category scores. If a Shared Savings Program ACO fails to meet data completeness on a measure in the APP Plus quality measure set, it will receive a 0/10 for the affected quality measure(s), resulting in a lower quality score used to determine eligibility for shared savings. For a Shared Savings Program ACO in the first PY of the ACO's first agreement period, the Shared Savings Program ACO must meet the MIPS data completeness requirement on all eCQMs/MIPS CQMs/Medicare CQMs in the APP Plus quality measure set and receive a MIPS quality performance category score. Shared Savings Program ACOs are eligible for the eCQM/MIPS CQM reporting incentive if they report all eCQMs/MIPS CQMs in the APP Plus quality measure set and meet data completeness requirements for all measures. Lastly, under the Complex Organization Adjustment, Shared Savings Program ACOs may receive one measure achievement point for each submitted eCQM that meets case minimum and data completeness requirements.

Shared Savings Program ACOs continue to express concerns related to the transition to dQM reporting including challenges with data aggregation, engagement of specialty practices, and patient matching. Shared Savings Program ACOs have shared with CMS that specialty electronic health record (EHR) systems are not designed to support the APP Plus quality measure set and that certain specialties may not be able to collect the needed data elements for quality reporting. Shared Savings Program ACOs noted that patients that are not managed by the Shared Savings Program ACO or do not have a primary care relationship with the Shared Savings Program ACO present data aggregation and patient deduplication challenges because specialists may not have quality reporting capabilities for the measures in the APP Plus quality measure set, which may not be part of specialists' clinical workflows. These challenges complicate a Shared Savings Program ACO's ability to meet the data completeness requirement. We have also received feedback that the MIPS data completeness requirement is a deterrent to specialist participation in Shared Savings Program ACOs. In the CY 2025 PFS final rule, some commenters stated that small independent practices and specialty practices are often unable to participate or continue to participate in the Shared Savings Program due to the technical and financial burden associated with the adoption of new technologies needed to meet reporting requirements (89 FR 98105). Several commenters requested that we consider adding exceptions or exclusions for small practices and certain specialties and/or altering data completeness requirements to address ongoing challenges and allow for Shared Savings Program ACOs to be successful in reporting eCQMs, MIPS CQMs, and Medicare CQMs (89 FR 98105).

With the sunset of the CMS Web Interface beginning in PY 2025 as finalized in the CY 2022 PFS final rule (86 FR 65440), Shared Savings Program ACOs are now required to report MIPS CQMs, eCQMs and/or Medicare CQMs and have reported difficulties with meeting the MIPS data completeness requirement. Shared Savings Program quality reporting data in PYs 2023 and 2024 indicates that Shared Savings Program ACOs have been slow to report eCQMs.

Since the CY 2021 PFS final rule was issued, Shared Savings Program ACOs and other interested parties have continued to express concerns about requiring Shared Savings Program ACOs to report all payer/all patient eCQMs/MIPS CQMs due to the cost of purchasing and implementing a system-wide infrastructure to aggregate data from multiple ACO participant taxpayer identification numbers (TINs) and varying electronic health record (EHR) systems (86 FR 65257). In the CY 2022 PFS final rule, commenters supported our acknowledgement of the complexity of the transition to all payer/all patient eCQMs/MIPS CQMs (86 FR 65259). In the CY 2023 PFS final rule, commenters expressed concerns regarding the requirement to report all payer/all patient eCQMs/MIPS CQMs beginning in PY 2025, such as issues related to meeting all payer data requirements, data completeness requirements, data aggregation and deduplication issues, and interoperability issues among different EHRs (87 FR 69837).

In light of these concerns, we proposed in the CY 2024 PFS proposed rule to establish the Medicare CQMs as a new collection type for Shared Savings Program ACOs to help ACOs build the infrastructure, skills, knowledge, and expertise necessary to aggregate patient data. We established the data completeness criteria threshold of at least 75 percent for the Medicare CQMs aligned with the data completeness criteria threshold established for eCQM and MIPS CQM collection types. We believed that the Medicare CQM collection type would address the concerns from ACOs regarding the capability of meeting the data completeness requirement for all payer data.

In the CY 2024 PFS final rule, many commenters also raised questions and concerns regarding how CMS will determine the appropriate Medicare CQM population for these measures (88 FR 79102). Some commenters noted that the proposed denominator eligibility criteria are similar to, but differ in timeline from, the current assignment methodology and this creates unnecessary complexity. Additionally, while the availability of the Medicare CQMs as a collection type assists with the transition from reporting eCQMs and/or MIPS CQMs to reporting dQMs, some commenters noted that reporting through the Medicare CQMs collection type will not inherently advance their capabilities to report on eCQMs. For instance, the commenters noted that the Medicare CQMs collection type does not address the adoption of CEHRT across Shared Savings Program ACO participants, processes to enable aggregation of quality measurement data across all Shared Savings Program ACO participants, the ability to assess data completeness, efficiently calculate quality measures outcomes, and the generation of a QRDA–III file (87 FR 79103 and 79104). To address these concerns, in the CY 2026 PFS final rule, we revised the definition of a ''beneficiary eligible for Medicare CQM'' to align with our modifications to the stepwise assignment methodology and the approach to identifying the beneficiaries assignable to a Shared Savings Program ACO. We intended for the revised definition to reduce Shared Savings Program ACOs' burden in the patient matching necessary to report Medicare CQMs because the list of ''beneficiaries eligible for Medicare CQMs'' would have greater overlap with the list of beneficiaries that are assignable to a Shared Savings Program ACO.

The Shared Savings Program continues to hear from Shared Savings Program ACOs and other interested parties about the challenges with reporting on all payer/all patient measures and meeting data management requirements given their muti-practice/multi EHR structure, the challenges to aggregate data with the health IT infrastructure in use by Shared Savings

Program ACOs and current state of interoperability (89 FR 98122).

Below we describe several proposals to address data completeness challenges for ACOs, in recognition of the heterogeneity in Shared Savings Program ACO composition, with many Shared Savings Program ACOs being made up of numerous TINs of varying specialties. These proposals are intended to support Shared Savings Program ACOs' success in meeting the MIPS data completeness requirement by allowing for flexibility on the universe of beneficiaries that the Shared Savings Program ACO would be required to report quality data on, while still requiring the Shared Savings Program ACOs to collect meaningful data on their quality performance (that is, allowing ACOs to exclude some clinicians from their quality reporting and/or alignment with the Shared Savings Program ACO's list of assigned beneficiaries).

(2) Proposal To Revise the Shared Savings Program Quality Reporting Requirements Beginning in PY 2026

Current Shared Savings Program quality reporting requirements at § 425.508(c) require that, for PYs beginning on or after January 1, 2025, Shared Savings Program ACOs must submit quality data on the APP Plus quality measure set to satisfactorily report on behalf of the eligible clinicians who bill under the TIN of a Shared Savings Program ACO participant for purposes of the MIPS quality performance category. Shared Savings Program ACOs have raised concerns about meeting reporting requirements in situations where they are unable to obtain data from a Shared Savings Program ACO Participant TIN. This situation may occur due to unforeseen circumstances such as the retirement of a provider in a solo practice or a practice closure. Additionally, Shared Savings Program ACOs have noted that specialty EHRs are not designed to support the APP Plus quality measure set and that certain specialties (for example, ophthalmology) provide little or no usable data.

In light of the concerns raised by Shared Savings Program ACOs regarding challenges meeting the Shared Savings Program quality reporting requirements, we are proposing to revise the quality reporting requirements at § 425.508(c), to include that for PYs beginning on or after January 1, 2026, Shared Savings Program ACOs may exclude one or more Shared Savings Program ACO participant TINs from a Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM (if finalized) data (as applicable) for each measure. As discussed in section III.G.3.d.(3) of this proposed rule, we are proposing to create the Medicare eCQMs collection type, which would be a new collection type for PY 2027 and subsequent PYs. We are proposing in § 425.508(c)(1)(i) through (iii) that a Shared Savings Program ACO may choose to exclude a Shared Savings Program ACO participant TIN from its submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure. Applicable exclusions may include: (i) unforeseen circumstance(s) that are outside of the control of the Shared Savings Program ACO such as the unexpected closure of a group or individual's practice that bills under the ACO participant TIN (for example, closure of the group or individual's practice in the middle of the PY due to an unforeseen reason (such as the retirement of a provider) and the Shared Savings Program ACO is unable to access quality data for the closed practice); (ii) the ACO participant TIN has a CEHRT that is intended for specialty use and does not support the measure(s) included in the APP Plus quality measure set (for example, an ophthalmology practice may provide little to no usable data because it utilizes a specialty-focused EHR that does not collect the necessary data elements for reporting on the primary care-focused APP Plus quality measure set; in this instance, the ACO would be unable to aggregate the ACO participant TIN's data); and (iii) other circumstances as determined by CMS. We further propose in § 425.508(c)(2)(i) through (iii) that Shared Savings Program ACOs may not exclude a Shared Savings Program ACO participant TIN from the Shared Savings Program ACO's quality data submission for each measure based on the demographics or health status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN or based on the estimated impact of the ACO participant TIN on the ACO's quality performance.

In addition, we are proposing in § 425.508(c)(3) that, after the exclusion of Shared Savings Program ACO participant TINs, the Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. Since a Shared Savings Program ACO may encounter an unforeseen circumstance that may be specific to reporting a clinical quality measure(s), the Shared Savings Program ACO may exclude one or more Shared Savings Program ACO participant TINs from the quality data submitted for only the impacted measure(s) for the applicable PY. As such, a Shared Savings Program ACO would be required to meet the 95 percent requirement for each measure at the measure level. This means that the quality data submitted by the Shared Savings Program ACO for each measure in the APP Plus quality measure set must meet this requirement independent of the other measures in the APP Plus quality measure set. We note that, due to each measure's inclusion and exclusion criteria as specified in the measure specification, a Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure may not include 95 percent of the beneficiaries assigned to the Shared Savings Program ACO. However, under our proposal, the data submitted for each measure must include ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. This 95 percent requirement would allow Shared Savings Program ACOs to exclude one or more Shared Savings Program ACO participant TINs from a measure submission based on applicable circumstances defined by CMS under the proposed regulation text at § 425.508(c)(1) and discussed later in this section, while ensuring CMS still receives sufficient data to assess Shared Savings Program ACO quality in the applicable PY and over time.

We note that our proposal to require that the Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications is different than the MIPS data completeness requirement for the MIPS quality performance category described at § 414.1340 (a) and (d) and proposed (e). Under our proposal, Shared Savings Program ACOs would still be required to meet the MIPS data completeness requirement (that is, the Shared Savings Program ACO must

report on at least 75 percent of the APM Entity's applicable beneficiaries who meet the measure's denominator criteria for PY 2027) for each eCQM/MIPS CQM/Medicare CQM/Medicare eCQM the Shared Savings Program ACO submits data for. MIPS data completeness is calculated based on the quality data submitted by a Shared Savings Program ACO and is assessed at the Shared Savings Program ACO-level; whereas, our proposal to allow a Shared Savings Program ACO to exclude one or more Shared Savings Program ACO participant TINs from a Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure would be applied by the Shared Savings Program ACO prior to its submission of quality data to MIPS. Under our proposal, a Shared Savings Program ACO would determine the denominator for a measure by applying the measure specifications using data from the participant TINs included in its quality data submission. MIPS data completeness would then be calculated based on that reported denominator.

To facilitate population-based activities related to improving health or reducing growth in health care costs, protocol development, case management, and care coordination under the existing § 425.702(c)(1)(ii) and to support Shared Savings Program ACOs in aggregating data for the Shared Savings Program ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure under the proposed § 425.508(c)(3), we would provide Shared Savings Program ACOs with a new aggregate report that would contain the data necessary to determine how many beneficiaries would be represented by the TINs the ACO plans to report on. Specifically, the report would be at the beneficiary-TIN level and contain the number of beneficiaries that will be assigned to the ACO and demonstrate how the assigned beneficiaries are matched to the TIN(s). This report would be provided in Quarter 3 and Quarter 4 of each applicable performance year beginning with PY 2026. This would allow the Shared Savings Program ACO to have access to the data that is necessary to determine if the ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure includes Shared Savings Program ACO participant TINs sufficient to represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. This new aggregate report would be delivered to Shared Savings Program ACOs via the Data Hub in the Shared Savings Program ACO Management System (*https://acoms.cms.gov*). If this proposal is finalized, we would provide instructions to Shared Savings Program ACOs in future education and outreach materials on how to use the new aggregate report to determine the Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications as required by the proposed § 425.508(c)(3) for purposes of submission of eCQM/MIPS CQM/Medicare eCQM data. The Quarter 3 report would be intended to provide Shared Savings Program ACOs with a preview of the necessary data, while the Quarter 4 report would be the definitive source for ACOs to determine whether the Shared Savings Program ACO meets the proposed Shared Savings Program requirement that the data submitted for each measure must include Shared Savings Program ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the Shared Savings Program ACO prior to the application of the measure specifications. We note that if our proposal is finalized, we would begin to provide ACOs with this report for Quarter 3 of PY 2026. For PY 2026 and subsequent PYs, Shared Savings Program ACOs must use the new Quarter 4 aggregate report to make the determination under the proposed § 425.508(c)(3). If this proposal is not finalized, we would not share the new aggregate reports.

Since we cannot align a beneficiary to a Shared Savings Program ACO participant TIN without eligible primary care claims, an ACO should not count beneficiaries without eligible primary care claims during the performance year when calculating the 95 percent of beneficiaries needed to meet the requirement proposed at § 425.508(c)(3). Moreover, beneficiaries that do not have at least one eligible primary care encounter during the performance year would not be included on the list of beneficiaries shared with ACOs in Quarter 3 and Quarter 4 during that performance year as proposed earlier in this section. For example, if a beneficiary is voluntarily aligned to the ACO but did not have an eligible primary care claim with a Shared Savings Program ACO participant during the performance year, that beneficiary would not be included on the list of beneficiaries shared with that ACO in Quarter 3 and Quarter 4 of the applicable performance year and the ACO would not include that beneficiary when calculating the numerator used to determine whether the ACO was compliant with the 95 percent requirement proposed at § 425.508(c)(3). For purposes of calculating the 95 percent requirement, the denominator would be the Shared Savings Program ACO's total number of assigned beneficiaries, inclusive of beneficiaries that did not have an eligible primary care claim during the reporting period with a Shared Savings Program ACO participant.

We note that, under the current definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20, beneficiaries eligible for Medicare CQMs for PY 2026 are closely aligned with the Shared Savings Program ACO's assignable population rather than the ACO's assigned population (as proposed in section III.G.3.d.(4) of this rule for PY 2027 and subsequent PYs). Shared Savings Program ACOs that choose to report Medicare CQMs for PY 2026 would have the option to exclude Shared Savings Program ACO participant TINs from their submission of Medicare CQM data provided that the remaining Shared Savings Program ACO participant TINs represent at least 95 percent of the beneficiaries assigned to the ACO prior to the application of the measure specifications.

In addition, in § 425.508(c)(4), we are proposing that we would retain the right to audit and validate eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for each measure reported by a Shared Savings Program ACO and may request documentation from the Shared Savings Program ACO related to the exclusion of Shared Savings Program ACO participant TINs from the Shared Savings Program ACO's quality data submission. We are also proposing that failure to report quality measure data accurately, completely, and timely may result in compliance actions as described in §§ 425.216 and 425.218.

Section 1871(e)(1)(A) of the Act prohibits the Secretary from applying substantive changes in regulations retroactively before the effective date of the change except where the Secretary determines, as relevant here, that failure to apply the change retroactively would be contrary to the public interest. It is in the public interest to apply our proposed changes to § 425.508 ''Incorporating quality reporting requirements related to the Quality Payment Program Beneficiary'' beginning in PY 2026 because, absent the proposed changes, Shared Savings Program ACOs that generated savings

while maintaining or improving quality of care may have difficulty meeting the quality reporting requirements at § 425.508(c). Based on the Shared Savings Program ACO public reporting requirements at § 425.308(b)(4)(ii), Shared Savings Program ACOs that generate shared savings must publicly report the total proportion of shared savings invested in infrastructure, redesigned care processes, and other resources required to support the triple aim of better health for populations, better care for individuals, and lower growth in expenditures, including the proportion distributed among Shared Savings Program ACO participants. If a Shared Savings Program ACO does not meet the quality reporting requirements, then that Shared Savings Program ACO would not be eligible to share in savings that could be used for quality improvement initiatives for the Medicare beneficiaries.

The evaluation of Shared Savings Program ACOs' PY 2026 quality performance, including evaluation of data completeness, occurs in 2027. As such, retroactive application of the proposed reporting requirement for PY 2026 would be in the public interest and would afford Shared Savings Program ACOs that earn shared savings the opportunity to devote greater resources to providing better quality of care to Medicare beneficiaries over time and improving care coordination that benefits the Medicare beneficiaries served by Shared Savings Program ACOs, in accordance with ACO public reporting requirements at § 425.308(b)(4)(ii).

Additionally, Shared Savings Program ACOs that participated in the interviews discussed in section III.G.3.c of this proposed rule have also shared that some practices have closed due to financial challenges associated with the transition to digital quality measurement and have begun to remove practices that cannot meet digital reporting requirements from their organization. Practices that do not meet the quality reporting requirements and, therefore, do not earn shared savings, could experience financial instability. For these practices, the loss of shared savings would compound these challenges and may cause them to close or may negatively affect their ability to provide continuity of care, coordination of care, preventive care initiatives, and quality improvement initiatives for Medicare beneficiaries they serve. As a result, beneficiaries may experience challenges with accessing care, ineffective utilization of services, fragmented care, or duplicative tests or services, and ACOs may be slower to adopt digital quality measurement as a result. The proposed changes would allow Shared Savings Program ACOs to devote greater resources to improving care coordination so that they are better positioned to deliver the right care at the right time, all to the benefit of Medicare beneficiaries served by the Shared Savings Program ACO and Medicare Trust Funds.

We believe the proposed changes would have minimal impact on Shared Savings Program ACOs' existing processes because the Shared Savings Program ACO would continue to aggregate quality data and apply the measure specifications prior to the submission of quality data. Additionally, Shared Savings Program ACOs would benefit from the ability to meet the MIPS data completeness requirement, in the event they are unable to acquire data from a subset of their participant TINs, which may enable them to achieve a quality score equivalent to the 40th percentile MIPS quality performance category score to be eligible to earn maximum shared savings and, for ENHANCED track Shared Savings Program ACOs, avoid shared losses.

In alignment with the proposals described in this section, we are proposing to revise the regulation text at § 425.508 as follows:

- Under new paragraph (c)(1), we would specify that, for PYs beginning on or after January 1, 2026, ACOs may exclude one or more TINs of ACO participants from an ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure. We would specify that applicable exclusions may include:
  - ++ Unforeseen circumstance(s) that are outside of the control of the ACO, such as the unexpected closure of a group or individual's practice that bills under the ACO participant TIN.
  - ++ An ACO participant TIN has a CEHRT that is intended for specialty use and does not support the measure(s) included in the APP Plus quality measure set.
  - ++ Other circumstances as determined by CMS.
- Under new paragraph (c)(2), we would specify that ACOs may not exclude an ACO participant TIN from the ACO's quality data submission for each measure based on the following:
  - ++ The demographics status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN.
  - ++ The health status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN.
  - ++ The estimated impact of the ACO participant TIN on the ACO's quality performance.
- Under new paragraph (c)(3), we would specify that the ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the ACO prior to the application of the measure specifications.
- Under new paragraph (c)(4), we would specify that CMS retains the right to audit and validate eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data reported by an ACO and may request documentation from the ACO related to the exclusion of ACO participant TINs under paragraph § 425.508(c)(1). We would further note that failure to report quality measure data accurately, completely, and timely may result in compliance actions as described at §§ 425.216 and 425.218.

We are seeking public comments on our proposals to revise the Shared Savings Program quality reporting requirements at § 425.508 beginning in PY 2026. We are also seeking comment on other circumstances we should consider that would allow ACOs to exclude one or more TINs of ACO participants from their submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data for a measure.

(3) Proposal for Shared Savings Program ACOs To Report Using the Medicare eCQMs Collection Type

Shared Savings Program ACOs have expressed concerns regarding the difficulty for multi-TIN Shared Savings Program ACOs to aggregate and deduplicate patient-level data. Additional challenges persist with integration across multiple EHRs, and these challenges can be an impediment for some Shared Savings Program ACOs. In light of the concerns raised by Shared Savings Program ACOs and other interested parties related to reporting quality measures using the eCQMs collection type and our commitment to supporting Shared Savings Program ACOs in the transition to dQM reporting, for PY 2027 and subsequent PYs, we are proposing in section IV.A.4.d.(1)(b) of this proposed rule to establish the Medicare eCQMs for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs) as a new collection type for Shared Savings Program ACOs reporting on the Medicare eCQMs (reporting quality data on beneficiaries eligible for Medicare eCQMs as proposed to be defined at

§ 425.20) within the APP Plus quality measure set. A Medicare eCQM is essentially an eCQM that is part of the APP Plus quality measure set and reported by a Shared Savings Program ACO on only the Shared Savings Program ACO's assigned beneficiaries, instead of its all payer/all patient population. That is, the Medicare eCQMs will generally follow the eCQM measure specifications; however, they will be reported on a different population and use a different identifier to distinguish that the submission is for a Medicare eCQM rather than for an eCQM.

In the CY 2025 PFS final rule, we noted the numerous benefits to using eCQMs, including their use of electronic standards that reduce reporting burden, and expressed intent to fully transition to digital quality measurement in CMS quality reporting and value-based purchasing programs (89 FR 98106). We believe the addition of Medicare eCQMs would support our efforts to transition to dQMs by supporting Shared Savings Program ACOs that want to report eCQMs but are not able to operationally report on all patient/all payer data due to data aggregation challenges.

Medicare eCQMs would serve to address concerns which are discussed in section III.G.3.d.(1) of this proposed rule by defining a population of beneficiaries that exists within the all payer/all patient eCQM specifications and tethering that population to a Shared Savings Program ACO's assigned beneficiary population. Shared Savings Program ACOs have expressed challenges with quality data reporting as their list of eligible beneficiaries has often contained beneficiaries for whom the Shared Savings Program ACO is unable to identify a primary care relationship. Specifically, Medicare eCQMs would address the concern raised by Shared Savings Program ACOs that for Shared Savings Program ACOs with a higher proportion of specialty practices and/or multiple EHRs, the broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the Shared Savings Program ACO. We intend to allow Shared Savings Program ACOs to continue to report using the existing collection types to maintain stability of collection types during the transition to dQMs. If finalized, Medicare eCQMs would provide an additional optional collection type for reporting quality data for Shared Savings Program ACOs. Medicare eCQMs would provide ACOs the option to report electronically only on their assigned beneficiary population, easing the operational considerations as outlined in this section, and support those Shared Savings Program ACOs with the transition to dQMs. For these reasons, we believe that it is appropriate to establish Medicare eCQMs as a new collection type for Shared Savings Program ACOs only. We also anticipate that in the future, when FHIR-based reporting becomes mandatory, Shared Savings Program ACOs would be able to continue to use the FHIR-based digital specifications to report only on their assigned beneficiary population.

We encourage ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on the ACO's unique composition and technical infrastructure. In addition to our proposal to allow ACOs the option to report quality data using the Medicare eCQMs collection type, for PY 2027 and subsequent PYs, ACOs would have the option to report quality data using the all payer/all patient eCQMs/MIPS CQMs, and/or the Medicare CQMs collection types. Our long-term goal continues to be to support ACOs in the adoption of dQMs. We would monitor the reporting of quality data using the Medicare eCQMs collection type.

To facilitate the reporting of Medicare eCQMs, in section IV.A.4.d.(1)(b) of this proposed rule, we are proposing to amend the definition of ''collection type'' in § 414.1305 to include Medicare eCQMs as an available collection type in MIPS for ACOs that participate in the Shared Savings Program.

Additionally, we are proposing to establish data submission and data completeness criteria, in §§ 414.1335(a)(5) and 414.1340(e), respectively, pertaining to the Medicare eCQMs collection type for the MIPS quality performance category as discussed in sections IV.A.4.d.(1)(c)(v) and IV.A.4.d.(1)(d)(ii) of this proposed rule.

We are proposing to define a ''beneficiary eligible for Medicare eCQMs'' at § 425.20 as a beneficiary identified for purposes of reporting Medicare eCQMs for Shared Savings Program ACOs participating in the Medicare Shared Savings Program (Medicare eCQMs), who is a beneficiary that is assigned to the Shared Savings Program ACO under subpart E.

In section IV.A.4.d.(1)(d)(ii) of this proposed rule, we are proposing to revise § 414.1340(e) to establish the data completeness criteria threshold for the Medicare eCQMs collection type, in which Shared Savings Program ACOs that meet reporting requirements under the APP submitting quality measure data on Medicare eCQMs must submit data on at least 75 percent of the ACO's applicable beneficiaries eligible for the Medicare eCQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria for MIPS payment year 2029 and future MIPS payment years (PY 2027 and subsequent PYs).

To facilitate population-based activities related to improving health under the existing § 425.702(c)(1)(ii) and to aid Shared Savings Program ACOs in the process of patient matching and data aggregation necessary to report Medicare eCQMs, we would provide Shared Savings Program ACOs with a list of beneficiaries that are assigned to the Shared Savings Program ACO and thus are eligible for Medicare eCQM reporting within the Shared Savings Program ACO. We anticipate that the list of beneficiaries eligible for Medicare eCQMs would be shared with Shared Savings Program ACOs on a quarterly basis, beginning with Quarter 1 of PY 2027. We anticipate that the list of beneficiaries eligible for Medicare eCQMs would be in the same format and delivery schedule as the list of beneficiaries eligible for Medicare CQMs that Shared Savings Program ACOs currently receive on a quarterly basis. The list of beneficiaries eligible for Medicare eCQMs would differ from the list of beneficiaries eligible for Medicare CQMs in that we would apply the eCQM specifications to generate the measure-specific indicators for the list of beneficiaries eligible for Medicare eCQMs (unlike the list of beneficiaries eligible for Medicare CQMs which uses the Medicare CQM specifications to generate the measure-specific indicators). This new report would be delivered to Shared Savings Program ACOs via the Data Hub in the Shared Savings Program ACO Management System (*https://acoms.cms.gov*), but would not be included in the Shared Savings Program ACO's Quarterly Reports Package. The Quarter 4 list would include all beneficiaries eligible for Medicare eCQMs based on available claims data for encounters with dates of service from January 1 through December 31 and may be used as the final list for quality reporting. Like eCQMs, Medicare eCQMs would be reported end-to-end electronically. As such, we recognize that Shared Savings Program ACOs may have other technologically feasible means to identify beneficiaries eligible for Medicare eCQMs within the Shared Savings Program ACO or Shared Savings Program ACO participant TIN CEHRT. For this reason, we are not proposing to require that Shared Savings Program ACOs use the list of

beneficiaries eligible for Medicare eCQMs to identify the universe of beneficiaries upon which the Shared Savings Program ACO would report Medicare eCQMs for an applicable PY; rather, the Quarter 4 list can be used as a resource to help Shared Savings Program ACOs identify beneficiaries eligible for Medicare eCQM reporting.

In section III.G.3.f.(2) of this proposed rule, we are proposing that there would be five eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs in the APP Plus quality measure set for Shared Savings Program ACOs for PY 2027 and subsequent PYs.

- Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001);
- Breast Cancer Screening (Quality ID: 112);
- Colorectal Cancer Screening (Quality ID: 113);
- Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Quality ID: 134); and
- Controlling High Blood Pressure (Quality ID: 236).

ACOs would have the option to report the five Medicare eCQMs, or a combination of eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs, to meet the Shared Savings Program quality reporting requirement at § 425.510(b) and the quality performance standard at § 425.512(a)(5).

To operationalize the reporting of the Medicare eCQMs collection type, if finalized, specifically to distinguish between the submission of data for a Medicare eCQM from the submission of data for an eCQM to CMS, we will create unique identifiers that are associated with each Medicare eCQM. These identifiers must be included in the submission files when reporting Medicare eCQMs beginning in PY 2027. Additional information on reporting Medicare eCQMs, if finalized, will be provided after the release of the CY 2027 PFS final rule.

We are not proposing to add Medicare eCQMs to the eCQM/MIPS CQM reporting incentive described at § 425.512(a)(5)(i)(B)(2) for PY 2027 and subsequent PYs. The eCQM/MIPS CQM reporting incentive intends to provide an incentive to ACOs to report the all payer/all patient eCQMs/MIPS CQMs while allowing them time to gauge their performance on the all payer/all patient eCQMs/MIPS CQMs. We are also not proposing to add Medicare eCQMs to the Complex Organization Adjustment described at § 414.1380(b)(1)(vii)(C) for PY 2027 and subsequent PYs. We reiterate that the Complex Organization Adjustment intends to account for the organizational complexities Shared Savings Program ACOs face when reporting all payer/all patient eCQMs (89 FR 98116).

In section IV.B.1.c.(2) of this proposed rule and in the regulations at § 414.1380(b)(1)(ii)(G)(*1*), we are proposing that, beginning with the CY 2027 performance period/2029 MIPS payment year, measures of the Medicare eCQMs collection type use flat benchmarks. As stated in the CY 2025 PFS final rule (89 FR 98118), the use of flat benchmarks may allow Shared Savings Program ACOs with high scores to earn maximum or near maximum measure achievement points while allowing room for quality improvement and rewarding that improvement in subsequent years. Use of flat benchmarks also helps to ensure that Shared Savings Program ACOs with high quality performance on a measure are not penalized as low performers.

As part of our proposals for Shared Savings Program ACOs to report the Medicare eCQMs collection type for PY 2027 and subsequent PYs, we propose to revise the regulation text at §§ 425.20 and 425.512 as follows:

Under a new paragraph at § 425.20, we would define a beneficiary eligible for Medicare eCQMs as a beneficiary identified for purposes of reporting Medicare eCQMs for Shared Savings Program ACOs participating in the Medicare Shared Savings Program (Medicare eCQMs), who is a beneficiary that is assigned to the Shared Savings Program ACO under subpart E of this part.

Under § 425.512(a)(2)(iv), we would incorporate Medicare eCQMs into the existing quality performance standard policies for new Shared Savings Program ACOs. Under paragraph (a)(5)(iii)(C), we would also incorporate Medicare eCQMs into the existing policies that describe when a Shared Savings Program ACO would not meet the quality performance standard or the alternative quality performance standard.

We are seeking public comments on our proposals for Shared Savings Program ACOs to report the Medicare eCQMs collection type for PY 2027 and subsequent PYs.

(4) Proposal To Revise the Definition of a ''Beneficiary Eligible for Medicare CQMs''

In the CY 2026 PFS final rule (90 FR 49797 through 49803), we finalized the revisions to the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 effective January 1, 2025. Specifically, beginning with PY 2025 and subsequent PYs, we revised the definition to require, in (1)(ii)(B) of the definition, ''at least one primary care service with a date of service during the applicable performance year from a Shared Savings Program ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.'' We stated that the revised definition of a ''beneficiary eligible for Medicare CQMs'' would reduce Shared Savings Program ACOs' burden in the patient matching necessary to report Medicare CQMs because the list of ''beneficiaries eligible for Medicare CQMs'' would have greater overlap with the list of beneficiaries that are assignable to a Shared Savings Program ACO. We stated that we believed our revised definition of a ''beneficiary eligible for Medicare CQMs'' would substantially address Shared Savings Program ACOs' and interested parties' concerns by better aligning the definitions and clarifying which beneficiaries' data to use for quality data reporting through Medicare CQMs. In the CY 2026 PFS final rule, some commenters suggested that CMS require Medicare CQMs be reported for ''attributed'' beneficiaries only (90 FR 49800). In response, CMS noted that Medicare CQMs are designed to help Shared Savings Program ACOs address challenges with aggregating patient data required to report the all payer/all patient MIPS CQMs and eCQMs by defining a population of beneficiaries that is broader than the assigned population but exists within the all payer/all patient MIPS CQM specification.

Since the publication of the CY 2026 PFS final rule and implementation of the revised definition aligning with assignable beneficiaries, we have heard from Shared Savings Program ACOs and other interested parties that the current definition of a ''beneficiary eligible for Medicare CQMs'' continues to cause confusion regarding which beneficiaries to use for quality data reporting. Specifically, Shared Savings Program ACOs have inquired about the differences between the current list of beneficiaries eligible for Medicare CQMs (which is broader than an ACO's assigned population) and the Shared Savings Program ACO's assigned and assignable populations. As discussed in the CY 2026 final rule, an analysis using PY 2024 data noted an average 85 percent overlap between a Shared Savings Program ACO's list of beneficiaries eligible for Medicare CQMs and the list of beneficiaries assignable to the Shared Savings

Program ACO (90 FR 49799). Moreover, we have heard from Shared Savings Program ACOs that the current definition aligning with assignable beneficiaries continues to create burden in patient matching, data aggregation and quality reporting for Shared Savings Program ACOs that elect to report Medicare CQMs. Lastly, Shared Savings Program ACOs have expressed that the current definition of ''beneficiaries eligible for Medicare CQMs'' that aligns with assignable beneficiaries includes beneficiaries for whom the Shared Savings Program ACO does not readily have data.

Considering the concerns raised by Shared Savings Program ACOs and other interested parties with reporting Medicare CQMs, we propose to revise the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 for PY 2027 and subsequent PYs, to align with the population of beneficiaries assigned to the ACO.

We implemented Medicare CQMs in PY 2024 to help some Shared Savings Program ACOs build the infrastructure, skills, knowledge and expertise necessary to report all payer/all patient MIPS CQMs and eCQMs (88 FR 79098). The confusion that Shared Savings Program ACOs have expressed about the differences between the list of beneficiaries eligible for Medicare CQMs and a Shared Savings Program ACO's assigned populations have complicated the process for Shared Savings Program ACOs to meaningfully implement Medicare CQMs for this purpose. Our proposed revision would build upon the revisions finalized in the CY 2026 PFS final rule and further refine and align the definition of a ''beneficiary eligible for Medicare CQMs'' to correspond to a Shared Savings Program ACO's assigned beneficiary list to continue to address Shared Savings Program ACOs' challenges with patient data aggregation. The proposed change to the definition of a ''beneficiary eligible for Medicare CQMs'' for PY 2027 and subsequent PYs intends to better support these Shared Savings Program ACOs in the transition to digital quality measurement and to eliminate an unintended barrier that Shared Savings Program ACOs have experienced in reporting Medicare CQMs, which have persisted after the revision of the definition in the CY 2026 PFS final rule to align with assignable beneficiaries.

The Shared Savings Program relies on primary care-based assignment, and the APP Plus quality measure set is primary care-based. Our proposals to use the Shared Savings Program ACO's assigned beneficiary population for the Medicare CQMs collection type beginning in PY 2027 would hold Shared Savings Program ACOs accountable for the quality of care for only the beneficiaries assigned to them and align with the voluntary risk they have undertaken to coordinate beneficiaries' care. Also, focusing on care provided by primary care providers would be a reasonable approach that addresses concerns with data aggregation and specialist participation. Similarly, we have heard from Shared Savings Program ACOs that the current definition of a ''beneficiary eligible for Medicare CQMs'' is a detriment to Shared Savings Program ACOs meeting the MIPS data completeness requirement described at § 414.1340. As such, the proposed change aims to support Shared Savings Program ACOs in meeting the MIPS data completeness requirement by tethering the universe of beneficiaries that a Shared Savings Program ACO is required to report on for Medicare CQMs to the universe of beneficiaries that have a primary care relationship with the Shared Savings Program ACO as demonstrated through the beneficiaries' assignment to the Shared Savings Program ACO. We anticipate that Shared Savings Program ACOs that choose to report Medicare CQMs would experience fewer barriers in aggregating the applicable numerator and denominator data for beneficiaries that are assigned to the Shared Savings Program ACO and, as a result, would be better positioned to meet the MIPS data completeness requirement described at § 414.1340.

In the CY 2024 PFS final rule, we finalized a new paragraph at § 425.702(c)(1)(iii) to share aggregate reports with Shared Savings Program ACOs with the aim of facilitating population-based activities related to the improvement of health through quality measurement using Medicare CQMs and to aid Shared Savings Program ACOs in the process of patient matching and data aggregation necessary to report Medicare CQMs (88 FR 79099). It was necessary at that time to revise the regulation text at § 425.702 because the list of beneficiaries eligible for Medicare CQMs, as finalized for PY 2024, was broader than the universe of beneficiaries assigned to the Shared Savings Program ACO. As discussed in this section of the proposed rule, we are proposing to align the definition of a ''beneficiary eligible for Medicare CQMs'' with the universe of beneficiaries assigned to the Shared Savings Program ACO. The sharing of aggregate reports for beneficiaries assigned to the Shared Savings Program ACO is regulated at § 425.702(c)(1)(ii). As such, since the list of beneficiaries eligible for Medicare CQMs would align with the universe of beneficiaries assigned to the Shared Savings Program ACO under this proposal, it is appropriate to also propose to sunset the regulation at § 425.702(c)(1)(iii) beginning in PY 2027. If finalized, we would provide Shared Savings Program ACOs with a quarterly list of beneficiaries eligible for Medicare CQMs, starting with PY 2027, that aligns with an ACO's list of assigned beneficiaries under the existing regulation at § 425.702(c)(1)(ii).

As part of our proposal to revise the definition of a ''beneficiary eligible for Medicare CQMs'' for PY 2027 and subsequent PYs, we would revise and republish the definition of a ''beneficiary eligible for Medicare CQMs'' at § 425.20 to include the following:

We would note that a beneficiary *eligible for Medicare CQMs* means a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who meets the following requirements (as applicable):

- For performance years 2024 through 2026, the beneficiary is either of the following:

++ A Medicare fee-for-service beneficiary (as defined at § 425.20) who—

—Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

—For performance year 2024, had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

- —For performance years 2025 and 2026, had at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

++ A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

- For performance years 2027 and subsequent performance years, a

beneficiary that is assigned to the ACO under subpart E of this part.

We would also revise the regulation text at § 425.702 to specify that paragraph (c)(1)(iii) applies for performance years 2024 through 2026. We are seeking public comments on our proposal to revise the definition of a ''beneficiary Eligible for Medicare CQMs''.

e. Proposal To Revise the Shared Savings Program Scoring Policy for Excluded APP Plus Measures and APP Plus Measures That Lack a Benchmark

(1) Background

In the CY 2024 PFS final rule (88 FR 79122 and 79123), we stated that given that the Shared Savings Program does not determine which quality measures are excluded and lack a benchmark and that Shared Savings Program ACOs do not have a choice of measures that they can report under the APP, we do not want to adversely impact shared savings determinations for events outside the Shared Savings Program ACOs' control, such as in the event a measure is excluded or does not have a benchmark. Therefore, we finalized a scoring policy for excluded APP measures and APP measures that lack a benchmark at § 425.512(a)(7). Specifically, we finalized that, to determine whether the Shared Savings Program ACO meets the quality performance standard required to share in savings at the maximum rate under its track (or payment model within a track), for PY 2024 and subsequent PYs, if a Shared Savings Program ACO reports all of the required measures, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP measure set and receiving a MIPS quality performance category score as described at § 414.1380(b)(1) of this subchapter, we will use the higher of the Shared Savings Program ACO's quality score or the equivalent of the 40th percentile MIPS quality performance category score across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, for the relevant performance year when the Shared Savings Program ACO meets either of the following:

- The ACO's total available measure achievement points used to calculate the ACO's MIPS quality performance category score is reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.
- At least one of the eCQMs/MIPS CQMs/Medicare CQMs does not have a benchmark as described at § 414.1380(b)(1)(i)(A) of this subchapter.

Shared Savings Program ACOs that qualify for this existing policy at § 425.512(a)(7) can meet the quality performance standard if one measure in the APP Plus quality measure set is excluded or lacks a benchmark, and the Shared Savings Program ACO will not be evaluated on their quality performance on the remaining quality measures reported by the Shared Savings Program ACO.

(2) Proposed Revisions

When our scoring policy for excluded APP measures and APP measures that lack a benchmark was finalized in the CY 2024 PFS final rule, there were six total measures in the APP quality measure set, and Shared Savings Program ACOs were required to report only three eCQMs/MIPS CQMs (in addition to administering the CAHPS for MIPS survey) for PY 2024 and subsequent PYs (88 FR 79113). In the CY 2025 PFS final rule, we finalized that, for PY 2025 and subsequent PYs, Shared Savings Program ACOs will be required to report the APP Plus quality measure set (89 FR 98105). Under our proposal in section III.G.3.f.(2) of this proposed rule, we are proposing that for PY 2027 and subsequent PYs, Shared Savings Program ACOs would be required to report on eight measures in the APP Plus quality measure set: five eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs, the CAHPS for MIPS survey, and two administrative claims-based measures that would be calculated by CMS. When CMS established the policy in the CY 2024 PFS final rule, we noted that there were two eCQMs in the legacy APP quality measure set that were suppressed by MIPS in PY 2022 (88 FR 79122). Since these two eCQMs were excluded, the growth in the number of quality measures Shared Savings Program ACOs are required to report increases the likelihood that a Shared Savings Program ACO's quality score would be based on a broader range of quality performance metrics than it would have been in PY 2022. This reduces the impact of measure exclusion on a Shared Savings Program ACO's MIPS quality performance category score. Applying the existing scoring policy at § 425.512(a)(7) when a single measure is excluded from MIPS would allow a Shared Savings Program ACO to meet the quality performance standard without an evaluation of the Shared Savings Program ACO's quality performance on the remaining measures in the APP Plus quality measure set.

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by Shared Savings Program ACOs and shall seek to improve the quality of care furnished by Shared Savings Program ACOs over time by specifying higher standards, new measures, or both for purposes of assessing such quality of care. We believe that revising the scoring policy at § 425.512(a)(7) such that it would only be applied when there are four or more excluded measures in PY 2027 would ensure that Shared Savings Program ACOs are fairly assessed on their quality performance in our determination of whether they meet the quality performance standard to be eligible to share in savings at the maximum rate available for the Shared Savings Program ACO's track and, for ACOs participating in the ENHANCED track, to avoid maximum shared losses. Specifically, we propose to revise the scoring policy at § 425.512(a)(7) for PY 2027 and subsequent PYs, such that it would apply only if the Shared Savings Program ACO's MIPS quality performance category score is calculated on less than five measures for a given PY. In other words, if there are four or more measures in the APP Plus quality measure set that are excluded from MIPS under § 414.1380(b)(1)(vii)(A) in PY 2027 or a subsequent PY, then the proposed scoring policy at § 425.512(a)(7)(iii) would apply.

We believe that our proposed revisions to § 425.512(a)(7) would result in a more accurate assessment of Shared Savings Program ACOs' quality performance, as each measure in the five-measure minimum threshold would contribute a reasonable weight (20 percent) to the Shared Savings Program ACO's MIPS quality performance category score. However, if there are fewer than five measures available in a given PY, Shared Savings Program ACOs would not risk losing the ability to meet the quality performance standard to be eligible to earn maximum shared savings, and for Shared Savings Program ACOs in the ENHANCED track, avoid maximum shared losses, due to issues with the measures outside of their control.

As discussed later in this section, we are proposing that the current scoring policy at § 425.512(a)(7) would no longer apply when at least one of the required measures in the APP Plus quality set does not have a benchmark for PY 2027 and subsequent PYs. Excluded measures do not contribute to the calculation of a Shared Savings Program ACO's MIPS quality performance category score for that PY. In section III.G.3.f.(2) of this proposed rule, we are proposing that the APP Plus quality measure set would have eight

measures in total for PY 2027 and subsequent PYs. Thus, we would calculate a Shared Savings Program ACO's MIPS quality performance category score if there are five or more measures in the APP Plus quality measure set that have not been excluded from MIPS. We note that this policy would only apply if a Shared Savings Program ACO's MIPS quality performance category score is impacted by measure exclusion under MIPS. We also clarify that the policy would not apply for other reasons based on which a measure may be unscored. Specifically, it would not apply if the Shared Savings Program ACO does not meet the MIPS case minimum requirement at § 414.1380 on any measure in the APP Plus quality measure set. Our proposal would allow us to better evaluate Shared Savings Program ACOs' quality performance and appropriately determine shared savings eligibility based on quality of care.

Therefore, we propose that, for PY 2027 and subsequent PYs, if the Shared Savings Program ACO's MIPS quality performance category score is calculated on less than five measures due to measure exclusion under MIPS and the Shared Savings Program ACO meets the other quality reporting requirements as described in the proposed § 425.512(a)(7)(iii), then we would use the higher of the Shared Savings Program ACO's quality score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS Quality performance category scores, excluding entities/providers eligible for facility-based scoring.

We provide two hypothetical examples of the application of this proposed policy for illustrative purposes. Hypothetical example 1: for PY 2027, a Shared Savings Program ACO reports three eCQMs (Quality IDs: 001, 112, and 236), one Medicare CQM (Quality ID: 134), and one MIPS CQM (Quality ID: 113) in the APP Plus quality measure set, meets the MIPS data completeness requirement at § 414.1340 on all of these five measures, and receives a MIPS quality performance category score. The Shared Savings Program ACO also administers the CAHPS for MIPS survey and has the two administrative claims-based measures in the APP Plus quality measure set calculated by CMS. Hypothetically, if Quality IDs 001, 112, 113, and 236 are excluded from MIPS under § 414.1380(b)(1)(vii)(A) for PY 2027, then the Shared Savings Program ACO's MIPS quality performance category score would be based on four measures: the two administrative claims-based measures, the CAHPS for MIPS survey, and Quality ID: 134. The proposed scoring policy at § 425.512(a)(7)(iii) would apply in this scenario since the Shared Savings Program ACO's MIPS quality performance category score would be based on less than five measures. Therefore, the Shared Savings Program ACO would receive the higher of the Shared Savings Program ACO's quality score or the equivalent of the 40th percentile MIPS Quality performance category score across all MIPS quality performance category scores. This would allow the Shared Savings Program ACO to meet the quality performance standard and be eligible to share in savings at the maximum rate available for their track and, for ENHANCED track Shared Savings Program ACOs, to avoid maximum shared losses.

Hypothetical example 2: for PY 2027, a Shared Savings Program ACO reports all five eCQMs in the APP Plus quality measure set, meets the MIPS data completeness requirement at § 414.1340 on all five eCQMs (Quality IDs: 001, 112, 113, 134, and 236), administers the CAHPS for MIPS survey, receives a MIPS quality performance category score, and has the two administrative claims-based measures calculated by CMS. Under this scenario, the eCQM version of Quality ID: 001 was excluded from MIPS under § 414.1380(b)(1)(vii)(A). Our proposed scoring policy would not apply in this case since the Shared Savings Program ACO's MIPS quality performance category score would be based on more than five measures: the two administrative claims-based measures, the CAHPS for MIPS survey, and four eCQMs.

In the CY 2024 PFS final rule (88 FR 79123), we stated that given that the Shared Savings Program does not determine which quality measures do not have a benchmark and that Shared Savings Program ACOs do not have a choice of measures they can report under the APP, we do not want to adversely impact shared savings determinations for events outside the Shared Savings Program ACOs' control, such as in the event a measure does not have a benchmark. Therefore, we finalized at § 425.512(a)(7) to include eCQMs, MIPS CQMs, and Medicare CQMs within the APP measure set that do not have a benchmark as described at § 414.1380(b)(1)(i)(A). In the CY 2025 PFS final rule (89 FR 98120), we finalized that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQMs collection type would be scored using flat benchmarks for their first two performance periods in MIPS. Also, in sections III.G.3.c. and III.G.3.d.(3) of this proposed rule, we are proposing that Medicare CQMs and Medicare eCQMs would be scored using flat benchmarks for PY 2027 and subsequent PYs. The use of flat benchmarks to score Medicare CQMs and Medicare eCQMs would mitigate the risk that MIPS would not be able to calculate benchmarks for these measures in the APP Plus quality measure set. Additionally, we note that none of the eCQMs, MIPS CQMs, or Medicare CQMs that Shared Savings Program ACOs have reported over the past four PYs lacked benchmarks. Therefore, we propose that the scoring policy at § 425.512(a)(7) would no longer apply when at least one of the required measures in the APP Plus quality set does not have a benchmark for PY 2027 and subsequent PYs.

We would revise the regulation text at § 425.512(a)(7) as follows:

- We are revising paragraph (a)(7)(ii) to specify that it applies for performance years 2025 and 2026.
- Under new paragraph (a)(7)(iii), we would specify that, for performance year 2027 and subsequent performance years, if an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1), for the relevant performance year, and the ACO meets the following—

++ The ACO's MIPS Quality performance category score is calculated on less than five measures; and

++ Any unscored measure(s) must meet all of the following-

— The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A).

— The ACO's total measure achievement points used to calculate the ACO's MIPS Quality performance category score are not reduced under § 414.1380(b)(1)(iii).

We are seeking public comments on our proposed revisions to the Shared Savings Program scoring policy at § 425.512(a)(7).

f. Proposal To Update the APP Plus Quality Measure Set

(1) Background

We finalized in the CY 2025 PFS final rule (89 FR 98104) that, for PY 2025 and subsequent PYs, Shared Savings Program ACOs will be required to report

the APP Plus quality measure set. We also finalized that Shared Savings Program ACOs will be required to report and be scored on all applicable quality measures in the APP Plus quality measure set according to the phase-in schedule for incorporating measures into the APP Plus quality measure set (89 FR 98105). We also stated in the CY 2025 PFS final rule (89 FR 98116 and 98117) that the APP Plus quality measure set for Shared Savings Program ACOs will include 11 measures (eight eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with PY 2028 or the PY that is one year after the eCQM specifications become available for the Screening for the Social Drivers of Health (Quality ID: 487) and Adult Immunization Status (Quality ID: 493) measures, whichever is later, and Shared Savings Program ACOs will be scored on the required 11 measures. The final APP Plus quality measure set for Shared Savings Program ACOs, for PY 2025 and subsequent PYs, was specified in Tables 39 through 42 of the CY 2025 PFS final rule (89 FR 98128 through 98132).

In the CY 2025 PFS final rule (89 FR 98130 through 98132), we finalized that Diabetes: Glycemic Status Assessment Greater Than 9% (Quality ID: 001), Preventive Care and Screening: Screening for Depression and Follow-up Plan (Quality ID: 134), and Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups (Quality ID: 479) would be incorporated into the APP Plus quality measure set for PY 2025. Additionally, we finalized that Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) will be incorporated into the APP Plus quality measure set for PY 2027 and Adult Immunization Status (Quality ID: 493) will be incorporated into the APP Plus quality measure set beginning with PY 2028 or the PY that is 1 year after the eCQM specification becomes available for Quality ID: 493, whichever is later.

In the CY 2026 PFS final rule (90 FR 49818), we finalized the removal of Screening for Social Drivers of Health (Quality ID: 487) from the APP Plus quality measure set (90 FR 49817 and 50311). With the removal of Quality ID: 487, the APP Plus quality measure set for Shared Savings Program ACOs will include ten measures (seven eCQMs/Medicare CQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with PY 2028 or the PY that is 1 year after the eCQM specification becomes available for Adult Immunization Status (Quality ID: 493), whichever is later (90 FR 49817). We stated that Shared Savings Program ACOs will be scored on the required ten measures (90 FR 49817). The final APP Plus quality measure set for Shared Savings Program ACOs, for PY 2028 or the PY that is 1 year after the eCQM specification becomes available for Quality ID: 493, whichever is later, was specified in Table B–G5 of the CY 2026 PFS final rule (90 FR 49818).

Shared Savings Program ACOs expressed concerns with increasing the number of measures in the APP Plus quality measure set each year. Shared Savings Program ACOs have suggested maintaining a stable measure set as they transition to digital quality reporting. In response to the CY 2026 PFS Digital Quality Measurement RFI, many commenters recommended that CMS maintain the APP Plus quality measure set as finalized without adding new measures to preserve resources for the transition to digital quality measurement and to consider challenges Shared Savings Program ACOs face in data aggregations for eCQM/MIPS CQM/Medicare CQM reporting (90 FR 49855 and 49856).

(2) Proposed Revisions

As discussed in section IV.A.4.b.(2) and Table Group D, in Appendix 1, of this proposed rule, we are proposing to adopt measure specification changes to the following measures that are included in the APP Plus quality measure set:

- *Diabetes:* Glycemic Status Assessment Greater Than 9% (Quality ID: 001) (eCQMs collection type only)
- *Preventive Care and Screening:* Screening for Depression and Follow-up Plan (Quality ID: 134)
- Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups (Quality ID: 479)

With the proposed removal of Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) and Adult Immunization Status (Quality ID: 493) from the APP Plus quality measure set as described in section IV.A.4.b.(2) of this proposed rule, we propose that the APP Plus quality measure set for Shared Savings Program ACOs would include eight measures (five eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs, two administrative claims-based measures, and the CAHPS for MIPS Survey measure) beginning with PY 2027. Shared Savings Program ACOs would be scored on the required eight measures. We believe that these proposals would lessen the burden associated with implementing new quality measures as Shared Savings Program ACOs move toward digital quality measurement. The proposed APP Plus quality measure set for Shared Savings Program ACOs, for PY 2027 and subsequent PYs is specified in Table B–G5. This table also reflects the proposed creation of the new Medicare eCQMs collection type for Shared Savings Program ACOs reporting the APP Plus quality measure set for PY 2027 and subsequent PYs, as discussed in section III.G.3.d.(3) and Table Groups D and DD, in Appendix 1, of this proposed rule.

TABLE B-G5: MEASURES INCLUDED IN THE APP PLUS QUALITY MEASURE SET FOR SHARED SAVINGS PROGRAM ACOS FOR PY 2027 AND SUBSEQUENT PYs

Quality #	Measure Title	Collection Type	Submitter Type	Measure Type
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Outcome^
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Outcome^
001	Diabetes: Glycemic Status Assessment Greater Than 9%	eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs	APM Entity/Third Party Intermediary	Intermediate Outcome^
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs	APM Entity/Third Party Intermediary	Process
236	Controlling High Blood Pressure	eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs	APM Entity/Third Party Intermediary	Intermediate Outcome^
112	Breast Cancer Screening	eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs	APM Entity/Third Party Intermediary	Process
113	Colorectal Cancer Screening	eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs	APM Entity/Third Party Intermediary	Process

^ Indicates this is an outcome measure for purposes of qualifying for the eCQM/MIPS CQM reporting incentive and the alternative quality performance standard.

g. Summary of Proposals

In Table B–G6 of this proposed rule, we summarize the quality reporting requirements and quality performance standard policies for PY 2027 and subsequent PYs, including our proposals in this proposed rule. This table also reflects the creation of the new Medicare eCQMs collection type and removal of Initiation and Engagement of Substance Use Disorder Treatment (Quality ID: 305) and Adult Immunization Status (Quality ID: 493) from the APP Plus quality measure set for Shared Savings Program ACOs, as discussed in sections III.G.3.d.(3) and III.G.3.f.(2), respectively, of this proposed rule. The quality reporting requirements and quality performance policies for PY 2026 were summarized in Table B–G6 of the CY 2026 PFS final rule (90 FR 49819 and 49820).

TABLE B-G6: APP PLUS QUALITY MEASURE SET REPORTING REQUIREMENTS AND QUALITY PERFORMANCE STANDARD POLICIES FOR SHARED SAVINGS PROGRAM ACOS FOR PY 2027 AND SUBSEQUENT PYS

	PY 2027 and Subsequent PYs
Shared Savings Program ACO Quality Reporting Requirements	ACOs are required to report **5** eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs in the APP Plus quality measure set and administer the CAHPS for MIPS survey (except if the ACO does not meet the minimum beneficiary sampling requirements specified at § 414.1380(b)(1)(vii)(B)). CMS will calculate 2 administrative claims-based measures.
Shared Savings Program ACO Quality Performance Standard and Alternative Quality Performance Standard*	**ACOs that report the APP Plus quality measure set can meet the quality performance standard used to determine eligibility for maximum shared savings and to avoid maximum shared losses (if applicable) via one of the three pathways:** 1. ***For all ACOs:*** Achieve a quality score that is equivalent to or higher than the **40th** percentile across all MIPS quality performance category scores, excluding entities/providers eligible for facility-based scoring, or **2. *For ACOs that report the 5 eCQMs/MIPS CQMs in the APP Plus quality measure set and meet the MIPS data completeness requirement at § 414.1340 for all 5 eCQMs/MIPS CQMs:*** Meet the eCQM/MIPS CQM reporting incentive by achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set and a quality performance score equivalent to or higher than the **40th** percentile of the performance benchmark on at least 1 of the remaining 7 measures in the APP Plus quality measure set. ***3. For ACOs in their first PY of their first agreement period under the Shared Savings Program***: Report the APP Plus quality measure set and meet the MIPS data completeness requirement at 414.1340 on the 5 eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs in the APP Plus quality measure set, administer the CAHPS for MIPS survey (except if the ACO does not meet the minimum beneficiary sampling requirements specified at § 414.1380(b)(1)(vii)(B)), and receive a MIPS quality performance category score. **Alternative quality performance standard used to determine shared savings using the sliding scale methodology:** ACOs that do not meet the quality performance standard based on the criteria above can meet the alternative quality performance by reporting quality data on the APP Plus quality measure set and achieving a quality performance score equivalent to or higher than the **10th** percentile of the performance benchmark on at least 1 of the 4 outcome measures in the APP Plus quality measure set will share in savings (if otherwise eligible) at a lower rate that is scaled by the ACO's quality score. If an ACO (1) does not report any of the 5 eCQMs /MIPS CQMs/Medicare CQMs/Medicare eCQMs in the APP Plus quality measure set and (2) does not administer a CAHPS for MIPS survey, unless the ACO does not meet the minimum beneficiary sampling requirements specified at § 414.1380(b)(1)(vii)(B), the ACO will not meet the quality performance standard or the alternative quality performance standard. This ACO will be ineligible for shared savings and will owe maximum shared losses, if applicable.

*The quality performance standard policies described in this table apply to ACOs that are not subject to the extreme and uncontrollable circumstances policies at § 425.512(c).

4. Shared Savings Program Certified Electronic Health Record Technology (CEHRT) Use Requirements

a. Background

Section 1899(b)(3)(D) of the Act authorizes the Secretary to incorporate reporting requirements and incentive payments from section 1848 of the Act into the Shared Savings Program, such as requirements and incentive payments related to electronic prescribing and electronic health records. The statute also authorizes the Secretary to use alternative criteria for determining whether to make such incentive payments.

Section 1833(z)(2)(C)(iii)(II)(bb) of the Act (as amended by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)) generally requires Advanced Alternative Payment Models (Advanced APMs) to require the use of CEHRT. Under this authority, we have codified Advanced APM CEHRT use criteria at § 414.1415(a). We have incorporated requirements related to the adoption and use of CEHRT in the Shared Savings Program regulations. We have adopted a definition of CEHRT in § 425.20 that cross references the Quality Payment Program's definition of CEHRT (§ 414.1305).

For the Shared Savings Program, CMS updated the CEHRT definition in the CY 2024 PFS final rule (88 FR 79309).

Under paragraph (3) of the CEHRT definition in § 414.1305, CEHRT currently means EHR technology (which could include multiple technologies) certified by the Office of the National Coordinator for Health Information Technology (ONC) under the ONC Health IT Certification Program as meeting the 2015 Edition Base EHR definition, or subsequent Base EHR definition (set forth at 45 CFR 170.102), and a designated set of health IT certification criteria adopted or updated in 45 CFR 170.315 that are determined applicable for the APM.

In the context of health IT, the secure exchange, access, and use of electronic health information supports better informed decision making and a more efficient health care system.[256] Interoperability (as defined at 45 CFR 170.102) enables this secure exchange and access. To this end, CMS intends to utilize approaches based on the HL7® (Health Level 7) Fast Healthcare Interoperability Resources® (FHIR) [257] standard to support the exchange of quality information, consistent with CMS' digital quality measurement initiatives, as described in the FHIR RFI in the CY 2026 PFS proposed rule (90 FR 32710 through 32715). FHIR is a widely used application program interface (API)-focused standard used to represent and exchange health information maintained by the standards development organization HL7.ONC adopts the FHIR standard (currently FHIR R4) as well as FHIR implementation guides for different API use cases in 45 CFR 170.215, and incorporates these standards into certification criteria for health IT.

In the CY 2019 PFS final rule (83 FR 59982 through 59988), we adopted requirements related to ACOs' use of CEHRT, beginning with PY 2019, and in subsequent years. In that final rule, we revised the Shared Savings Program annual certification requirements at § 425.302(a)(3)(iii) to require ACOs to certify at the end of each PY that the percentage of eligible clinicians participating in the ACO who used CEHRT to document and communicate clinical care to their patients or other health care providers met or exceeded the applicable percentage specified in the requirements established in § 425.506(f) (83 FR 60092). Specifically, we codified that beginning with PY 2019, and in subsequent years, for ACOs in a track that did not meet the financial risk standard to be an Advanced APM (for example, ACOs participating under BASIC track Levels A through D), the ACO was required to certify that 50 percent of the ACO's eligible clinicians used CEHRT to document and communicate clinical care to their patients or other health care providers. For ACOs in a track that met the financial risk standard to be an Advanced APM (for example, ACOs participating under BASIC track Level E or the ENHANCED track), the ACO was required to certify that the percentage of eligible clinicians participating in the ACO that use CEHRT to document and communicate clinical care to their patients or other health care providers met or exceeded the threshold established under the Quality Payment Program at § 414.1415(a)(1). Under this requirement (§ 425.506(f)(2)), for PY 2019 through PY 2024, 75 percent of eligible clinicians were required to use CEHRT to document and communicate clinical care to their patients or health care providers (§ 1415(a)(1)(i)). In the same final rule, we updated our regulations at § 425.20 to incorporate the definition of CEHRT at § 414.1305 that applies under the Quality Payment Program (83 FR 60092).

In the CY 2024 PFS proposed rule (88 FR 52435), we stated our belief that aligning Shared Savings Program CEHRT use requirements with Merit-Based Incentive Payment System (MIPS) Promoting Interoperability performance category requirements would reduce burden on ACOs, because they would no longer have to meet distinct Shared Savings Program attestation requirements and MIPS Promoting Interoperability requirements. We also referred back to our statements in the CY 2019 PFS rule where we conveyed our desire to continue to promote and encourage CEHRT use by ACOs and their ACO participants and ACO providers/suppliers, and our desire to better align with the goals of the Quality Payment Program and the criteria for participation in certain alternative payment models tested by the CMS Innovation Center. We expressed our belief that our proposal to end the CEHRT attestation requirements and align the Shared Savings Program with the MIPS Promoting Interoperability performance category requirements would allow ACOs to focus on a unified set of program requirements for the use of CEHRT and reduce the administrative burden of managing compliance with a different set of program requirements with the same aim (88 FR 52435).

In the CY 2024 PFS final rule (88 FR 79124 through 79132), we modified the Shared Savings Program CEHRT requirements to end the CEHRT attestation requirements and align the Shared Savings Program with MIPS' Promoting Interoperability performance category requirements. We modified § 425.302(a)(3)(iii) to make the Shared Savings Program Annual CEHRT Certification requirement applicable only for PYs 2019 through 2024. This effectively sunset the Shared Savings Program CEHRT requirement that ACOs certify that the percentage of eligible clinicians participating in the ACO that used CEHRT to document and communicate clinical care to their patients or other health care providers met or exceeded the applicable percentage specified at § 425.506(f). We also revised the CEHRT reporting policy at § 425.507(a) for PYs beginning on or after January 1, 2025, to require, unless otherwise excluded, that ACO participants, ACO provider/suppliers, and ACO professionals who are MIPS eligible clinicians, Qualifying APM Participants (QP), or Partial QPs (each as defined at § 414.1305), regardless of track, must (88 FR 79131):

- Report the MIPS Promoting Interoperability performance category measures and requirements to MIPS according to 42 CFR part 414, subpart O at the individual, group, virtual group, or APM entity level; and
- Earn a MIPS performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level.

In the CY 2024 PFS final rule, we also finalized § 425.507(b), under which ACO participants, ACO providers/suppliers, or ACO professionals are excluded from the requirements specified in § 425.507(a) based on applicable policies that exclude or exempt eligible clinicians from reporting the MIPS Promoting Interoperability performance category as set forth in 42 CFR part 414, subpart O. We included in that provision the qualifier that an ACO participant, ACO provider/supplier, or ACO professional cannot be excluded from the requirements specified at § 425.507(a) solely on the basis of being a QP or Partial QP (88 FR 79131). We finalized that applicable exclusions may apply to ACO participants, ACO providers/suppliers, or ACO professionals that meet the low volume threshold as set forth at § 414.1310(b)(1)(iii), are non-MIPS eligible clinicians [eligible clinician as defined at § 414.1305; who

[256] CMS Interoperability—CMS—Center for Medicare & Medicaid Services found at *https://www.cms.gov/priorities/key-initiatives/burden-reduction/interoperability/cms-interoperability*.

[257] Health Level 7 (HL7) Fast Healthcare Interoperability Resources (FHIR)—ONC—Office of the National Coordinator for Health Information Technology found at *https://healthit.gov/interoperability/investments/fhir/*.

is not a MIPS eligible clinician as set forth in § 414.1310(b)(2)], or have a reweighted MIPS Promoting Interoperability performance category to zero percent of the final score in accordance with applicable policies set forth at § 414.1380(c)(2).

Lastly, in the CY 2024 PFS final rule, we updated public reporting requirements at § 425.308(b)(9) to reflect the MIPS Promoting Interoperability performance category measures and activities (88 FR 79132). We required ACOs to publicly report the number of MIPS eligible clinicians, QPs, and Partial QPs (each as defined at § 414.1305) participating in the ACO who earned a MIPS Promoting Interoperability performance category score at the individual, group, virtual group, or APM entity level, as set forth in § 425.507. This includes:

- The number of ACO participants, ACO providers/suppliers, and ACO professionals that meet the requirements of § 425.507(a) and are not excluded under § 425.507(b) for the applicable PY; and
- The number of ACO participants, ACO providers/suppliers, and ACO professionals that are excluded under § 425.507(b) that voluntarily reported and received a MIPS Promoting Interoperability performance category score for the applicable PY.

For PY 2025, we exercised enforcement discretion for the Shared Savings Program CEHRT requirements and will not take compliance actions under §§ 425.216 or 425.218 for PY 2025 if an ACO does not meet the requirements of §§ 425.507 and 425.308(b)(9). There will also be no impact on the ACO's ability to earn or receive shared savings for PY 2025.[258]

In the Frequently Asked Questions document where we provided notice that we were exercising enforcement discretion for PY 2025, we also stated that we would release additional information regarding Shared Savings Program Promoting Interoperability requirements for PY 2026. We are now providing ACOs with notice that we will extend the enforcement discretion that applied for PY 2025 to PY 2026. We will not take compliance actions under §§ 425.216 or 425.218 for PY 2026 if an ACO does not meet the requirements of §§ 425.507 and 425.308(b)(9). There will also be no impact on the ACO's ability to earn or receive shared savings for PYs 2025 or 2026.

Shared Savings Program ACOs, professional associations, and vendors reporting quality on behalf of ACOs have expressed concern with the burden of the Shared Savings Program requirement that all Shared Savings Program ACO participants report all MIPS Promoting Interoperability performance category measures and activities. Most Shared Savings Program ACOs (74 percent) are in tracks that qualify as Advanced APMs (BASIC level E and ENHANCED).[259] Qualifying APM participants in these ACOs are exempt from Promoting Interoperability performance category reporting for the purposes of MIPS under 42 CFR 414.1310(b)(i). Therefore, they are only being required to report MIPS Promoting Interoperability performance category measures and activities by the Shared Savings Program. ACOs have expressed confusion about MIPS Promoting Interoperability performance category reporting requirements, exclusions, and exceptions. Specifically, ACOs have requested clarification about how to aggregate and report across their organizations, especially when their practices use different EHRs or when ACOs have some practices that qualify for applicable exclusions.

We also recognize that ACOs are often comprised of many ACO professionals who serve large patient populations and that such ACOs may need to aggregate data across multiple EHR systems. An internal CMS analysis described in the CY 2025 PFS final rule that analyzed PY 2022 data indicates that Shared Savings Program ACOs reported substantially higher numbers of denominator-eligible patients for certain eCQM measures than other MIPS reporters, including 33 times more denominator eligible patients for eCQM 001—Diabetes: HbA1c Poor Control (≤9 percent), 53 times more denominator eligible patients for eCQM 134—Preventative Care and Screening: Screening for Depression and Follow-Up Plan, and 25 times more denominator eligible patients for eCQM 236—Controlling High Blood Pressure. CMS data analysis also showed that ACOs provide a high volume of services, particularly those related to preventative screening measures; for example, in PY 2022, one ACO reported on over 700,000 denominator eligible beneficiaries for a single eCQM (89 FR 98436). Additionally, ACOs and related interested parties have shared that relatively few ACOs use one EHR, while a greater share use two to ten.[260] These data underscore the operational scale and complexity associated with this reporting.

Thus, providing additional flexibility to ACOs would be helpful in light of the complex populations they serve, the high volume of data they process, and the necessity of aggregating data across multiple EHRs. Changes to simplify the Shared Savings Program requirement for ACOs to fulfill CEHRT use requirements would also be consistent with the Administration's interest, as expressed in the ''Request for Information: Deregulation'' (90 FR 15481 through 15482), in identifying proposals to rescind or replace regulations that burden American businesses. In response to that RFI, several commenters asked that CMS reduce burdensome requirements for ACOs to report MIPS Promoting Interoperability performance category measures and activities, including a few specific suggestions that we reverse the Shared Savings Program's MIPS Promoting Interoperability performance category reporting requirement due to the increased burden on ACOs without adding any value. Others suggested that we revert to an attestation requirement, revise the definition of CEHRT, re-evaluate numerator and denominator requirements for CEHRT use reporting, or recognize CMS Innovation Center model participation, use of FHIR, or participation in health information exchanges as evidence of interoperability without the need for additional reporting or attestation.

From commenters' responses to a CMS RFI on digital quality measurement included in the CY 2026 PFS proposed rule (90 FR 32710 through 32715), we learned that interested parties broadly supported CMS' efforts to move toward FHIR-based digital quality measurement. Commenters noted that the use of interoperable sources that are available at the point of care would ultimately increase efficiency, reduce administrative burden, and empower patients and providers to make informed care decisions. Many commenters also stated that significant technical and operational work remains to be completed before implementation of FHIR-based digital quality measurement, to ensure there is sufficient infrastructure to support the migration to and execution of FHIR.

[258] Please see the notice of enforcement discretion in the Shared Savings Program Requirement to Report Objectives and Measures for Merit-based Incentive Payment Systems (MIPS) Promoting Interoperability Performance Category FAQ (*https://www.cms.gov/files/document/frequently-asked-questions-shared-savings-program-requirement-report-objectives-measures-mips.pdf*)

[259] See Shared Savings Program Fast Facts as of January 1, 2026 (*https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf*).

[260] See *https://www.naacos.com/ecqms-for-acos-recommendations-from-the-naacos-digital-quality-measurement-task-force/*.

Several commenters described that the phased adoption, technical assistance, and incentives for use of EHR data would promote a successful transition to FHIR-based digital quality measurement. Some commenters opposed movement to FHIR-based digital quality measurement, with noted concerns including the ability of small practices to transition, potential performance issues with technology, need for clarity around exclusions, and difficulty with aggregating across large organizations.

b. Proposal To Simplify Shared Savings Program CEHRT Use Requirements

We believe that reduction in burden for reporting CEHRT use will free ACO resources to focus on meaningful advancement toward digital exchange of health information, including digital quality measurement. As noted above, commenters on the Request for Information: Deregulation asked that we recognize ACO use of FHIR technologies and that we simplify Shared Savings Program CEHRT use requirements. We believe that these suggestions would advance FHIR-based digital quality reporting by giving credit for incremental advances toward digital quality reporting.

In response to the concerns and suggestions detailed above and in line with CMS' priorities to reduce burden and promote FHIR-based digital quality reporting and exchange of health information, we are proposing to sunset, beginning with PY 2027, the requirements at § 425.507(a) for Shared Savings Program ACO participants, ACO provider/suppliers, and ACO professionals that are MIPS eligible clinicians, Qualifying APM Participants, or Partial Qualifying APM Participants to report all MIPS Promoting Interoperability performance category measures and requirements and to earn a performance category score for the MIPS Promoting Interoperability performance category at the individual, group, virtual group, or APM entity level. Accordingly, we also propose to sunset the associated exclusions that complement this requirement at § 425.507(b). We are proposing to replace the requirement in § 425.507(a) with different options for ACOs to meet CEHRT use requirements for the Shared Savings Program, described in further detail below.

As Shared Savings Program ACOs cover 12.6 million beneficiaries, served by over 700,000 participating clinicians and facilities,[261] we believe that a shift to FHIR-based digital quality reporting and exchange of health information at this scale would meaningfully advance care coordination and quality improvement. We further believe reducing the burden of Shared Savings Program participation could lead to increased program participation from ACOs and ACO professionals, which would magnify the impact, moving even more clinicians toward meaningful use of EHR technology to improve care for beneficiaries.

To encourage widespread adoption of FHIR-based transmission of clinical data, enable bi-directional exchange of clinical data across practices within ACOs, and support the capture of robust clinical quality information, we propose, in § 425.507(c), that for PY 2027 and subsequent PYs, to meet the Shared Savings Program CEHRT use requirement, ACOs would be required to perform at least one of three allowable activities. The three allowable CEHRT use activities, from which ACOs would choose at least one, are described in further detail in this section. In summary, they are:

(1) Completely report at least one of the five ACO-reported measures in the APP Plus quality measure set through the eCQMs collection type or the proposed Medicare eCQMs collection type (proposed in section III.G.3.d.(3) of this proposed rule) using CEHRT; OR

(2) Attest to the ACO's use of FHIR capabilities to support reporting of at least one of the five ACO-reported measures in the APP Plus quality measure set using CEHRT. Section IV.A.4.b.(2) of this proposed rule contains measures in the APP Plus quality measure set that are reportable by ACOs in PY 2027; OR

(3) Select and attest to one of the proposed Shared Savings Program CEHRT use metrics, which are based on a subset of MIPS Promoting Interoperability performance category measures, and which may be updated annually if there are changes.

We also propose to sunset existing public reporting requirements at § 425.308(b)(9) and propose to add a new section at § 425.308(b)(11), which would require ACOs to publicly report which of the allowable CEHRT use options proposed above they elected to perform to meet CEHRT use requirements for the Shared Savings Program for PY 2027 and subsequent PYs.

(1) Meeting Shared Savings Program CEHRT Use Requirement by Reporting at Least One ACO-Reported Measure Through the eCQMs or Medicare eCQMs Collection Types

As discussed earlier in this section, commenters have asked that CMS recognize efforts that ACOs are already undertaking to advance CEHRT use, without the need for additional reporting or attestation. Accordingly, we are proposing to recognize ACO reporting of eCQMs without additional reporting requirements, for the purpose of satisfying the Shared Savings Program CEHRT use requirements. Because reporting of eCQMs or the proposed Medicare eCQMs would require the use of CEHRT and submission of CEHRT IDs [262] to communicate care quality to CMS, we believe that an ACO's reporting of measures using the eCQM collection type or the proposed Medicare eCQM collection type (see section III.G.3.d.(3) of this proposed rule for discussion of the proposal to establish Medicare eCQM collection type) is a concrete example of ACO CEHRT use that supports improved patient care. Clinical quality measure reporting helps identify areas for potential care improvement, and use of CEHRT to report quality of care is a step toward bi-directional exchange of health information and digital quality measurement.

We propose, in § 425.507(c)(1), that one option ACOs could select to meet the Shared Savings Program CEHRT use requirement is using EHR technology that meets the requirements in paragraph (3) of the CEHRT definition at § 414.1305. ACOs would need to use EHR technology that is also certified to certification criteria that support the recording, calculation, and reporting of clinical quality measures by being certified to the ONC Health IT Certification Program certification criteria at 45 CFR 170.315(c)(1) (included in the Base EHR definition in 45 CFR 170.102), (c)(2) and (c)(3) to completely report at least one measure in the APP Plus quality measure set, through the eCQMs or the proposed Medicare eCQMs collection type. Paragraph (3) of the CEHRT definition at § 414.1305 is the CEHRT definition applicable to Advanced APMs. The requirement that Shared Savings program ACOs use CEHRT that is certified to the ONC Health IT Certification Program certification criteria at 45 CFR 170.315(c)(2) and

[261] See Shared Savings Program Fast Facts as of January 1, 2026 (*https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf*).

[262] For more information, please find the MIPS Data Submission User Guide on the QPP Resource Library: *https://qpp.cms.gov/resources/resource-library*.

(c)(3) would be consistent with CEHRT use requirements under MIPS, as specified in paragraph (2)(ii)(B) of the CEHRT use definition at § 414.1305, which includes a specific requirement for use of EHR technology certified been certified to the ONC health IT certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3).

To ''completely report'' as we use that phrase in the proposed regulatory text, for the purpose of using this option to satisfy Shared Savings Program CEHRT use requirements, would mean that the ACO meets the Shared Savings Program quality reporting requirements proposed at § 425.508(c)(1) to (c)(4) and as discussed in section III.G.3.d.(2) of this rule as well as the MIPS data completeness requirements at § 414.1340 for the measure submission. The measure must be completely reported as part of annual quality reporting. Under this proposal, ACOs that completely report at least one quality measure through the eCQMs or the proposed Medicare eCQMs collection types, as determined by MIPS, would not be required to complete an attestation to meet Shared Savings Program CEHRT use requirements. Please note that, in section III.G.3.d.(2) of this proposed rule, we are proposing changes to the Shared Savings Program quality reporting requirements at § 425.508, which may alter the universe of patients used to determine compliance with the MIPS data completeness requirements at § 414.1340 and would be applicable to the proposed changes for the Shared Savings Program CEHRT use requirement. Under this Shared Savings Program CEHRT use requirement proposal, ACOs electing to meet the Shared Savings Program CEHRT use requirement by completely reporting at least one ACO-reported measure in the APP Plus quality measure set through the eCQMs or the proposed Medicare eCQMs collection type would be required to meet the proposed Shared Savings Program quality reporting requirement changes proposed in section III.G.3.d.(2) of this proposed rule, if finalized, along with the MIPS data completeness requirements at § 414.1340 for that eCQM or the proposed Medicare eCQM measure submission.

We understand that ACOs may still face challenges in aggregating data. As discussed more fully in section III.G.3.d. of this proposed rule, we believe that the proposed data completeness requirement changes would help to mitigate the issues facing ACOs in aggregating data for eCQM or proposed Medicare eCQM reporting. We also note that eCQM or proposed Medicare eCQM reporting is just one of three proposed ways an ACO could meet the Shared Savings Program CEHRT use requirement.

(2) Meeting Shared Savings Program CEHRT Use Requirements by Attesting To Using FHIR Capabilities in Certified Health IT To Support Reporting of At Least One of the Five ACO-Reported Measures in the APP Plus Measure Set

We are proposing, in § 425.507(c)(2), that another option ACOs could select for PY 2027 and subsequent PYs, to meet the Shared Savings Program CEHRT use requirement, is completely reporting at least one of the measures in the APP Plus quality measure set and meeting the data completeness requirement under § 414.1340.

The ACO must also attest that it used technology certified to ONC Certification Criteria for Health IT (45 CFR 170.315) supporting FHIR-based exchange to meet paragraph (3) of the CEHRT definition at § 414.1305 to support measure data collection. Specifically, it must attest to the use of a Health IT Module (as defined in 45 CFR 170.102) that has been certified to an unexpired criterion or criteria in 45 CFR 170.315 to make information in the U.S. Core Data for Interoperability (USCDI) available through a FHIR-based API (currently USCDI version 3; 45 CFR 170.213(b)). Data represented by the USCDI can be used to support meeting the data requirements for measures in the APP Plus quality measure set. By mapping data elements in USCDI to measure specifications, users could leverage this functionality in their CEHRT to obtain data needed to calculate measures in the APP plus measure set. For instance, an initial analysis found data requirements for several MIPS CQMs/Medicare CQMs identified in the APP Plus quality measure set could be met using the data in USCDI version 3 obtained via an API meeting the requirements of 45 CFR 170.315(g)(10) in previous performance years.[263]

We note that eligible clinicians and APM entities already have the flexibility to use data obtained via Health IT Modules certified to certification criteria in 45 CFR 170.315 to report MIPS CQMs and Medicare CQMs, as CMS does not specify how eligible clinicians and APM entities must collect data for MIPS CQMs and Medicare CQMs, and no further updates are needed to our quality reporting policies to permit use of this technology. Rather, our proposed policy aims to encourage Shared Savings Program ACOs to use this approach to obtain data for quality measure reporting. Using standardized data from FHIR APIs can support more seamless aggregation of data across different EHR systems used by ACO participants. To meet the Promoting Interoperability requirement for the Shared Savings Program at the APM entity level as presently required in § 425.507(a), ACOs are already required to demonstrate use of CEHRT through the MIPS requirement to use CEHRT at § 414.1375(b)(1). Specifically, current policy requires that ACOs use EHR technology that is certified to certification criteria in 45 CFR 170.315(g)(10), as it is a part of the ''Base EHR'' definition at 45 CFR 170.102. The Base EHR definition is included in paragraph (3) of the ''Certified Electronic Health Record Technology (CEHRT)'' definition at 42 CFR 414.1305 used by the Shared Savings Program. For the purpose of meeting this option, ACOs electing to attest would attest that it used data collected from a FHIR-based API to support data collection using a Health IT Module certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access, to support reporting a measure in the APP Plus measure set.

We are proposing to require ACOs to attest because, for the MIPS CQMs or Medicare CQMs collection types we cannot ascertain (absent attestation) whether an ACO used FHIR technology to support collection of data used to report these measures. For the proposed CEHRT use activity option in § 425.507(c)(1), discussed above, we will be able to identify the ACOs that met that CEHRT use activity from quality reporting submission data; however, attestation would be required for an ACO electing to meet Shared Savings Program CEHRT use requirements by using standardized data from FHIR APIs to support collection of data for reporting at least one measure in the APP Plus measure set. We note that, while the option to meet Shared Savings Program CEHRT use requirements by attesting to use of a FHIR-based API to support complete reporting of at least one measure in the APP Plus measure set could conceivably be used for any available measure collection type, it would not be necessary for ACOs electing to report eCQMs or Medicare eCQMs collection

[263] *See* ''Advancing Digital Quality Reporting Using Regulated Endpoints'' *https://leavittpartners.com/wp-content/uploads/2026/04/Advancing-Digital-Quality-Reporting-Using-Regulated-Endpoints.pdf.*

types. This is because those ACOs electing to report via eCQMs or Medicare eCQMs collection types would receive automatic credit for reporting through those collection types, as CMS would be able to ascertain based on quality data submissions that ACOs completely reported a measure in the APP Plus measure set using the eCQM or Medicare CQM collection type, and that is one option that would satisfy the Shared Savings Program CEHRT use requirement. Accordingly, the discussion here focuses only on the MIPS CQMs and Medicare CQMs collection types. For ACOs electing to meet Shared Savings Program CEHRT use requirements by attesting to use of data collected from a FHIR-based API to support complete reporting using a Health IT module certified to an unexpired criterion or criteria that supports standardized API access, for at least one measure through the MIPS CQMs or Medicare CQMs collection types, the measure must be completely reported as part of annual quality reporting. We propose that ACOs would attest to meeting this requirement through ACO–MS, after the conclusion of annual quality reporting, which occurs in the first quarter of the year following the PY. For example, we anticipate that the attestation would be available in ACO–MS in the second quarter of 2028, after the conclusion of quality reporting for PY 2027. This proposed option for meeting Shared Savings Program CEHRT use requirements through the use of standardized data from FHIR APIs to report MIPS CQMs or Medicare CQMs would serve to recognize efforts underway by ACOs taking an interim step in the transition to FHIR-based digital quality reporting.

CMS described a parallel goal to implement FHIR reporting for eCQMs in an RFI posted in the CY 2026 proposed rule (90 FR 32710 through 32715), and requests comment on a timeline for transitioning to FHIR-based digital quality measurement in section IV.A.4.c. of this proposed rule. In the RFI regarding the timeline to transition to FHIR-based reporting in this proposed rule, we indicated that following this transition period, FHIR-based reporting would be required for those applicable measures that were available as FHIR-based dQM reporting options during the transition period, beginning with the 2030 performance period. These Shared Savings Program CEHRT use proposals are aligned with our efforts to recognize ACO movement toward FHIR-based digital quality measurement and take into consideration comments received on the Request for Information: Deregulation, where a few commenters noted that leveraging FHIR technology supports multidisciplinary collaboration and efficient information sharing without additional attestations. While we disagree that use of FHIR technology alone obviates the needs for an attestation, since we are presently not able to discern whether an ACO has utilized a certified Health IT Module (for example, a 45 CFR 170.315(g)(10)-certified Health IT Module) to obtain standardized data from a FHIR-based API to aggregate data for quality reporting without an attestation, we acknowledge the value in use of FHIR technology. In response to commenters' concerns about reporting burden, we believe that this attestation would represent a significantly reduced burden in comparison to the current requirement in § 425.507(a) that all ACO participants report all MIPS Promoting Interoperability performance category measures and activities. Another commenter responded that CMS should incorporate FHIR-based capabilities as a fundamental requirement in the Shared Savings Program. We believe that an ACO's use of a Health IT Module certified to an unexpired criterion or criteria within 45 CFR 170.315 to obtain standardized data from FHIR APIs to support collecting data is a concrete step toward interoperability that will enable both digital quality reporting and bi-directional exchange of health information.

Under this proposed option for meeting the Shared Savings Program CEHRT use requirement, ACOs choosing to attest that they used a Health IT Module certified to an unexpired criterion or criteria within 45 CFR 170.315 to obtain standardized data from a FHIR API to support collection of data for reporting at least one measure in the APP Plus measure set would also need to have completely reported that measure, according to data completeness requirements detailed earlier in this section.

(3) Meeting Shared Savings Program CEHRT Use Requirements by Attesting to One of the Three ACO CEHRT Use Metrics

We are proposing, in § 425.507(c)(3), that another option ACOs could select to meet the Shared Savings Program CEHRT use requirement, is to attest to at least one of the Shared Savings Program CEHRT use metrics from the list of metrics established for the applicable performance year. We are proposing three Shared Savings Program ACO CEHRT use metrics for PY 2027, listed in Table B–G7. Like similar measures that are included in the MIPS Promoting Interoperability performance category, these three Shared Savings Program ACO CEHRT use metrics represent meaningful ACO use of CEHRT for improved patient care. We are proposing to allow ACOs to attest that the ACO meets one of these three metrics to satisfy the Shared Savings Program CEHRT use requirement. This proposal is responsive to public comments on the deregulatory RFI (90 FR 15481 to 15482). Responses to the RFI included several comments asking that CMS permit attestation for meaningful use of CEHRT and exchange of health information, to ease reporting burdens and encourage small practices to participate in the Shared Savings Program. One commenter also suggested CMS incentivize organizations to utilize real-time data exchange. We believe that allowing ACOs to attest to the use of bi-directional exchange of health information as one of the three options would promote ACOs engaging in this valuable activity while representing a significantly reduced burden as compared to our current Shared Savings Program CEHRT requirement that ACOs report on all MIPS Promoting Interoperability performance category measures and activities.

We would update the list of allowable metrics through notice and comment rulemaking if there are any changes for future years.

The ACO CEHRT use metrics we are proposing are based on the following parallel MIPS Promoting Interoperability performance category measures: Electronic Prescribing,[264] Health Information Exchange (HIE) Bi-Directional Exchange,[265] and Provide Patients Electronic Access to Their Health Information.[266] The parallel MIPS Promoting Interoperability performance category measures provide instructions on how MIPS eligible clinicians can report the measures, with instructions to aggregate across all MIPS eligible clinicians for group and APM-level reporting in each of the measure specification documents. We are not proposing, however, that ACOs would be required to report Shared Savings Program ACO CEHRT use metrics for every ACO provider/supplier in the

[264] *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2026-MIPS-Promoting-Interoperability-e-Prescribing-Measure.pdf.*

[265] *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2026-MIPS-Promoting-Interoperability-HIE-Bi-Directional-Exchange-Measure.pdf.*

[266] *https://qpp.cms.gov/docs/pi_specifications/Measure%20Specifications/2026-MIPS-Promoting-Interoperability-Provide-Patients-E-Access-to-Their-Health-Info-Measure.pdf.*

ACO, as is required under the MIPS measure specifications, because we understand that this level of information may be difficult or burdensome for ACOs to aggregate. To recognize the varying capacities for ACO participants to report on CEHRT use and for ACOs to report on CEHRT use for all of their ACO participants, we are proposing that ACOs would be allowed to attest ''Yes'' if at least one ACO provider/supplier in each of the ACO's participating TINs performed the action described in the Shared Savings Program ACO CEHRT use metric using EHR technology certified to the ONC Certification Criteria for Health IT (45 CFR 170.315) necessary to meet paragraph (3) of the CEHRT definition at § 414.1305 to complete the action described in each metric.

As discussed earlier in this section, ACOs have faced challenges in reporting a high volume of participant data involving multiple EHRs for MIPS Promoting Interoperability measures and activities. An additional source of confusion is the requirement to report on behalf of all participants when an ACO reports at the APM entity level, including participants who would have been excluded or have received special status for reporting purposes when reporting at the individual or group level. Similarly, because QPs do not receive MIPS scores or payment adjustments, the requirement that QPs report the MIPS Promoting Interoperability performance category and earn a performance category score is a burden unique to Shared Savings Program Promoting Interoperability requirements. ACOs have also reported incidents of practices included on the ACO's Participant Agreement closing throughout the year, which requires the ACO to report on behalf of groups with whom contact may be difficult. Given this, we no longer believe it is reasonable to require them to report on every ACO provider/supplier in the ACO. We recognize and have been reminded by interested parties that participation in an ACO itself represents a commitment to coordinating care. ACOs in the Advanced APM tracks of the Shared Savings Program (BASIC track Level E and ENHANCED track), whose qualifying participants are exempt from MIPS, have taken on financial risk for providing coordinated, efficient care. We believe that in addition to that undertaking, our proposal to allow ACOs to attest that one ACO provider/supplier from each of the ACO's participating TINs has completed the action required under one of the ACO CEHRT use metrics we are proposing would be sufficient to demonstrate CEHRT use. We note that providers and suppliers who are MIPS eligible clinicians and who participate in ACOs in Shared Savings Program tracks that do not meet the definition of an Advanced APM (BASIC track levels A–D) and those in Advanced APM tracks who are not QPs will still be required to report MIPS Promoting Interoperability performance category measures (unless they are otherwise excluded under MIPS) to earn a score for the Promoting Interoperability performance category.

In this section, we provide summary level information of the three proposed ACO CEHRT use metrics. These details generally align with the measure specifications for the respective MIPS Promoting Interoperability measures; however, they reflect ACO-level attestation. From these, ACOs would be allowed to select one metric to which the ACO would be able to attest ''Yes,'' to meet Shared Savings Program ACO CEHRT use requirements. Following the discussion of the three proposed metrics, we describe proposed allowable exclusions from ACO attestation. For each of these proposed activities, to attest ''Yes,'' the ACO's participant TINs must use EHR technology certified to the ONC Certification Criteria for Health IT (45 CFR 170.315) necessary to meet paragraph (3) of the CEHRT definition at § 414.1305. We further describe the specific certified Health IT Modules that must be used to complete the action in the measure, consistent with information provided by the MIPS program for corresponding measures. If finalized, we would make public on our website more detailed information on each of these metrics.

(i) ACO Electronic Prescribing: An ACO could attest ''Yes,'' if, during the PY, at least one permissible prescription was written by at least one ACO provider/supplier in each of the ACO's participant TINs, and the prescription was transmitted electronically using CEHRT. In addition to the allowable exclusions from Shared Savings Program CEHRT use attestation discussed later in this section, ACOs choosing to attest to this metric would be permitted to exclude from their assessment any ACO participant TIN whose providers and suppliers wrote fewer than 100 total permissible prescriptions during the PY. This exclusion would align with a similar exclusion in the parallel MIPS Promoting Interoperability e-Prescribing measure, which provides an exclusion for any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period. This would mean that an ACO could attest that it met this metric even if no electronic prescription was written by any provider or supplier in one of the ACO's ACO participant TINs, where all of the ACO's participants TINs were composed of providers and suppliers who wrote fewer than 100 total permissible prescriptions. Similar to the MIPS e-Prescribing measure, a prescription would be defined as the authorization by an ACO provider or supplier to a pharmacist to dispense a drug that the pharmacist wouldn't dispense to the patient without such authorization. A permissible prescription is a prescription, as described in the preceding sentence, including electronic prescription of controlled substances, where creation of an electronic prescription for the medication is feasible using CEHRT and where allowable by state and local law. An ACO electing to attest to this metric to meet the Shared Savings Program CEHRT use requirement would be required to attest that at least one ACO provider or supplier in each of its ACO participant TINs used CEHRT, including health IT certified to the ''electronic prescribing'' criterion in 45 CFR 170.315(b)(3) to complete the actions of this Shared Savings Program CEHRT use metric.

(ii) ACO Health Information Exchange (HIE) Bi-Directional Exchange: An ACO could attest ''Yes'' if, during the PY, at least one ACO provider or supplier from each of the ACO's participant TINs has, for at least one patient seen by the provider or supplier used EHR technology certified to the ONC Certification Criteria for Health IT (45 CFR 170.315) necessary to meet paragraph (3) of the CEHRT definition at § 414.1305 to support bi-directional exchange with an HIE that: enables secure, bi-directional exchange to occur for every patient encounter, transition or referral, and record stored or maintained in the provider or supplier's EHR during the PY in accordance with applicable law and policy; and that the HIE is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs and does not engage in exclusionary behavior when determining exchange partners. These elements of this Shared Savings Program ACO CEHRT use metric align with those in the parallel MIPS Promoting Interoperability measure. An ACO electing to attest to this metric to meet the Shared Savings Program CEHRT use requirement would not be required to attest that at least one ACO provider or supplier from each ACO

participant TIN used CEHRT functionality to perform bi-directional exchange for every patient throughout the PY. Rather, attesting ''yes'' to the measure requires that at least one ACO provider or supplier from each of the ACO's participant TINs used CEHRT functionality to perform bi-directional exchange for at least one patient with an HIE that has the capability to enable secure, bi-directional exchange for all patients, without excluding exchange partners. We recognize that a provider/supplier may have different options with respect to the certified health IT that it uses to connect to an HIE. Health IT certified to criteria including, but not limited to, the ''transitions of care'' criterion in 45 CFR 170.315(b)(1), the ''Clinical information reconciliation and incorporation'' criterion in 45 CFR 170.315(b)(2), and the ''Standardized API for patient and population services'' 45 CFR 170.315(g)(10), could be utilized to support bi-directional exchange through an HIE. An ACO attesting to this metric, for the purpose of meeting the Shared Savings Program CEHRT use requirement, would be required to attest that at least one ACO provider or supplier in each of its ACO participant TINs used CEHRT, including health IT certified to but not limited to the criteria previously discussed, to complete the actions of this Shared Savings Program CEHRT use metric.

We note that the MIPS Promoting Interoperability performance category includes a corresponding measure under the HIE objective entitled ''Enabling Exchange Under TEFCA,'' which enables eligible clinicians to earn credit for the HIE Objective if they participate as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability) to enable secure, bi-directional exchange of information for every patient encounter, transition of care or referral, and record stored or maintained in the EHR during the performance period, using CEHRT. We note that, while we have not proposed to adapt this measure for the proposed ACO CEHRT use requirements, ACO providers or suppliers who are able to attest ''Yes'' to the ''Enabling Exchange Under TEFCA'' measure under the MIPS Promoting Interoperability performance category would meet the requirement to have used CEHRT to perform bi-directional exchange for at least one patient. Accordingly, an ACO choosing to attest to having met this metric could consider an ACO provider or supplier who could attest to the MIPS Promoting Interoperability measure, ''Enabling Exchange Under TEFCA'' for a particular performance year to count as having met the requirement for their ACO participant TIN when determining whether one ACO provider or supplier from each of its ACO participant TINs has met the requirement for the proposed ACO Health Information Exchange (HIE) Bi-Directional Exchange metric.

(iii) ACO Provider to Patient Exchange: An ACO could attest ''Yes'' to this metric if, during the PY, at least one ACO provider or supplier from each of the ACO's participant TINs has, for at least one patient seen by the ACO provider or supplier (or the patient-authorized representative): provided timely access to view online, download, and transmit his or her health information; and ensured the patient's health information is available for the patient (or the patient's personal representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the clinician's CEHRT. Similar to the MIPS Promoting Interoperability performance category measure, ''Provide Patients Electronic Access to Their Health Information,'' for the ACO to attest ''Yes,'' the patient would need to be able to access this information on demand, such as through a patient portal or personal health record (PHR) or by other online electronic means.

As detailed in the measure specifications for the parallel MIPS measure, specific rights and privacy protections apply to the provision of protected health information (PHI) to individuals. While a covered entity may be able to fully satisfy a patient's request to access the patient's information through view, download, or transmit functionality, the metric would not replace a covered entity's responsibilities to meet the right of access requirements under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (45 CFR part 160 and subparts A and E of part 164) to provide an individual, upon request, with access to PHI in a designated record set. There may be patients who can't access their health information electronically because of a disability. In these cases, ACO providers or suppliers who are covered by civil rights laws are required to provide individuals with disabilities equal access to information and appropriate auxiliary aids and services as provided in the applicable statutes and regulations.

An ACO electing to attest to this metric to meet the Shared Savings Program CEHRT use requirement would be required to attest that at least one ACO provider or supplier in each of its ACO participant TINs used health IT certified to the ''view, download, and transmit to 3rd party'' criterion in 45 CFR 170.315(e)(1) to provide view, download, or transmit capabilities to at least one patient. The ACO participant would also be required to use health IT certified to the ''application access—patient selection'' criterion in 45 CFR 170.315(g)(7), the ''application access—all data request'' criterion in 45 CFR 170.315(g)(9), and the ''standardized API for patient and population services'' criterion in § 170.315(g)(10) to support information access through an API to their patients. We note, however, as we discussed with respect to the MIPS Promoting Interoperability performance category in section IV.A.4.d.(4) of this proposed rule, ONC proposed to remove the criteria in 45 CFR 170.315(g)(7) and (g)(9) as of January 1, 2027 in the HTI–5 Proposed Rule (90 FR 60998). If ONC finalizes these proposals, we would no longer require ACOs to use health IT certified to the removed criteria to meet the measure and rather, the ACO would be required to attest to having used health IT certified to the ''view, download, and transmit to third party'' criterion in 45 CFR 170.315(e)(1) to provide view, download, or transmit capabilities to patients and to the ''standardized API for patient and population services'' criterion in § 170.315(g)(10), to meet the requirements of this Shared Savings Program ACO CEHRT use metric. ACOs electing to attest to any one of the three ACO CEHRT use metrics, including this one, would also still be required to attest that their participating ACO providers and suppliers used EHR technology necessary to meet paragraph (3) of the CEHRT definition at § 414.1305, as described previously. Patient health information would need to be made available to the patient to view, download, or transmit within 4 business days of the information being available to the ACO provider or supplier for every time that information is generated. Also, in alignment with the MIPS Promoting Interoperability performance category measure, for ''view, download, or transmit'' functionality, the required content would be: an unexpired version of the USCDI adopted at 45 CFR 170.213; Provider's name and office contact information; Laboratory test report(s); Diagnostic image report(s), and for API functionality, the required data set is the USCDI.

(iv) Allowable ACO exclusions from Shared Savings Program CEHRT use metrics: Based on feedback we received from the RFIs discussed earlier in this section and questions we have received from ACOs on the existing Shared Savings Program CEHRT use requirements that we are proposing to sunset and replace, we understand that ACOs may face difficulties in determining whether an ACO provider or supplier from each of its ACO participant TINs has performed the required action for a given proposed Shared Savings Program ACO CEHRT use metric. We, therefore, propose to allow certain exclusions for ACOs electing to meet the Shared Savings Program CEHRT use requirement by attesting to one of the available Shared Savings Program CEHRT use metrics. By ''exclusion,'' we mean that an ACO would be able to attest to having performed the activity required by the metric, even if one or more of the ACO's participant TINs did not have at least one ACO provider/supplier that performed the activity, if that TIN or TINs meets one of the exclusions described below.

We propose that ACOs would be permitted to apply exclusions for similar circumstances as the exclusions and exceptions under MIPS, when ACOs choose to report one of the three proposed Shared Savings Program ACO CEHRT use metrics for purposes of satisfying the Shared Savings Program CEHRT use requirement in PY 2027 and future years. We note under MIPS, special statuses result in automatic reweighting of the Promoting Interoperability performance category to zero. For hardship circumstances, MIPS eligible clinicians or groups may be required to submit a hardship exception application that is subject to CMS approval. However, for the purposes of the Shared Savings Program CEHRT use requirement, we propose that an ACO may exclude from their Shared Savings Program CEHRT attestation an ACO participant TIN that meets certain exclusion criteria outlined below without requesting approval from CMS. This means that the ACO may still attest to having performed the action required by the metric, without consideration of whether at least one ACO provider or supplier from a TIN meeting these criteria performed the required action, when at least one ACO provider or supplier in each of the ACO's other participant TINs (that are not permitted to be excluded) performed the required action. The criteria under which an ACO would be permitted to exclude an ACO participant TIN are that the ACO determines the TIN is comprised solely of ACO providers and/or suppliers who:

- Would meet the definition of ''special status''; or
- Are facing hardship circumstances that would qualify for MIPS Promoting Interoperability hardship exception requests, had such requests been submitted by a MIPS eligible clinician.

For Shared Savings Program CEHRT use metric exception purposes, the following would be considered special statuses. The definitions of these special statuses would be similar to the MIPS definitions at § 414.1305 except that they would not be limited to MIPS ECs, for the purpose of Shared Savings Program CEHRT use metric exceptions. For Shared Savings Program CEHRT use metric exclusion purposes, ACOs would be permitted to exclude an ACO participant TIN if the ACO determines that the TIN is comprised solely of ACO providers and suppliers meeting the following special statuses:

- ASC-based—ACO providers or suppliers who furnish 75 percent or more of their covered professional services during the performance period in sites of service identified by the POS codes used in the HIPAA standard transaction [267] as an ambulatory surgical center setting based on claims.
- Facility-based—ACO providers or suppliers who:

++ Furnish 75 percent or more of their covered professional services in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, or emergency room setting based on claims for a 12-month segment beginning on October 1 of the calendar year 2 years prior to the applicable performance period and ending on September 30 of the calendar year preceding the performance period with a 30-day claims run out; and

++ Furnish at least 1 covered professional service in sites of service identified by the place of service codes used in the HIPAA standard transaction as an inpatient hospital, or emergency room setting; and

++ Can be assigned to a facility with a value-based purchasing score, determined under the methodology specified in § 414.1380(e)(5), for the applicable period.

- Hospital-based—ACO providers or suppliers who provide 75 percent or more of their covered professional services during the PY in sites of service identified by the POS codes used in the HIPAA standard transaction as an inpatient hospital, on-campus outpatient hospital, off campus outpatient hospital, or emergency room setting based on claims.
- Non-patient facing—ACO providers or suppliers who billed 100 or fewer patient-facing encounters (including Medicare telehealth services defined in section 1834(m) of the Act) during the performance year. A patient-facing encounter is an instance in which the provider or supplier bills for items and services furnished such as general office visits, outpatient visits, and procedure codes under the PFS, as specified by CMS.
- Located in a health professional shortage area (HPSA)—ACO providers and suppliers are located in areas as designated under section 332(a)(1)(A) of the Public Health Service Act
- Rural area—ACO providers or suppliers that are in a ZIP code designated as rural by the Federal Office of Rural Health Policy (FORHP), using the most recent FORHP Eligible ZIP Code file available as described in the definition of ''Rural area'' at § 414.1305.

As noted earlier in this section, the special status definition for the Shared Savings Program CEHRT use metric exclusions would be similar to the one used for MIPS eligible clinicians at § 414.1305. In contrast to the MIPS special status definition, however, small practices would not be considered a special status for the purpose of exclusion from ACO CEHRT use metric attestation because we believe that joining an ACO should be a way for small practices to receive assistance with care coordination and quality improvement efforts such as use of CEHRT.

The hardship circumstances that would qualify an ACO participant TIN for exclusion from Shared Savings Program CEHRT use metric attestation would parallel those described in § 414.1380(c)(2)(i)(C), except that neither the ACO nor the ACO provider or supplier would need to submit an application to CMS. An ACO could exclude, for purposes of determining whether the ACO can attest ''yes'' to a Shared Savings Program CEHRT use metric, ACO participant TINs comprised solely of providers or suppliers meeting any of the following conditions:

- The ACO providers or suppliers lacked sufficient internet access during the performance period, and insurmountable barriers prevented them from obtaining sufficient internet access.
- The ACO providers or suppliers were subject to extreme and

[267] For more information on HIPAA transactions, please see the CMS HIPAA and Administrative Simplification web page: *https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification/hipaa.*

uncontrollable circumstances that caused their CEHRT to be unavailable.

- The ACO providers or suppliers were located in an area affected by extreme and uncontrollable circumstances as identified by CMS.
- 50 percent or more of the ACO providers' or suppliers' outpatient encounters occurred in practice locations where they had no control over the availability of CEHRT.
- The ACO providers' or suppliers' CEHRT was decertified under the Office of the National Coordinator for Health IT (ONC) Health IT Certification Program) either during the PY, or decertified during the calendar year preceding the performance year and the ACO providers or suppliers made a good faith effort to adopt and implement another CEHRT in advance of the performance year.

We are proposing that an ACO may exclude ACO participant TINs composed entirely of ACO providers or suppliers who meet these criteria from their determination as to whether at least one ACO provider or supplier from each of its ACO participant TINs has completed the action required by the ACO CEHRT use metric and still attest that the metric is met, because ACO participant TINs comprised solely of MIPS eligible clinicians meeting the definition of ''special status'' under MIPS would be exempt from reporting MIPS Promoting interoperability and those facing circumstances that would qualify for a MIPS Promoting Interoperability hardship may be granted an exception under MIPS. We recognize providers and suppliers in Shared Savings Program ACO participant TINs would face the same challenges in these situations. We are proposing that ACOs be allowed to determine whether any of their ACO participant TINs meet the criteria without requesting an exception from CMS because those ACO providers or suppliers who are QPs in an ACO that is in an Advanced APM track are exempt from MIPS and therefore cannot request MIPS hardship exceptions. They also cannot qualify for automatic reweighting due to special status. We therefore believe it would be appropriate to allow ACOs to exclude such ACO participant TINs from the ACO's assessment of whether at least one ACO provider or supplier from each of the ACO's participant TINs met the requirement of the Shared Savings Program CEHRT use metric and still attest that the metric has been met. For example, an ACO participant whose ACO providers or suppliers have fewer than 100 patient-facing encounters in a PY may not have engaged in e-Prescribing, exchange of health information, or provider to patient exchange of health information, so the ACO can make the determination to exclude the ACO participant for the purposes of attesting to one of the proposed metrics. In another example, an ACO may not be able to ascertain whether at least one ACO provider or supplier in an ACO participant TIN comprised of hospital-based physicians who are employed at a hospital that does not participate in the ACO, have participated in an HIE. This ACO participant and its suppliers would be exempt from MIPS Promoting Interoperability reporting, so we believe it would be appropriate to recognize and account for these situations under the Shared Savings Program.

ACOs would be required to maintain documentation of excluded ACO participant TINs, including evidence that the TINs met one of the criteria for exclusion from the ACO's attestation to Shared Savings Program CEHRT use metrics, in the event of a CMS audit. ACOs that fail to maintain adequate documentation may be subject to compliance actions, as discussed in further detail in the Compliance with Shared Savings Program CEHRT Use Requirements paragraph of this proposed rule.

(4) New Public Reporting Requirements

We are proposing to sunset the requirement at § 425.308(b)(9) that ACOs must publicly report the total number of ACO participants, ACO providers/suppliers, and ACO professionals that are MIPS eligible clinicians, QPs, or Partial QPs (each as defined at § 414.1305) that earn a MIPS performance category score for the MIPS Promoting Interoperability performance category beginning with PY 2027. We propose to revise § 425.308(b)(9) by sunsetting its applicability after PY 2026. We propose to replace this reporting requirement, beginning with PY 2027, with a new requirement in proposed § 425.308(b)(11) that ACOs must publicly report which of the allowable CEHRT use activities in proposed § 425.507(c) (as proposed in this section of this proposed rule) the ACO has selected to perform to meet CEHRT use requirements for the Shared Savings Program. We believe that one important aspect of patient-centered care is patient engagement and transparency, which can be achieved by the public reporting of ACO quality and cost performance. Public reporting helps to hold ACOs accountable and may improve a beneficiary's ability to make informed health care choices as well as facilitate an ACO's ability to improve the quality and efficiency of its care.

(5) Compliance With Shared Savings Program CEHRT Use Requirements

We reserve the right to audit an ACO's compliance with the Shared Savings Program CEHRT use requirements proposed at § 425.507(c). Our audit, under § 425.314(a), could include, for example, requesting documentation from an ACO regarding its attestation to having used a Health IT Module certified to a criterion or criteria in 45 CFR 170.315 to obtain standardized data from a FHIR-based API to support collection of measure data to completely report at least one measure in the APP Plus quality measure set, as proposed at § 425.507(c)(2), for ACOs electing that option to satisfy Shared Savings Program CEHRT use requirements. As further example, an audit could also include requesting documentation from an ACO regarding any ACO participant TINs excluded for purposes of the ACO attesting to any of the CEHRT use metrics, for ACOs electing the option proposed at § 425.507(c)(3) to report one of three allowable ACO Shared Savings Program CEHRT use metrics for the purpose of meeting Shared Savings Program CEHRT use requirements. As part of an audit, CMS may also require that ACOs produce the CMS EHR Certification IDs [268] for the EHRs used by ACOs to meet ACO CEHRT use requirements. For ACOs reporting via the eCQMs or Medicare eCQMs collection types, they would be required to produce this information at the time of submission when using that collection type, but for ACOs electing one of the other two Shared Savings Program CEHRT use options, the ACO would be required to maintain documentation of CMS EHR Certification IDs from the Certified Health IT Product List (CHPL). This would mean ACOs attesting they used a Health IT Module certified to an unexpired criterion or criteria within 45 CFR 170.315 to obtain standardized data from a FHIR-based API to support collection of data for reporting at least one measure in the APP Plus measure set would need to provide, on request, the CMS EHR Certification ID for the certified technology used. Similarly, for ACOs electing to attest to one of the three proposed ACO CEHRT use metrics, ACOs would need to provide, on request, the CMS EHR Certification ID for each of its participant TINs from

[268] The Office of the National Coordinator of Technology (ONC) maintains a searchable database of Certified Electronic Health Record Technology (CEHRT) IDs at CHPL Search (*https://chpl.healthit.gov/#/search*).

which it attested at least one ACO provider or supplier utilized CEHRT to meet the requirements of the metric. ACOs are required under § 425.314(b)(1) to maintain and give CMS, DHHS, the Comptroller General, the Federal Government or their designees access to records sufficient to enable the audit, evaluation, investigation, and inspection of the ACO's compliance with program requirements. Furthermore, we propose that if ACOs fail to meet Shared Savings Program CEHRT use requirements, lack adequate documentation to demonstrate that TIN exclusions applied for an ACO's Shared Savings Program CEHRT use metric were appropriate, or fail to provide such adequate documentation upon request, we may apply compliance actions under §§ 425.216 or 425.218. Such actions could include providing a warning notice, requesting a corrective action plan from the ACO, or placing the ACO on a special monitoring plan.

(6) No Impact on Current Shared Savings Program Quality or MIPS Scoring Policies or Process

The proposed options for Shared Savings Program ACOs to meet the Shared Savings Program CEHRT use requirement will not change the existing scoring methodology for the MIPS Promoting Interoperability performance category. This means that, regardless of which of the three activities (or which option within their selected activity) ACOs choose to meet the Shared Savings Program CEHRT requirement, the MIPS Promoting Interoperability performance category reporting requirements for MIPS eligible clinicians participating in an ACO will remain unaffected. Additionally, an ACO performing any of the three the CEHRT use requirement activities will not impact an ACO's quality score for purposes of determining the quality performance standard. For example, an ACO may choose to report an eCQM to meet the Shared Savings Program's ACO CEHRT use requirement; however, the eCQM will not necessarily be included in the MIPS quality performance category score as determined under § 414.1380. If an ACO reports multiple collection types for a given measure, including eCQMs, scoring is based on the highest scoring collection type which may not be eCQMs. Therefore, reporting the eCQM to meet the CEHRT use requirement may or may not contribute to the final quality performance score. In this example, even if the eCQM submission was not included in the ACO's MIPS quality performance category score as determined under § 414.1380, the ACO's complete reporting of the measure using the eCQMs collection type would satisfy the Shared Savings Program's CEHRT use requirement. Similarly, if an ACO uses FHIR technology to completely report a measure in the APP Plus measure set and attests to having done so, for the purpose of meeting the Shared Savings Program CEHRT use requirement, the requirement will be met, regardless of whether that measure submission is used to calculate the ACO's MIPS quality performance category score under § 414.1380. By extension, in this example, an ACO's quality score for the purposes of determining shared savings as calculated under § 425.512 would be unaffected. The ACO's MIPS quality performance category score is an aggregate of the highest measure-level scores submitted by the ACO. However, submissions that do not contribute to an ACO's final MIPS quality performance category score are still eligible for purposes of meeting the Shared Savings Program CEHRT use requirement.

(7) Proposed Regulatory Changes

We are proposing the following revisions to the regulatory text at § 425.308(b):

- Revising paragraph (b)(9) to remove the introductory phrase that made the subsequent requirements applicable to performance year 2025 and subsequent performance years, and limiting them to performance years 2025 and 2026.
- Adding new paragraph (b)(11) to specify that for performance year 2027 and subsequent PYs, the ACO must publicly report the CEHRT use activity selected by the ACO for the purpose of meeting the ACO CEHRT use requirement at § 425.507(c).

We are proposing the following revisions to the regulation text at § 425.507:

- Revising paragraph (a) to remove the introductory phrase that made the paragraph applicable to performance years beginning on or after January 1, 2025 and adding in its place an introductory phrase that would limit its applicability to performance years 2025 and 2026.
- Revising paragraph (b) by adding an introductory phrase that would limit its applicability to performance years 2025 and 2026.
- Adding new paragraph (c) to specify that, for PYs beginning on or after January 1, 2027, an ACO would be required to demonstrate the use of CEHRT as defined at § 425.20 in one of the following manners—

++ Use CEHRT (as defined in paragraph (3) of the CEHRT definition at § 414.1305) that also supports the calculation and reporting of clinical quality measures by being certified to the ONC health IT certification criteria at 45 CFR 170.315(c)(2) and (c)(3) to completely report at least one of the measures in the APP Plus quality measure set using the eCQMs or Medicare eCQMs collection types and meets the data completeness requirement at § 414.1340 of this chapter for the applicable PY; or

++ Completely report at least one measure in the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this chapter for the applicable performance year using EHR technology that meets paragraph (3) of the CEHRT definition at § 414.1305 and attests that it used data collected from an HL7® Fast Healthcare Interoperable Resources (FHIR®)-based API to support quality measurement using a Health IT module (as defined in 45 CFR 170.102) that has been certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access.

++ Attest to at least one of the Shared Savings Program CEHRT use metrics from the list of metrics established for the applicable PY.

We are requesting public comment on these proposed changes to the policy at §§ 425.308(b) and 425.507.

c. Request for Information on Applying Electronic Prior Authorization Measures to Shared Savings Program ACOs

In section IV.A.4.d.(4) of this proposed rule, we include proposals on the use of electronic prior authorization measures in the MIPS Promoting Interoperability performance category. Specifically, in that section of this proposed rule, for the MIPS Promoting Interoperability performance category, we are proposing to (1) change the Electronic Prior Authorization measure from a required measure to a bonus measure for the CY 2027 performance period/2029 MIPS payment year and a required measure beginning with the CY 2028 performance period/2030 MIPS payment year and (2) require a new measure, Electronic Prior Authorization for Prescription Drugs, that requires requesting prior authorization for at least one prescription drug electronically using CEHRT. This measure would be required for the MIPS Promoting Interoperability performance category beginning with the CY 2028 performance period/2030 MIPS payment year.

We are seeking feedback on the use of electronic prior authorization by ACOs that participate in the Shared Savings Program. Specifically, we are seeking comment on the following:

• Requiring the use of specific FHIR-enabled Health IT Modules within CEHRT to complete at least one prior authorization request and determination for at least one medical item or service during the performance period or allowing it to be an option for meeting Shared Savings Program CEHRT use requirements beginning with the CY 2028 performance year.

• Creating a new, ACO-specific electronic prior authorization measure to require use of specific FHIR-enabled health IT modules within CEHRT to complete at least one prior authorization request and determination for at least one prescription drug during the performance period, beginning with the CY 2028 performance year.

• Considerations CMS should take into account, in developing electronic prior authorization measures to apply to Shared Savings Program ACOs.

5. Financial Methodology

a. Overview

As explained in greater detail below and in the regulatory impact section, the Shared Savings Program has demonstrated a strong track record of generating savings for Medicare while achieving high quality care for beneficiaries assigned to ACOs. For example, the Shared Savings Program has had eight consecutive years of generating savings for Medicare relative to benchmarks, with over $12 billion in total savings and a trend of increasing savings year-over-year between 2017 and 2024. As described in the CY 2026 PFS final rule Regulatory Impact Analysis (90 FR 49975 through 49976) and in the regulatory impact section of this rule, the Shared Savings Program has maintained a net savings percentage on total FFS spending of 0.5 percent. At the same time, ACOs in the Shared Savings Program have demonstrated higher quality relative to other physician groups, indicating that the Shared Savings Program is achieving savings while improving quality of care. For example, in PY 2024, Shared Savings Program ACOs helped more patients improve markers of good health, such as controlled blood pressure, hemoglobin A1c control (an indicator for diabetes), and depression screening with a follow-up plan, compared to 2023.[269] In PY 2024, nearly all ACOs outperformed similar types of physician groups on quality measures. As described in further detail later in this proposed rule, based on an internal CMS analysis of 87 ACOs that participated continuously in the Shared Savings Program between 2014 and 2023, Shared Savings Program ACOs showed statistically significant and substantial improvement across 7 comparable CMS Web Interface quality measures used during that period where quality performance improved across a wide range of clinical practice areas including screening and preventive measures, control of health conditions such as hypertension and diabetes. ACOs have performed consistently better than comparable physician groups on the patient experience survey measure, Getting Timely Care, Appointments, and Information, for every year that the survey has been fielded since 2019.

Based on the experience of the Shared Savings Program and as part of our effort to align spending and value in OM, we are focused on developing policies that would grow the number of health care providers and beneficiaries in accountable care relationships and grow savings to the Medicare Trust Funds while improving the quality of care for beneficiaries. To achieve these goals, in this section of the proposed rule, we are proposing several complementary modifications to the benchmarking and financial methodology under the Shared Savings Program to encourage new and sustained participation by ACOs in the program. Specifically, we are proposing to: (1) increase the sharing rate under BASIC track Level E (section III.G.5.c.(1) of this proposed rule), (2) reduce the weight on the regional adjustment for ACOs in the ENHANCED track (section III.G.5.c.(2) of this proposed rule), (3) modify the prior savings adjustment to increase the scaling factor (section III.G.5.d. of this proposed rule), (4) risk adjust the 5 percent cap on upward adjustments to the historical benchmark (section III.G.5.e. of this proposed rule), (5) incentivize new participation through a growth adjustment (section III.G.5.f of this proposed rule), and (6) reform the Accountable Care Prospective Trend (ACPT) component of the benchmark update factor to address projection error and allow for greater consistency in the calculations across agreement periods (section III.G.5.g. of this proposed rule).

Across the financial methodology proposals described in sections III.G.5.c.(1) (proposal to increase the sharing rate under BASIC track Level E), III.G.5.c.(2) (proposal to reduce the weight on the regional adjustment for ENHANCED track ACOs), and III.G.5.d (proposal to modify the prior savings adjustment scaling factor), we describe our observations of recurring patterns, that ENHANCED track ACOs receive larger positive regional adjustments than BASIC track ACOs, which inflate benchmarks and increases the probability of generating gross savings independent of operational efficiencies. At the same time, as discussed in section III.G.5.c.(1), BASIC track Level E ACOs generate higher net savings for the Trust Funds despite lower gross savings, as the 75 percent shared savings rate under the ENHANCED track requires disproportionately higher gross savings to achieve equivalent net outcomes for the Trust Funds. Combined analyses described in sections III.G.5.c.(2) and III.G.5.d further show that the interaction of regional adjustment weighting, prior savings scaling, and track-specific sharing rates may incentivize ACOs to progress into the ENHANCED track based on benchmark generosity rather than demonstrated capacity to reduce expenditures. Together, these overlapping findings support the proposed recalibration of incentives reflected in our proposals discussed in these sections—namely increasing the BASIC track Level E sharing rate, lowering the positive regional adjustment weight applied to ENHANCED track ACOs, and strengthening the prior savings adjustment methodology—to better align benchmark dynamics with underlying efficiency, reduce distortions driven by regional cost variation, and reinforce long-term net savings objectives for the Shared Savings Program.

b. Summary of Statutory and Regulatory Background on Adjusting the Historical Benchmark

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established, updated, and reset at the start of each agreement period under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for OM beneficiaries assigned to the ACO. The benchmark shall be reset at the start of each agreement period. Section 1899(d)(1)(B)(ii) of the Act also provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Under this authority, over time we have adopted a variety of methods to adjust the historical benchmark to meet certain policy goals.

[269] Medicare Shared Savings Program Performance Year 2024 Financial and Quality Results Fact Sheet, *https://www.cms.gov/files/document/fact-sheet-ssp-py24-financial-quality-results.pdf.*

Benchmarking policies applicable to all ACOs in agreement periods beginning on January 1, 2024, and in subsequent years, are specified at § 425.652. We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (see November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991; December 2018 final rule, 83 FR 68005 through 68030; CY 2023 PFS final rule, 87 FR 69875 through 69928; CY 2024 PFS final rule, 88 FR 79174 through 79208; CY 2025 PFS final rule, 89 FR 98155 through 98203; and CY 2026 PFS final rule, 90 FR 49831 through 49835).

In the CY 2023 PFS final rule, we adopted policies to modify the regional adjustment under § 425.656 (87 FR 69915 through 69923) and to reinstate a prior savings adjustment under § 425.658 (87 FR 69898 through 69915). The modifications to the regional adjustment were designed to limit the impact of negative regional adjustments on ACO historical benchmarks and further incentivize program participation among ACOs serving high-cost beneficiaries (87 FR 69916). We also reinstated the prior savings adjustment policy, such that a renewing or re-entering ACO may be eligible to receive an adjustment to its benchmark to account for savings generated in performance years that correspond to the benchmark years of its new agreement period (87 FR 69898 through 69915).

In the CY 2024 PFS final rule (88 FR 79185 through 79196), we modified the regional adjustment policy further to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment. We modified the prior savings adjustment policy further to account for the following: a change in savings earned by the ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries or a change in the amount of savings or losses for a benchmark year as a result of a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315 (88 FR 79196 through 79200).

In the CY 2025 PFS final rule (89 FR 98155 through 98167), we finalized a health equity benchmark adjustment (HEBA) (revised to the ''population adjustment'' in the CY 2026 PFS final rule (90 FR 49831 through 49835)) that adjusts upward some ACOs' historical benchmarks based on the number of beneficiaries the ACO serves who are dually eligible or enrolled in the Medicare Part D and receive the Low-Income Subsidy (LIS).

c. Proposed Changes to the Shared Savings Program Financial Methodology To Encourage Additional Savings in Two-Sided Risk

(1) Proposal To Increase the Sharing Rate Under Level E of the BASIC Track

(a) Background

As finalized in the December 2018 final rule (83 FR 67831 through 67841), for agreement periods beginning on July 1, 2019, and in subsequent years, eligible ACOs enter into an agreement period of not less than 5 years under one of two tracks of the Shared Savings Program, either the BASIC track (see §§ 425.600(a)(4) and 425.605) or the ENHANCED track (see §§ 425.600(a)(3) and 425.610).

As finalized in the December 2018 final rule (83 FR 67841 through 67857), the BASIC track includes a glide path from one-sided model Levels A and B to incrementally higher levels of performance-based risk under Levels C, D, and E. The ENHANCED track offers the highest level of risk and potential reward under the Shared Savings Program. Level E of the BASIC track and the ENHANCED track each qualify as an Advanced APM under the Quality Payment Program. In rulemaking following the December 2018 final rule, we modified the approach for determining an ACO's eligibility for participation options in the BASIC track and ENHANCED track, along with the number of performance years an ACO may remain under a one-sided model of the BASIC track's glide path.[270] In the following discussion, we provide select regulatory background on our establishment of the BASIC track's glide path, and relatedly the level of risk and potential reward under the glide path, as well as our considerations for ACOs' progression from participation in BASIC track Level E to the ENHANCED track.

With the December 2018 final rule (83 FR 67863 through 67922), we established an approach for determining an ACO's eligibility for participation options in the BASIC track and ENHANCED track, based on a combination of factors: ACO participants' Medicare FFS revenue (low revenue ACOs versus high revenue ACOs) and the experience of the ACO legal entity and its ACO participants with performance-based risk Medicare ACO initiatives. We finalized an approach under § 425.600(d) where ACOs eligible for the BASIC track's glide path that are inexperienced with performance-based risk Medicare ACO initiatives would have the flexibility to enter the glide path at any one of the five levels, with a limited exception under § 425.600(a)(4)(i)(B)(*1*) (see, for example, 83 FR 67904 through 67905). With the December 2018 final rule, we finalized provisions on the progression of ACOs along the BASIC track's glide path under § 425.600(a)(4)(i)(B), and finalized an approach to allow ACOs in the BASIC track's glide path to take on higher risk and potential reward within their current agreement period by more rapidly progressing along the glide path (see 83 FR 67844, and 67858 through 67859; and § 425.226(a)(2)). We also finalized that the BASIC track's highest Level of risk and potential reward (Level E) may be elected for any performance year by ACOs that enter the BASIC track's glide path, but it will be required no later than the ACO's fifth performance year of the glide path (83 FR 67844; 67850).[271]

To provide incentives for ACOs to move towards higher levels of performance-based risk, we limited the amount of potential shared savings under the one-sided model of the BASIC track (Levels A and B), while offering higher potential reward in relation to each level of higher risk as ACOs under the two-sided model levels of the BASIC track (Levels C, D and E) (see, for example, 83 FR 67848 and 67849). We explained in the December 2018 final rule that ACOs have reduced incentives to enter or remain in a one-sided model of the BASIC track's glide path if they are prepared to take on risk, and we anticipated that ACOs would seek to accept greater performance-based risk in exchange for the chance to earn greater reward (see 83 FR 67844).

In the December 2018 final rule, we stated that the approach to determining the maximum amount of shared losses under BASIC track Level E strikes a

[270] We refer readers to discussions in earlier rulemaking, including: December 2018 final rule (83 FR 67863 through 67922); May 8, 2020 COVID–19 IFC (85 FR 27575 and 27576) and CY 2021 PFS final rule (85 FR 84767 through 84769); Fiscal Year (FY) 2022 Medicare Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital (LTCH) Prospective Payment System (PPS) final rule (86 FR 45502 through 45506); CY 2023 PFS final rule (87 FR 69805 through 69821); and CY 2026 PFS final rule (90 FR 49760 through 49775).

[271] In in the December 2018 Final Rule (83 FR 67844 through 67846) we also described advancing to Level E would be required for ACOs in their fourth performance year if they previously participated in Track 1, or new ACOs identified as re-entering ACOs because more than 50 percent of their ACO participants have recent prior experience in a Track 1 ACO.

balance between (1) placing ACOs under a higher Level of risk to recognize the greater potential reward under this financial model and the additional tools and flexibilities available to BASIC track ACOs under performance-based risk and (2) establishing an approach to help ensure the maximum Level of risk under the BASIC track remains moderate (83 FR 67845). Further, this approach recognizes that eligible ACOs in Level E have the opportunity to earn the greatest share of savings under the BASIC track, and should therefore be accountable for a higher share of losses, particularly in light of their access to tools for care coordination and beneficiary engagement. We finalized higher maximum sharing rates for ACOs participating in two-sided levels of the BASIC track as a means of encouraging participation in the program and potentially providing greater resources to ACOs to support their transition to performance-based risk (87 FR 69951).

In the CY 2023 PFS final rule (87 FR 69819 through 69821), we removed the cap on the number of performance years an ACO was allowed to participate in BASIC track Level E, allowing ACOs to continue to participate in BASIC track Level E in future agreement periods and not requiring ACOs to advance to the ENHANCED track. We explained that, in our implementation of the Shared Savings Program, we intend to achieve larger programmatic goals by encouraging ACO participation and thereby promoting high quality, value-based care for OM beneficiaries (87 FR 69819). We continuously seek to balance creating sufficient incentives for participation in a voluntary program with ensuring that our policies achieve program goals to increase quality of care for Medicare beneficiaries and reduce expenditure growth to protect the Trust Funds. Accordingly, we discussed our belief that it would be in the best interest of the program and OM beneficiaries to permit eligible ACOs to continue participating under BASIC track Level E, rather than risk significant numbers of experienced, successful ACOs terminating their participation in the program instead of progressing to the higher level of risk and potential reward under the ENHANCED track (87 FR 69819). Our experience as of the CY 2023 PFS final rule showed that ACOs in BASIC track Level E and ACOs in the ENHANCED track had similar performance results (we have since gained additional experience as discussed later in this section, that shows ACOs in BASIC track Level E produce greater net savings for CMS compared to ACOs in the ENHANCED track). We noted our belief that it is important to offer the option to remain in BASIC track Level E, to encourage ACOs that may be ready to take on the higher level of risk and potential reward under the ENHANCED track to progress to that participation option, secure in the knowledge that the more moderate level of risk and potential reward under BASIC track Level E would be available to the ACO in the future if the ACO concludes based on experience that that participation option is more appropriate for the ACO than the ENHANCED track (87 FR 69819).

We refer readers to the provisions of BASIC track under § 425.605, and the ENHANCED track under § 425.610, for policies on the calculation of shared savings and losses under each track/level (as applicable). With the CY 2026 PFS final rule (90 FR 49782 through 49783), we provided a summary of the level of risk and potential reward under Levels A through E of the BASIC track and ENHANCED track. In the following discussion we provide a consolidated summary.

In general, an ACO that meets or exceeds its minimum savings rate (MSR), and otherwise qualifies for a shared savings payment, shares in savings at a sharing rate specified by the ACO's participation track (and level, if applicable), not to exceed a performance payment limit (a percentage of the ACO's updated historical benchmark).[272] [273] An ACO under a two-sided model that meets or exceeds its minimum loss rate (MLR) shares in losses at a shared loss rate[274] specified by the ACO's participation track (and level, if applicable), not to exceed a loss recoupment limit (a percentage of the ACO's updated historical benchmark).

Under Levels A and B of the BASIC track (§ 425.605(d)(1)(i) and (ii)), ACOs may share in savings at a sharing rate of up to 40 percent, not to exceed 10 percent of the updated benchmark. Levels C, D, and E of the BASIC track (§ 425.605(d)(1)(iii), (iv) and (v)) each offer a sharing rate of up to 50 percent capped at 10 percent of the updated benchmark, with a fixed 30 percent loss sharing rate in each level's two-sided model. The loss recoupment limits increase across these levels. Under Level C (§ 425.605(d)(1)(iii)(D)), an ACO's shared losses may not exceed 2 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 1 percent of updated benchmark. Under Level D (§ 425.605(d)(1)(iv)(D)), an ACO's shared losses may not exceed 4 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 2 percent of updated benchmark. Under Level E (§ 425.605(d)(1)(v)(D)), an ACO's shared losses may not exceed 8 percent of total Medicare Parts A and B FFS revenue of the ACO participants in the ACO capped at 4 percent of updated benchmark. Under Level E, the loss recoupment limit is the percentage of revenue specified in the revenue-based nominal amount standard under the Quality Payment Program (QPP) (42 CFR 414.1415(c)(3)(i)(A)) capped at 1 percentage point higher than the expenditure-based nominal risk amount (§ 414.1415(c)(3)(i)(B)). Under the ENHANCED track (§ 425.610), ACOs may share in savings at up to 75 percent (§ 425.610(d)), not to exceed 20 percent of the updated benchmark (§ 425.610(e)), and share in losses at a rate of 40 to 75 percent (§ 425.610(f)), capped at 15 percent of the updated benchmark (§ 425.610(g)). Since the establishment of the ENHANCED track (formerly named Track 3) with the June 2015 final rule (see 80 FR 32778 through 32779), and the BASIC track's glide path with the December 2018 final rule (as previously described in this section), we have not modified the maximum upside potential reward with the final sharing rates or downside potential risk with the loss sharing rates under each track/level (as applicable).

(b) Proposed Revisions

In 2020, the first full performance year under the glide path, 13.5 percent of ACOs in the Medicare Shared Savings Program participated under BASIC track Level E. As ACOs became more experienced and progressed through the glide path, participation in BASIC track Level E experienced modest increases, which peaked in PY 2023 at 27.2 percent. As of PY 2026, participation in BASIC track Level E has decreased to 16 percent.

The disparity in sharing rates between the highest risk option under the BASIC track (BASIC track Level E) and the next highest risk option (ENHANCED track) has potentially disproportionately driven ACOs to take on the maximum risk allowed. For PY 2026, 58 percent of ACOs are participating in the

[272] We note that provisions of §§ 425.605(d)(1) and 425.610(d) refer to the applicable ''final sharing rate'', which we sometimes refer to as the ''sharing rate'' (for brevity), or alternatively the ''shared savings rate''. We consider these terms synonymous.

[273] There is a limited exception for eligible low revenue ACOs participating under the BASIC track, under which an ACO that does not meet the MSR requirement but meets other criteria may qualify for a shared savings payment, at a lower sharing rate, in accordance with § 425.605(h).

[274] We note that the ''shared loss rate'' is also referred to as the ''loss sharing rate''.

ENHANCED track. This in part is likely a result of the 40 percent sharing rate in Levels A and B of the BASIC track and 50 percent sharing rate in Levels C, D, and E of the BASIC track, compared to the 75 percent sharing rate in the ENHANCED track. Based on current participation trends across the various risk tracks, we anticipate that the participation in BASIC track Level E may continue a downward trend as a percentage of total participation unless some action is taken. We believe that some ACOs cease longer term program participation in BASIC track Level E before they otherwise would because they transition to the ENHANCED track based on the incentives of the higher sharing rate, and this transition occurs before they're ready for the increased demands associated with the higher risk track. Decreased Shared Savings Program retention rates of ACOs that transition too quickly to the ENHANCED track, in combination with the decreased net savings rates associated with the ENHANCED track, ultimately result in decreased savings for the Medicare Trust Fund. Table B–G8 summarizes the distribution of ACO participation across the various risk tracks for PY 2022 through CY 2026.

TABLE B-G8: COUNT OF ACOS PARTICIPATING IN BASIC TRACK LEVELS AND ENHANCED TRACK FOR PYS 2022 THROUGH 2026

Performance Year	Total	BASIC Track			ENHANCED Track
		Levels A and B	Levels C and D	Level E	
PY 2022	483	199 (41%)	40 (8%)	98 (21%)	146 (30%)
PY 2023	456	151 (33%)	19 (4%)	125 (28%)	161 (35%)
PY 2024	480	159 (33%)	10 (2%)	104 (22%)	207 (43%)
PY 2025	476	137 (29%)	5 (1%)	81 (17%)	253 (53%)
PY 2026	511	121 (24%)	12 (2%)	82 (16%)	296 (58%)

While we still have the goal of ACOs transitioning to performance-based risk, we want to be conscious of long-term impacts to the Shared Savings Program related to participation, success, and growth. Participation in the ENHANCED track is a positive, but we believe that some ACOs may be taking on additional risk more quickly than they otherwise would because the ENHANCED track offers a 50 percent increase in savings compared to BASIC track Level E, while both tracks include two-sided risk. If ACOs progress to higher levels of risk before they are adequately prepared, they may take on too much risk with higher shared losses rates in the ENHANCED track, potentially resulting in program termination and a subsequent reduction in both program participation and care coordination for beneficiaries. We believe by reducing the savings percentage gap between BASIC track Level E and the ENHANCED track, we may increase participation in BASIC track Level E as well as the Shared Savings Program and increase long-term success of ACOs, particularly those with less experience, with unique patient or provider populations, and low revenue ACOs (which tend to be small, rural and physician-only ACOs).

Additionally, data analysis from the CMS Office of the Actuary of benchmark performance for cohorts of ACOs that participated in both PY 2022 and PY 2023 indicates that ACOs participating in the BASIC track generated 42 percent higher net savings for CMS as a percentage of their benchmark than ACOs transitioning to or continuing participation in the ENHANCED track, despite favorable regional adjustments likely inflating gross savings for ACOs under the ENHANCED track. Analysis of PY 2024 financial performance also indicates net savings for the Trust Funds has remained higher on average for BASIC track ACOs. This also is largely due to the 50 percent differential in sharing rate currently present between BASIC track Level E and the ENHANCED track, which results in ENHANCED track ACOs needing to generate twice the gross savings to equal the same net savings for the Trust Funds as ACOs participating under BASIC track Level E. For example, if an ACO participated in BASIC track Level E and generated $2,000,000 in gross savings, and the ACO received the maximum sharing rate of 50 percent, the ACO would receive a $1,000,000 shared savings payment and net savings for the Trust Funds would be $1,000,000. If this same ACO participated in the ENHANCED track and generated $2,000,000 in gross savings, and the ACO received the maximum sharing rate of 75 percent, the ACO would receive a $1,500,000 shared savings payment and net savings for the Trust Funds would be $500,000. So, to generate the same net savings for the Trust Funds, the ENHANCED track ACO would need to have generated twice the gross savings, $4,000,000, to have generated $1,000,000 ($4,000,000 x 25 percent) net savings for the Trust Funds. For PY 2024, gross savings was higher for the ENHANCED track ACOs, but net savings as a percentage of gross savings and per capita net savings are higher for ACOs participating in BASIC track Level E, as shown in Table B–G9.

TABLE B-G9: PY 2024 GROSS AND NET SAVINGS FOR BASIC TRACK LEVEL E AND ENHANCED TRACK

Risk Track	Aggregate Gross Savings/Losses	Aggregate Net Savings/Losses	Per Capita Net Savings/Losses	Net Savings as a percent of Gross Savings
BASIC Track Level E	$1,114,104,073	$555,399,727	$286	50%
ENHANCED Track	$4,224,728,667	$1,129,061,411	$206	27%

As we seek to increase the percentage of Medicare beneficiaries in accountable care arrangements, we are balancing incentives and participation options to serve the dual purposes of sustaining participation by existing ACOs and increasing program growth, recognizing that ACOs vary in their composition of providers/suppliers, the needs of the populations they serve, and have varying degrees of efficiency relative to their region and experience with accountable care initiatives. We also reiterate our intention to achieve larger programmatic goals by encouraging ACO participation and thereby promoting high quality, value-based care for OM beneficiaries. We continuously seek to balance creating sufficient incentives for participation in a voluntary program while ensuring that our policies achieve program goals to increase quality of care for Medicare beneficiaries and reduce expenditure growth to protect the Trust Funds.

Trends in recent performance years indicate ACOs participating in BASIC track Level E have roughly one-third fewer assigned beneficiaries and participating providers than ACOs participating in the ENHANCED track. Understanding that ACOs participating in BASIC track Level E face additional obstacles to success given their different compositions and experience, we believe that narrowing the gap in sharing rates between these two tracks will encourage long-term participation and growth in the Shared Savings Program by encouraging less experienced ACOs to only progress to the ENHANCED track when they're adequately prepared to do so.

Increasing the sharing rate for BASIC track Level E presents an opportunity to reverse the decreased participation in the BASIC track, increase net savings opportunities for the Trust Funds, and increase program participation. However, before considering whether to propose changes, we analyzed what change to the sharing rate was needed to ensure our goals were met without unintended consequences.

As we did when we established the BASIC track in the December 2018 final rule, we considered many sharing rates before arriving at our proposal. With the current sharing rate for BASIC track Level E set at 50 percent and ENHANCED track set at 75 percent, we analyzed alternative sharing rates for BASIC track Level E between 55 percent and 65 percent.

For the 104 ACOs entering an agreement period beginning on January 1, 2024 that participated in BASIC track Level E, we found that if all else is equal, the increase in shared savings payments under the alternative sharing rates we considered for BASIC track Level E ranged between 9.1 percent and 22.8 percent. After considering other policy changes proposed elsewhere in section III.G.5. of this proposed rule, such as the proposal to reduce the weight on regional adjustment for ACOs under the ENHANCED track and the proposal to modify the prior savings adjustment to increase the scaling factor, we determined a 65 percent sharing rate was too high to maintain a sufficient gap in incentives between the two tracks and a 55 percent sharing rate was an inadequate incentive to achieve our goals of increasing participation in the program and increasing savings to the Trust Funds.

We believe that increasing the sharing rate to 60 percent for BASIC track Level E appropriately balances creating sufficient incentive to increase program participation and savings to the Trust Funds. We believe that there would still be sufficient benefits for ACOs to take on the higher risk and reward offered under the ENHANCED track, so that ACOs would continue to progress the ENHANCED track when they're ready to take on those higher levels of risk and reward.

We are proposing to increase the savings rate for BASIC track Level E from 50 percent to 60 percent for agreement periods beginning on or after January 1, 2027. The proposal to apply a modified sharing rate for agreement periods beginning on or after January 1, 2027 would ensure we maintain a consistent sharing rate for Level E throughout the duration of an ACO's an agreement period under the BASIC track, in accordance with § 425.212(a).[275] Closing the gap in the sharing rates between BASIC track Level E and the ENHANCED track would likely increase savings for the Trust Funds, while striking a better balance among incentivizing robust participation in the Shared Savings Program, incentivizing ACOs' move to two-sided risk, and offering a lower risk option than is offered under the ENHANCED track.

Analysis of the PY 2024 financial results indicates the average impact of increasing the sharing rate for BASIC track Level E from 50 percent to 60 percent was an increase in shared savings payments of $1,348,867 and a total increase of $110,607,059 in shared savings payments for the 104 ACOs that participated in BASIC track Level E. While the total shared savings payments for BASIC track Level E would increase under this proposal, we anticipate net savings to the Trust Funds to increase because of increased participation in the Shared Savings Program, higher retention of ACOs, and some ACOs opting to delay transition into the ENHANCED track.

Under our proposed approach, the current maximum 50 percent sharing rate under BASIC track Level E specified in § 425.605(d)(1)(v)(A)(*4*) (which is applicable for PYs beginning on or after January 1, 2024) would continue to apply to ACOs completing existing agreement periods in the BASIC track. Specifically, the maximum 50 percent sharing rate would apply in determining financial performance for a BASIC track ACO participating in an agreement period beginning on January 1, 2022, 2023, 2024, 2025, and 2026, that is participating in Level E for PY 2025 or any subsequent PY of the ACO's existing agreement period.

We propose to specify in a new paragraph (d)(1)(v)(A)(*5*) added to

[275] In accordance with § 425.212(a), an ACO is subject to all regulatory changes that become effective during the agreement period, with the exception of the following program areas, unless required by statute: (1) eligibility requirements concerning the structure and governance of ACOs, and (2) calculation of the sharing rate.

§ 425.605 the sharing rate for BASIC track Level E, applicable for agreement periods beginning on or after January 1, 2027, for performance years beginning on or after January 1, 2027. Accordingly, this new paragraph would specify that an ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in § 425.605(d)(1)(v)(B)). Except as provided in § 425.605(h) (which specifies an additional opportunity for an eligible low revenue BASIC track ACO to share in savings even if it does not meet the MSR requirement), the percentage would be as follows:

(1) 60 percent for an ACO that that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(2) 60 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

We also propose technical and conforming changes to other provisions of § 425.605. We propose to revise the heading text in the first sentence of § 425.605(d)(1)(v)(A)(*4*) introductory text, to specify the provisions are applicable for ACOs in agreement periods beginning July 1, 2019, through January 1, 2026, for performance years beginning on or after January 1, 2024. For completeness and clarity, this proposed heading text would be inclusive of ACOs participating in agreement periods beginning on July 1, 2019 and January 1, 2020, which were previously reconciled for participation in BASIC track Level E for the performance year beginning on January 1, 2024. We note that agreement periods of 5 years and 6 months beginning on July 1, 2019, and 5-year agreement periods beginning on January 1, 2020, concluded on December 31, 2024. As we explained previously in this section of this proposed rule, the final sharing rate provisions specified under § 425.605(d)(1)(v)(A)(*4*) would continue to apply to ACOs participating in agreement periods beginning on January 1, 2022, 2023, 2024, 2025 and January 1, 2026, that would be reconciled for participation in BASIC track Level E for PY 2025 and any remaining PY of their agreement period. We also propose to amend § 425.605(h)(2), describing calculation of the sharing rate applied to a low revenue BASIC track ACO eligible for the expanded opportunity to share in savings if it does not meet the MSR, to revise the existing list of cross-references to include a reference to new paragraph § 425.605(d)(1)(v)(A)(*5*).

We also propose several technical corrections to the regulations in § 425.605. With the CY 2026 PFS final rule (see 90 FR 49816 through 49817, and 50018), we finalized amendments to phrasing in § 425.605, including in paragraphs (d)(1)(v)(A)(*3*)(*ii*) and (d)(1)(v)(A)(*4*)(*ii*) (describing the sharing rate applied under BASIC track Level E, by PY, for an ACO that meets the alternative quality performance standard). There were technical errors in the implementation of these finalized changes in the Code of Federal Regulations (CFR). We propose the following technical corrections:

- To revise § 425.605(d)(1)(v)(A)(*3*)(*ii*) to read, 50 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).
- To revise § 425.605(d)(1)(v)(A)(*4*)(*ii*) to read, 50 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

We seek comment on the proposal to increase the sharing rate under BASIC track Level E from 50 percent to 60 percent, applicable for ACOs in agreement periods beginning on or after January 1, 2027, for performance years beginning on or after January 1, 2027, and the proposal to specify related provisions in the Shared Savings Program regulations under new § 425.605(d)(1)(v)(A)(*5*), as well as proposed technical and conforming changes to § 425.605(d)(1)(v)(A)(*4*) introductory text and § 425.605(h)(2). We also seek comment on our proposed technical corrections to § 425.605(d)(1)(v)(A)(*3*)(*ii*) and (d)(1)(v)(A)(*4*)(*ii*).

(2) Proposal To Reduce the Maximum Weight on the Regional Adjustment for ACOs Under the ENHANCED Track

(a) Background

In the June 2016 final rule (81 FR 37962 through 37974), we introduced a regional adjustment to ACOs' historical benchmarks to increase participation in the Shared Savings Program and recognize efficiency of providers/suppliers in their regional service area. To implement the regional adjustment, we also established a methodology for defining regional Medicare spending. We defined an ACO's ''regional service area'' at § 425.20 as the counties in which its assigned beneficiaries reside and calculated regional costs using county-Level Medicare fee-for-service expenditures for assignable beneficiaries in those counties (81 FR 37958). These county expenditures were then aggregated to estimate average per-capita spending in the ACO's region, which served as the basis for the regional adjustment applied when benchmarks were rebased (81 FR 37957 and 37958).

In the June 2016 final rule (81 FR 37954 through 37991), we finalized a Shared Savings Program benchmark rebasing methodology to include a regional adjustment to the historical benchmark. More specifically, we finalized that the regional adjustment would be calculated as a percentage of the difference between risk-adjusted average per capita expenditures in the ACO's regional service area and the ACO's rebased historical expenditures (81 FR 37966). We finalized that the regional adjustment would be applied for second or subsequent agreement periods, while benchmarks for an ACO's first agreement period would continue to be based solely on the ACO's historical spending and were not adjusted for regional expenditures (81 FR 37973).

To provide time for ACOs to anticipate and adapt to the regional adjustment being applied to historical benchmarks, we implemented a phased approach that gradually increased the weight applied to regional spending. The first time an ACO's benchmark was rebased using the regional adjustment, we applied 35 percent of the difference between regional spending and the ACO's rebased historical benchmark if the ACO's spending was below the regional average, and 25 percent if the ACO's spending was above the regional average. The second time the benchmark was rebased, CMS increased the weight to 70 percent for ACOs with spending below their regional average and 50 percent for those with spending above the regional average. Beginning with the third rebasing and in subsequent agreement periods, the adjustment was set at 70 percent of the difference between regional and ACO spending for all ACOs, unless CMS established a different weight through future rulemaking (81 FR 37971 through 37973).

In the 2016 final rule, we also finalized that if we adjust an ACO's benchmark during the term of the agreement period due to changes in participating providers/suppliers, the agency would reassess whether the ACO's spending was above or below the regional average to determine the

appropriate adjustment percentage (81 FR 37964). Together, these provisions increased the role of regional spending in benchmark calculations while providing a transition period intended to limit abrupt benchmark reductions for higher-spending ACOs.

In the December 2018 final rule (83 FR 68018), we revised the methodology to address concerns that the 2016 regional adjustment could inadvertently inflate benchmarks for low-spending ACOs while discouraging participation by high-spending ACOs relative to their region. Under the revised rule, we also applied the regional adjustment starting with the first agreement period. By design, the regional adjustment results in more generous benchmarks for ACOs that spend below their regions. In the December 2018 final rule (83 FR 68018), we noted that our initial experience with the regional adjustment found that 80 percent of ACOs that renewed for a second agreement period starting in 2017 received a positive adjustment. These ACOs saw their benchmarks increase by 1.8 percent, on average, when the adjustment was applied with the 35 percent weight, with several ACOs seeing increases of over 5 percent, and one over 7 percent. We also noted that for ACOs that renewed for a second agreement period starting in 2018, they showed a similar share of ACOs receiving a positive adjustment and one ACO seeing an adjustment of over 10 percent. We noted our concern that as the weight applied to the regional adjustment increases, benchmarks for the ACOs with the lowest spending relative to their region would become overly inflated to the point where they would need to do little to change their care practices to generate savings, which could reduce incentives for these ACOs to improve the efficiency of care provided to beneficiaries. To limit the influence of regional cost disparities, we reduced the maximum weight that could be applied to the regional adjustment in any agreement period from 70 percent to 50 percent. Additionally, we capped the total dollar impact of the regional adjustment at ±5 percent of national OM per capita expenditures for each beneficiary category (83 FR 68017 through 68024, and 42 CFR 425.603).

In the CY 2023 PFS final rule (87 FR 69915 through 69923), we finalized additional policies to modify the regional adjustment to further support participation by high-cost or high-risk ACOs. We implemented a set of policies designed to mitigate the impact of negative regional adjustments on ACOs' benchmarks. First, we reduced the maximum negative adjustment from −5 percent to −1.5 percent of national OM per capita expenditures for Parts A and B services (based on benchmark year 3 for assignable beneficiaries). Second, we established an approach that gradually decreased the size of the negative regional adjustment for ACOs that have a higher proportion of dually eligible Medicare and Medicaid beneficiaries or a higher weighted-average prospective Hierarchical Condition Category (HCC) risk score (87 FR 69923). In the CY 2023 PFS final rule (87 FR 69919), we expressed our belief that by reducing the impact of negative regional adjustments, these policies would incentivize ACOs that serve high-cost beneficiaries to join or continue to participate in the Shared Savings Program.

Most recently, in the CY 2024 PFS final rule (88 FR 79185 through 79196), we modified the regional adjustment policy further to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment.

As part of CMS's effort to align spending and value in OM, we are focused on developing policies that would accelerate accountable care service delivery across a spectrum of risk-bearing options. To achieve this vision, our proposed change to the regional adjustment is informed by strategic objectives focused on strengthening financial incentives for ACOs to participate in the Shared Savings Program and driving savings for ACOs and the Trust Funds.

(b) Proposed Revisions

For the reasons discussed in this section, we are proposing to reduce the maximum weight used in calculating the positive regional adjustment for lower-spending ACOs participating in agreement periods under the ENHANCED track from 50 percent to 35 percent, while leaving the weights for ACOs with a higher spending than the regional average unchanged.

Under the Shared Savings Program, an ACO's historical benchmark is adjusted to reflect differences between its own historical spending and average spending in its region—the regional adjustment. For ACOs with expenditures below their regional average, this adjustment is positive, increasing the ACO's benchmark and expanding savings opportunities available to the ACO. Analysis of PY 2024 financial reconciliation data indicates that ACOs in the ENHANCED track receive substantially larger positive regional adjustments on average than ACOs in BASIC track Level E ($304 versus $166 per beneficiary). Taken together with observed differences in gross savings—where ENHANCED track ACOs achieve higher gross savings [276] per beneficiary than BASIC track Level E ACOs ($961 versus $714 in CY 2024)—this pattern suggests that more favorable benchmark adjustments may be contributing to the higher levels of observed gross savings for ENHANCED track ACOs. To assess whether the magnitude of the regional adjustment is associated with ACO performance, we calculated Pearson's correlations [277] between regional adjustment size and gross savings for ACOs reconciled in PY 2024.[278] Within the ENHANCED track, the larger regional adjustments are strongly associated with higher gross savings performance (r=0.691, n=59), a relationship that is not observed among BASIC track Level E ACOs (r=0.09, n=17). The contrast between tracks raises the possibility that the scale of positive regional adjustments to the benchmark are partly driving performance rather than genuine efficiency gains. While this is a descriptive finding, it is consistent with our concern motivating the proposed reduction in the positive regional adjustment weight from 50 percent to 35 percent. Moreover, the average size of the adjustment has gone up—from $206 in PY 2020 to $344 in PY 2025, while the share of ACOs receiving a positive regional adjustment has remained mostly stable within a range between 70 and 86 percent over the same time period. This pattern suggests that, while the prevalence of regional adjustments has remained broadly unchanged, the financial impact of those adjustments has increased over time, amplifying the influence of regional adjustments on ACO benchmark calculations.

As discussed in the overview, there is limited evidence suggesting that the ENHANCED track is generating additional Trust Funds savings relative to the BASIC track. First, the size of the regional adjustment may be contributing to higher gross savings performance in the ENHANCED track, which causes us to question whether those savings

[276] Gross savings were calculated as the ACO's total savings amount divided by the total assigned beneficiary person years.

[277] Pearson's correlation coefficient is a statistical measure that summarizes the strength and direction of the linear relationship between two variables, taking values from −1 (perfect negative relationship) to +1 (perfect positive relationship), with 0 indicating no linear relationship.

[278] Internal analysis of financial performance according to track/level of participation of Medicare Shared Savings Program ACOs that participated in PY2024, including assessment of whether the magnitude of regional adjustment is associated with ACO performance.

reflect genuine cost reduction. Second, lower spending ACOs (defined as those with historical expenditures below their regional average) in the ENHANCED track currently benefit from both a higher shared savings rate and larger regional adjustments on average. Together, these advantages may incentivize selection into the ENHANCED track independent of an ACO's capacity to achieve genuine cost savings to Medicare. The proposed reduction in the positive regional adjustment weight for these ACOs, paired with an increase in the shared savings rate for BASIC track Level E, is designed to rebalance financial incentives across tracks and encourage ACOs to select their tracks based on their actual capacity to reduce costs rather than differences in financial advantages embedded in track design, thereby potentially improving Trust Funds net savings. Refer to the discussion in section III.G.5.a. and the data analysis described in section III.G.5.c.(1) for additional details.

We believe a 35 percent positive regional adjustment would maintain consistency with the current schedule of weights used to calculate the regional adjustment, a structure with which ACOs are already familiar. We also believe this approach would minimize complexity by maintaining a single weight for lower-spending ENHANCED track ACOs for all participation years. At the same time, it would preserve an appropriate balance between rewarding regional efficiencies demonstrated at the start of the agreement period and rewarding improvement relative to an ACO's past historical performance over time.

TABLE B-G10: PROPOSED PERCENTAGE WEIGHT APPLIED IN CALCULATING THE REGIONAL ADJUSTMENT

Agreement Period When ACO is Subject to Regional Adjustment	Weight Used to Calculate Regional Adjustment for BASIC Track ACOs that are Lower Spending Compared to Their Region	Weight Used to Calculate Regional Adjustment for ENHANCED Track ACOs that are Lower Spending Compared to Their Region	Weight Used to Calculate Regional Adjustment for ACOs that are Higher Spending Compared to Their Region
First	35%	35%	15%
Second	50%		25%
Third			35%
Fourth and subsequent			50%

NOTE: Refer to § 425.601(e)(2)(ii) and (f), and § 425.656(e) and (f). Refer to the December 2018 final rule (83 FR 67908–67909) Table 6 for examples of existing phase-in of regional adjustment weights based on agreement start date and applicant type.

We propose this change to be effective for agreement periods beginning on January 1, 2027, and in subsequent years. Reducing the weight used in calculating the regional adjustment applied to ACOs considering participation in the ENHANCED track would reduce the contribution of baseline regional efficiency on historical benchmark calculations. As a result, it would put a stronger emphasis on rewarding improvement in the provision of coordinated care and lowering costs rather than baseline efficiency at entry to the agreement period. The focus on improvement is accentuated when paired with the proposed higher prior savings adjustment weighting, discussed in section III.G.5.d. of this proposed rule. One goal of this proposal—reducing the regional adjustment weight—is to encourage ACOs to select a diverse cross-section of participants so that ACOs' success is driven by operational efficiencies and clinical performance rather than passive capture of ACO participants with pre-existing regional efficiencies. More modest regional adjustment amounts could also result in ACOs opting for participation in BASIC track Level E instead of the ENHANCED track, and therefore result in the Trust Funds retaining a greater share of savings while still offering ACOs a long-term incentive for creating savings because of the proposed higher prior savings adjustments in future agreement periods.

Under this proposal, the phase-in of weights used in the regional adjustment calculation for agreement periods beginning on January 1, 2027, and in subsequent years, as determined by an ACO's expenditures relative to their region, would change for ENHANCED track ACOs. We are not proposing to modify the negative regional adjustment weights, so the negative regional adjustment would remain unchanged. We propose that the maximum weight used to calculate the regional adjustment for ENHANCED track ACOs that are lower spending relative to their region would be set at 35 percent for all agreement periods, replacing the current phase-in schedule. The weights used for ACOs that are higher spending relative to their region, and for BASIC track ACOs that are lower spending would remain unchanged.

To assess the impact of the proposed policy change, we conducted a simulation [279] using PY 2024 historical benchmarks, in which the maximum positive regional adjustment weight was reduced from 50 percent to 35 percent for lower spending ACOs,[280] all other parameters, including the prior savings adjustment, were held constant. ACOs with an agreement start date prior to January 1, 2024 (n=53) experience larger percentage reductions in historical benchmarks (−0.87 percent) than ACOs with agreement start dates of January 1, 2024 (n=48, −0.69 percent). The difference reflects the benchmark methodology applicable to ACOs with agreement period start dates of January 1, 2024, under which ACOs are eligible for multiple upward adjustments and CMS applies the highest for which an ACO qualifies. In this simulation, ACOs that transition from receiving a regional adjustment to receiving the prior savings adjustment (because the regional adjustment has decreased to

[279] Internal simulation analysis using PY2024 historical benchmarks, in which the positive regional adjustment weight was reduced from 50 percent to 35 percent for lower spending ACOs to assess the impact of the proposed policy change. This analysis did not stratify by agreement period; all ACOs with the same start date (before or after January 1, 2024) were treated as a single cohort.

[280] Defined as ACOs with historical expenditures below their regional service area average.

below the prior savings adjustment) experience smaller decreases in historical benchmarks than ACOs that remain subject to the regional adjustment. For lower spending ACOs, the prior savings adjustment can partially offset reductions to the benchmark when the weight of the regional adjustment is reduced. ACOs with agreement period start dates prior to January 1, 2024, do not have prior savings adjustments included in historical benchmark calculations, so they would be more impacted by our proposal to reduce the maximum weight of the regional adjustment.

Our proposal to reduce the maximum weight used in calculating the positive regional adjustment for ACOs participating in agreement periods under the ENHANCED track is consistent with our authority under section 1899(d)(1)(B)(ii) of the Act, which we have consistently relied on to make regional adjustments to the historical benchmark (81 FR 37962). Under this framework, ACO benchmarks are adjusted for beneficiary characteristics and other factors deemed appropriate by the Secretary, updated to reflect the projected absolute growth in national per capita expenditures for the original Medicare fee-for-service program, and reset at the commencement of each agreement period.

We propose to amend § 425.656 to specify the phase-in of weights used in calculating the regional adjustment as applicable by agreement period start date. We propose to amend the introductory text of paragraph (e) of § 425.656 to specify the paragraph includes the phase-in of weights used in the regional adjustment calculation for agreement periods beginning on or after January 1, 2024 and before January 1, 2027. We propose to redesignate paragraph (f) of § 425.656 as paragraph (g). We propose to add a new paragraph (f) to specify the phase-in of weights used in the regional adjustment calculation for agreement periods beginning on January 1, 2027, and in subsequent years. Accordingly, we propose to specify the following under new proposed § 425.656(f)(1) through (4):

- Under new paragraph (f)(1) we would specify that the first time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, we would calculate the regional adjustment as follows:

++ Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area.

++ Using 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

- Under new paragraph (f)(2) we would specify that the second time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, we would calculate the regional adjustment as follows:

++ For an ACO participating under the BASIC track—

— Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

— Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

++ For an ACO participating under the ENHANCED track—

— Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

— Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

- Under new paragraph (f)(3) we would specify that the third time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, we would calculate the regional adjustment as follows:

++ For an ACO participating under the BASIC track—

— Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

— Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

++ For an ACO participating under the ENHANCED track—

— Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

— Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

- Under new paragraph (f)(4) we would specify that the fourth or subsequent time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, we would calculate the regional adjustment as follows:

++ For an ACO participating under the BASIC track, using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark.

++ For an ACO participating under the ENHANCED track—

— Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

— Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

We propose to specify under new § 425.656(f)(5) the approach we would use to determine if an ACO has lower or higher spending compared to the ACO's regional service area, which would be identical to the existing approach for making this determination as specified under § 425.656(e)(5), except to include updated cross-references to provisions within the proposed new paragraphs (f)(1) through

(4) rather than paragraphs (e)(1) through (3).

We also propose the following technical and conforming changes to the Shared Savings Program regulations, for completeness and clarity:

- In § 425.656(a), describing (generally) the purpose of the section on calculating the regional adjustment to the historical benchmark and the timing of applicability, we propose to revise the last sentence to denote the section ''applies to regional adjustment calculations for agreement periods beginning on January 1, 2024, and in subsequent years, *except as specified otherwise*'' (emphasis added to reflect revised text).
- In § 425.656(c)(2), describing percentage weight applied in the calculation of the regional adjustment, we propose to amend the existing cross-reference to § 425.656(e) to include cross-references to both § 425.656(e) and the proposed new § 425.656(f).
- Redesignating § 425.656(f) as § 425.656(g), and in redesignated § 425.656(g) introductory text, describing special rules for determining the weights used in the regional adjustment calculation for a re-entering ACO, we propose to replace the existing cross-references to § 425.656(b) through (e) with cross-references to § 425.656(b) through (f), to include proposed new § 425.656(f) in the cross-references.
- In § 425.600(f)(4)(ii), describing the program requirements that phase in over multiple agreement periods, and specifically the weight used in calculating the regional adjustment to the ACO's historical benchmark, we propose replacing the existing cross-references to §§ 425.601(f) and 425.656(e), with cross-references §§ 425.601(f), § 425.656(e), and § 425.656(f), to include proposed new § 425.656(f) in the cross-references.

We seek comment on the proposal to reduce the maximum weight on the regional adjustment for lower-spending ACOs under the ENHANCED track to a weight of 35 percent for agreement periods beginning on January 1, 2027, and in subsequent years. Under this proposal, the weight for higher-spending ACOs, and for BASIC track ACOs that are lower spending would remain unchanged. We also seek comment on proposed technical and conforming changes to other provisions of § 425.656, and § 425.600.

d. Proposal To Increase the Prior Savings Adjustment by Increasing the Scaling Factor

(1) Background

Under section 1899(d)(1)(B)(ii) of the Act, an ACO's benchmark must be reset at the start of each agreement period. Section 1899(d)(1)(B)(ii) of the Act provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Under this authority, as described in the June 2015 final rule (80 FR 32785 through 32791), we established a prior savings adjustment [281] that applied when establishing the benchmark for ACOs entering a second agreement period beginning on January 1, 2016, to account for the average per capita amount of savings generated during the ACO's prior agreement period (79 FR 72838). The prior savings adjustment was originally designed to adjust an ACO's benchmark for its second agreement period to account for the average per capita amount of savings generated by the ACO across the 3 performance years of its first agreement period. This average per capita amount also accounted for the ACO's quality performance in each performance year under its first agreement period. We limited the adjustment to the benchmark for the second agreement period to the average number of assigned beneficiaries in the prior agreement period (80 FR 32789).

We removed the prior savings adjustment introduced as part of the June 2015 final rule and replaced it with the existing regional adjustment as part of the June 2016 final rule (81 FR 37954 through 37992). We reintroduced the prior savings adjustment as an ongoing component of the Shared Savings Program as part of the CY 2023 PFS final rule (87 FR 69898 through 69915).

In the CY 2023 PFS final rule, we established the methodology, codified at § 425.658 of the regulations, for the prior savings adjustment that applied in the establishment of benchmarks for renewing ACOs and re-entering ACOs entering an agreement period beginning on January 1, 2024, and in subsequent years. We describe the steps for calculating the prior savings adjustment in the CY 2023 PFS final rule (87 FR 69898). We finalized revisions to § 425.656 that specify how we express the regional adjustment as a single value and use this value in determining whether a regional adjustment or prior savings adjustment will be applied to the ACO's benchmark.

In the CY 2024 PFS final rule (88 FR 79185 through 79196), in response to concerns that negative regional adjustments may make it more difficult for ACOs to succeed in the Shared Savings Program financially, we finalized revisions to § 425.652 to specify that if the regional adjustment, when expressed as a single value, is negative then no regional adjustment will be applied to an ACO's historical benchmark. We also finalized revisions to § 425.658 to specify that we will calculate the per capita prior savings adjustment as the lesser of 50 percent of the prorated average per capita savings amount (computed as described in § 425.658(b)(3)(ii)) and the cap equal to 5 percent of national per capita OM expenditures for assignable beneficiaries for BY3, expressed as a single value.

In the CY 2024 PFS final rule we also finalized modifications to the approach to calculate and apply the regional adjustment, or the regional adjustment in combination with the prior savings adjustment, if applicable, for ACOs in agreement periods starting on January 1, 2024, or the regional adjustment, prior savings adjustment, or population adjustment, if applicable, for ACOs in agreement periods starting on January 1, 2025, and in subsequent years. Specifically, we finalized revisions to § 425.652 that specify how we will determine and apply the adjustment to an ACO's benchmark depending on whether the ACO is eligible for a prior savings adjustment, whether the ACO is eligible for the population adjustment, and whether the ACO's regional adjustment, expressed as a single value, is positive or negative. An ACO will receive the most favorable of the adjustments, as applicable, with each adjustment capped at 5 percent of BY3 national assignable expenditures.

In the CY 2024 PFS proposed rule (88 FR 52494 through 52495), we requested information on potential changes to the 50 percent scaling factor used in determining the prior savings adjustment. Most commenters supported increasing the prior savings adjustment, with several commenters recommending using the maximum shared savings rate the ACO was eligible to receive during the benchmark years. For the full summary of comments, refer to the CY 2024 PFS final rule (88 FR 79228).

(2) Proposed Revisions

In the CY 2023 PFS final rule (87 FR 69910), we stated that we believed that a 50 percent scaling factor used to calculate the prior savings adjustment would be appropriate because it represents a middle ground between the maximum sharing rate of 75 percent under the ENHANCED track and the lower sharing rates available under the BASIC track. However, after further

[281] In the June 2015 final rule (80 FR 32788), we referred to this policy as accounting for shared savings payments when resetting the benchmark, after which we refer to it as the prior savings adjustment.

analysis of this policy and gaining additional years of experience with the current policy, we believe changing the prior savings adjustment scaling factor from 50 percent to 75 percent is warranted because the current methodology may not provide sufficiently strong or consistent incentives for ACOs to generate and sustain savings. We likewise believe the current methodology may not provide sufficient incentives for ACOs to continue participation in future agreement periods when the ACOs are compared against benchmarks that include their own previous success in reducing expenditures. As noted in the CY 2023 PFS final rule (87 FR 69909), in an analysis estimating how the prior savings adjustment may impact ACOs participating in the Shared Savings Program if the prior savings adjustment would have been in place at that time, among 123 ACOs entering a new agreement period in PY 2020 and reconciled in one or more benchmark years, only 27 (22 percent) would have received a final adjustment that included prior savings. Among 153 ACOs entering a new agreement period in PY 2022 and reconciled in one or more benchmark years, only 43 (28.1 percent) would have received such an adjustment. These findings suggested that relatively few ACOs would benefit from the prior savings adjustment under the methodology that included the 50 percent scaling factor. Furthermore, after gaining initial experience with the prior savings adjustment applicable to agreement periods beginning on January 1, 2024, and in subsequent years, we have seen a relatively small number of ACOs receiving the prior savings adjustment with 82 (17 percent) of ACOs in CY 2025 receiving a prior savings adjustment and 18 (4 percent) of ACOs in PY 2024 receiving a prior savings adjustment.

In the CY 2023 PFS final rule (87 FR 69904), we also described scenarios in which ACOs with strong prior savings may not receive the prior savings adjustment. For example, as illustrated in Table 68 (87 FR 69907), pro-rating and scaling of prior savings using the 50 percent scaling factor can result in the final prior savings adjustment being smaller than the regional adjustment, even when the ACO's prior savings adjustment prior to applying the scaling factor exceeds the regional adjustment. This dynamic may weaken incentives for ACOs to generate and sustain savings over time.

We conducted a simulation limited to ACOs participating in the ENHANCED track with lower spending than their regional service area, because these ACOs would be directly impacted by the proposed change to the weight of the regional adjustment. The simulation applied both the proposed reduction of the regional adjustment weight from 50 percent to 35 percent and increasing the prior savings adjustment scaling factor from 50 percent to 75 percent. See section III.G.5.c.(2) for a description of the proposed change to the regional adjustment weight. The simulation was conducted on two cohorts: 37 ENHANCED track ACOs that began an agreement period on January 1, 2024, and 107 ENHANCED track ACOs that began an agreement period on January 1, 2025. For both cohorts, we focused on PY1 of the agreement period; 2024 and 2025, respectively. Table B–G11 reports the results for five mutually exclusive groups of ACOs. Group 1 (had regional adjustment and still would have it, no benchmark change due to 5 percent cap) includes ACOs that remain at the existing 5 percent cap, leaving benchmarks unchanged, as the reduction in the regional adjustment weight did not decrease the regional adjustment below the 5 percent cap. Group 2 (had regional adjustment, now would have prior savings adjustment) consists of ACOs that currently receive a regional adjustment and for which the proposed increase in the prior savings adjustment scaling factor is large enough to either fully offset the reduced regional adjustment, resulting in benchmarks that do not decline and may increase, or to mitigate the effect of the reduced regional adjustment to some degree as the applicable adjustment to the benchmark would change as a result of the proposed policy changes. Group 3 (had regional adjustment and still would have it, net benchmark decrease) includes ACOs that receive the full proposed reduction to the weight of the regional adjustment and for which the prior savings adjustment, even at the proposed 75 percent scaling factor, remains smaller than the regional adjustment. For these ACOs, the final adjustment category would remain the regional adjustment both before and after the changes, resulting in a net decrease to the benchmark. Group 4 (subject to the current 50 percent prior savings adjustment scaling factor) includes ACOs for which the prior savings adjustment calculated under the current 50 percent scaling factor was already the applicable adjustment prior to the proposed policy change to the regional adjustment weight; because the prior savings adjustment remains the applicable adjustment, any benchmark change for these ACOs reflects the effect of the proposed increase in the prior savings adjustment scaling factor. Group 5 (not subject to the proposed regional adjustment weight change) includes ACOs that are not exposed to the regional adjustment weight adjustment—either because they are higher spending or already subject to the 35 percent positive weight—but that received the increased prior savings adjustment (see footnote on Table B–G11). One ACO in the 2025 cohort had the population adjustment as their applicable adjustment and would continue to have it with any of the proposed changes.

TABLE B-G11: ESTIMATED BENCHMARK IMPACT OF PROPOSED REDUCTION IN REGIONAL ADJUSTMENT WEIGHT AND INCREASING PRIOR SAVINGS ADJUSTMENT

	ACOs beginning an Agreement Period on January 1, 2024			ACOs beginning an Agreement Period on January 1, 2025		
Group	Number of ACOs (N=37)*	Percent of ACOs (%)	Mean Change Per Capita Benchmark ($)	Number of ACOs (N=107)*	Percent of ACOs (%)	Mean Change Per Capita Benchmark ($)
(1) Regional Adjustment retained (no benchmark change)	0	0.0%	$0.00	0	0.0%	$0.00
(2) Had regional adjustment would transition to prior savings adjustment	9	24.3%	$29.79	42	39.3%	$16.70
(3) Had regional adjustment and would continue to have it	21	56.8%	-$113.31	31	29.0%	-$85.36
(4) Subject to the current percent prior savings adjustment	7	18.9%	$105.98	33	30.8%	$110.30
(5) Not subject to the proposed regional weight change**	21	36.2% of total (n=58)	$15.98	24	18.3% of total (n=131)	$27.71

Table notes:
* Number of ACOs subject to the proposed policy changes.
** ACOs in this group are not subject to the regional adjustment weight reduction, but where applicable, the proposed 75 percent prior savings adjustment scaling factor was applied.

For ACOs that began an agreement period on January 1, 2025, the proposed policies would produce no meaningful net aggregate impact on benchmarks for ACOs in group 1. After applying the reduced regional adjustment weight, no ACO remains constrained by the 5 percent cap. Of the 107 ACOs, 42 (39.3 percent) fall in Group 2, with benchmarks increasing by a mean of $16.70, 33 (30.8 percent) fall in Group 4, where the prior savings adjustment was already dominant, and 31 ACOs (29.0 percent) fall in Group 3 with benchmark decreases averaging $85.36 in magnitude. For the 2025 cohort, the increase in the scaling of the prior savings adjustment more than offsets the reduction in the weight of the regional adjustment in aggregate, producing a modest net benchmark increase concentrated among ACOs with proven savings records. The larger share of ACOs in this cohort for which the prior savings adjustment is the applicable adjustment (70.1 percent; Groups 2 and 4) reflects, in part, cohort-specific differences in benchmark composition and adjustment eligibility—specifically, a greater prevalence of ACOs with prior savings large enough that the prior savings adjustment exceeds the regional adjustment and therefore determines the final benchmark adjustment.

For ACOs that began an agreement period on January 1, 2024, the combined effect of the two proposed policies produces a net downward aggregate impact on benchmarks. No ACO in this cohort is constrained by the 5 percent cap, leaving most directly affected by the proposed regional adjustment weight reduction, with limited offset from the increase in the prior savings adjustment scaling factor. As a result, 21

ACOs (56.8 percent of those impacted) would experience benchmark decreases. A smaller share of ACOs hold the prior savings adjustment as their applicable adjustment (43.2 percent). Prior savings amounts are generally insufficient to exceed regional adjustments, and for these ACOs, the net effect of the two policies is a downward adjustment, consistent with the intended effect for ACOs whose benchmarks might have been inflated by the generous regional adjustment. As ACOs have additional incentives to focus on increasing savings in the future, prior savings amounts may continue to grow, resulting in different impacts than what are initially observed in these analyses.

We extended this analysis by re-running the simulation and incorporating the proposed risk adjustments to the 5 percent cap on positive regional adjustments and to the prior savings adjustment cap (Table B–G12) as outlined in section III.G.5.e. of this proposed rule.

TABLE B-G12: ESTIMATED IMPACT OF PROPOSED REGIONAL ADJUSTMENT WEIGHT REDUCTION, INCREASING PRIOR SAVINGS ADJUSTMENT, AND RISK-ADJUSTED CAPS ON ACO BENCHMARK ADJUSTMENTS

	ACOs beginning an Agreement Period on January 1, 2024			ACOs beginning an Agreement Period on January 1, 2025		
Group	Number of ACOs (N=37)*	Percent of ACOs (%)	Mean Change Per Capita Benchmark ($)	Number of ACOs (N=107)*	Percent of ACOs (%)	Mean Change Per Capita Benchmark ($)
(1) Regional Adjustment retained (no benchmark change)	0	0.0%	0.00	0	0.0%	0.00
(2) Had regional adjustment, would transition to prior savings adjustment	9	24.3%	13.97	41	38.3%	7.22
(3) Had regional adjustment and would continue to have it	21	56.8%	-115.91	32	29.9%	-93.72
(4) Subject to the current percent prior savings adjustment	7	18.9%	107.03	33	30.8%	121.36
(5) Subject to the population adjustment and would transition to regional adjustment	0	0	0	1	0.9	11.03

Table notes:

* Number of ACOs subject to the proposed policy changes.

Results in Table B–G12 under the proposed risk-adjusted 5 percent cap are largely consistent with those in Table B–G11. The distribution of ACOs across Groups 2 through 4 remains largely unchanged, and the reduction in the weight of the regional adjustment continues to be the primary driver of benchmark changes in both cohorts. The similar results between both analyses are a result of three factors. First, weighted mean risk scores in this sample are clustered near 1.0 (approximately 0.94 to 0.99 across enrollment statuses and cohorts), so risk-adjusting the caps changes their values only modestly (between 1 to 6 percent) and generally does not materially affect ACOs' effective regional or prior savings adjustments. Second, for most ACOs eligible for the prior savings adjustment, the scaling factor is the applicable constraint rather than the cap; therefore, modifying a non-binding cap has little or no effect on the adjustment. Third, the reduction in the weight of the regional adjustment from 0.50 to 0.35 produces benchmark impacts substantially larger than those associated with risk-adjusting the caps, making it an important driver of changes to the benchmark under both analyses.

To strengthen incentives and mitigate impacts from ACOs' past performance on future agreement periods, we propose increasing the prior savings adjustment scaling factor, program-wide, from 50 percent to 75 percent, beginning with agreement periods starting January 1, 2027, and subsequent agreement periods. We have heard from interested parties that the prior savings adjustment scaling factor should be 100 percent to encourage further savings and address rebasing concerns. However, we believe that increasing the prior savings adjustment scaling factor above 75 percent would limit incentives for ACOs to continue to decrease spending in second and subsequent agreement periods, since they would be rewarded largely for previously demonstrated savings and would not be incentivized to continue to decrease costs (approaching 100 percent reward if the prior savings adjustment scaling factor is above 75 percent). Without a sufficient incentive level to decrease spending, this would jeopardize the ability of the Shared Savings Program to generate future savings to the Trust Funds. We believe that a prior savings adjustment scaling factor of 75 percent strikes the appropriate balance between encouraging long-term participation in the program and encouraging ACOs to save, while also supporting savings to the Trust Funds.

Table B–G13 shows simulated results of the proposal to increase the prior savings adjustment scaling factor to 75 percent while holding the weight on the regional adjustment constant. Table B–G13 is divided into several sections that correspond to the various criteria ACOs would be required to meet to receive the proposed prior savings adjustment. The first segment of the Table (rows [A] and [B]) identifies the total number of ACOs entering a new agreement period in the respective performance year (PY 2024 or PY 2025) and what proportion of all ACOs starting an agreement period in that performance year were reconciled in one or more benchmark years. This is the first eligibility criterion ACOs must meet to receive the prior savings adjustment. The second segment of the Table (row [C]) identifies the proportion of ACOs, among those reconciled in one or more benchmark years, that had positive prorated average prior savings, which is the second criterion of the CMS methodology. All ACOs that do not receive a regional adjustment and have positive prorated average prior savings would receive some benefit from the prior savings adjustment. However, ACOs that receive a positive regional adjustment and have positive prorated average prior savings would only receive a benefit if the prior savings adjustment is greater than the positive regional adjustment the ACO otherwise would have received. The third section in Table B–G13 (row [D]) identifies the proportion of ACOs that were simulated to actually receive the prior savings adjustment among ACOs that were reconciled in one or more benchmark years. The fourth segment in Table B–G13 (row [E]) summarizes the positive impact of the prior savings adjustment relative to the regional adjustment the ACO would otherwise have received for ACOs that were simulated to receive the prior savings adjustment. This table demonstrates that more ACOs could receive the prior savings adjustment instead of the regional adjustment in later agreement periods when increasing the scaling factor for the prior savings adjustment to 75 percent.

TABLE B-G13: MODELED IMPACT OF 50 percent AND 75 percent PRIOR SAVINGS ADJUSTMENT SCALING FACTORS ON PY 2025 BENCHMARKS FOR 2024 AND 2025 STARTERS

	50% Prior Savings Adjustment Scaling Factor	75% Prior Savings Adjustment Scaling Factor
[A] ACOs Entering a New Agreement Period in 2024 or 2025	336	336
[B] ACOs Reconciled in One or More Benchmark Years	256	256
Percent of ACOs in [B] out of total in [A]	76%	76%
[C] ACOs with Positive Pro-rated Average Prior Savings Among ACOs Reconciled in One or More Benchmark Years	223	223
Percent of ACOs in [C] out of total in [B]	87%	87%
[D] ACOs Whose Final Adjustment Includes Adjustment for Prior Savings Among ACOs Reconciled in One of More Benchmark Years	82	137
Percent of ACOs in [D] out of total in [C]	37%	61%
[E1] Net Benefit to Benchmarks from Prior Savings Adjustment Relative to Regional Adjustment Otherwise Received ($) Under 50% Prior Savings Adjustment Scaling Factor (Calculated Among ACOs in [D] that began an agreement period on January 1, 2024)		
Minimum		$0.85
Average		$45.72
Maximum		$113.87
[E2] Net Benefit to Benchmarks from Prior Savings Adjustment Relative to Regional Adjustment Otherwise Received ($) Under 75% Prior Savings Adjustment Scaling Factor (Calculated Among ACOs in [D] that began an agreement period on January 1, 2025)		
Minimum		$0.52
Average		$62.01
Maximum		$157.53

In the CY 2023 PFS final rule (87 FR 69907), we explained our belief that incorporating an adjustment for prior savings—when more advantageous for ACOs than the regional adjustment—would help limit the negative ratchet effects of benchmark rebasing. Under the existing benchmarking methodology, savings an ACO achieves in one agreement period can reduce its rebased benchmark for a subsequent agreement period by lowering the historical spending that forms the basis for that benchmark. To illustrate the effect of the proposed scaling factor increase in reducing the impacts from rebasing: if an ACO reduces per capita expenditures by $1,000 relative to a $10,000 benchmark, its rebased benchmark would otherwise decrease to $9,000. Under the current 50 percent scaling factor, the prior savings adjustment restores $500, yielding a benchmark of $9,500. Under the proposed 75 percent scaling factor, $750 would be restored, resulting in a benchmark of $9,750 and a smaller effective downward adjustment of the benchmark.

The proposed increase to the prior savings adjustment scaling factor from 50 percent to 75 percent would provide additional relief from rebasing while continuing to incentivize ACOs to achieve further savings in future agreement periods. This change would shift a subset of ACOs from receiving the regional adjustment to receiving the prior savings adjustment, as the larger prior savings adjustment becomes more likely to exceed the regional adjustment. ACOs with higher regional or population adjustments would remain largely unaffected, while those with moderate to high levels of prior savings would particularly benefit.

Although MedPAC has previously urged CMS to use the prior savings adjustment to phase out the regional adjustment entirely,[282] we continue to disagree that a full phase-out is appropriate. We believe that the regional adjustment continues to provide valuable incentives, and that ACOs that are efficient relative to their regions should continue to receive a benchmark adjustment that recognizes that efficiency, consistent with our longstanding goal of reducing disincentives for high-performing ACOs that successfully lower spending. We are, however, also proposing to reduce the maximum weight applied to the regional adjustment for lower-spending ENHANCED track ACOs. Taken together, these proposals are intended to better balance incentives between regionally efficient ACOs and those that have demonstrated program success,

[282] Medicare Payment Advisory Commission (MedPAC) comment on the CY 2023 PFS proposed rule. *https://www.medpac.gov/wp-content/uploads/2022/09/09022022_Part_B_2023_CMS1770P_MedPAC_COMMENT_v2_SEC.pdf.*

through a history of earning shared savings, while further mitigating the ratcheting effects that may occur when prior savings are incorporated into future benchmarks (see section III.G.5.c.(2) of this proposed rule for details on the proposed regional adjustment changes).

We propose that this policy would apply for agreement periods beginning on January 1, 2027, and in subsequent years.

We propose to revise § 425.658(c), describing calculation of the per capita prior savings adjustment, to include proposed revised paragraph (c)(2), with the calculation methodology applicable for agreement periods beginning on January 1, 2027, and in subsequent years. Currently paragraph (c)(2) of § 425.658 is reserved. Under proposed § 425.658(c)(2), we would specify the use of a scaling factor of 75 percent (described in this section of this proposed rule), and a proposed risk adjusted 5 percent cap (described in section III.G.5.e.(2)(b) of this proposed rule) in determining the amount of the prior savings adjustment an ACO may receive (if eligible). Specifically, for agreement periods beginning on January 1, 2027, and in subsequent years, if an ACO is eligible for the prior savings adjustment as determined in § 425.658(b)(3), the prior savings adjustment would equal the lesser of the following: (i) 75 percent of the pro-rated average per capita amount computed in § 425.658(b)(3)(ii); or (ii) a single per capita value that would be the result of risk adjusting the 5 percent cap (the calculation of which is described in section III.G.5.e.(2)(b) of this proposed rule).

We also propose the following technical and conforming changes to other provisions of § 425.658, for completeness and clarity:

- In § 425.658(c)(1) introductory text, we propose to add a new first sentence to specify the existing provisions on calculation of the per capita prior savings adjustment apply for agreement periods beginning on or after January 1, 2024 and before January 1, 2027.
- In § 425.658(d), describing CMS' comparison of the per capita prior savings adjustment with the regional adjustment and the population adjustment, in determining which (if any) adjustment applies to an ACO's benchmark, we propose to amend the existing cross-reference to § 425.658(c)(1) to refer instead more generally to § 425.658(c).

We seek comment on our proposal to increase the prior savings adjustment scaling factor from 50 percent to 75 percent for agreement periods beginning on January 1, 2027, and in subsequent years, and the proposal to specify related provisions in the Shared Savings Program regulations in § 425.658(c)(2), as well as proposed technical and conforming changes to other provisions of § 425.658.

e. Proposal To Risk Adjust the 5 percent Cap on Upward Adjustments to the Historical Benchmark

(1) Background

For agreement periods beginning on January 1, 2025, and in subsequent years, in calculating the historical benchmark, CMS applies the highest of three upward adjustments for which the ACO is eligible: a positive regional adjustment, prior savings adjustment, or population adjustment, as described at § 425.652(a)(8)(ii)(B)(*1*). Each of these adjustments is subject to a cap of 5 percent of national per capita OM expenditures for the assignable beneficiary population, a limit first established in the CY 2018 PFS final rule (83 FR 68072).

In the June 2016 final rule (81 FR 37973), we introduced a regional adjustment to the ACO's historical benchmark. In the CY 2023 PFS final rule (87 FR 69915 through 69923), we finalized the application of a cap on the negative regional adjustment at negative 1.5 percent of national per capita expenditures for Parts A and B services and further modified the adjustment to limit its negative impact on ACO historical benchmarks. In the CY 2024 PFS final rule (88 FR 79185 through 79196), we further modified the regional adjustment to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment.

In the June 2015 final rule (80 FR 32785 through 32791), we established a prior savings adjustment to account for the average per capita amount of savings generated during an ACO's prior agreement period. We removed the adjustment in the June 2016 final rule (81 FR 37954 through 37992) and then reinstated it in the CY 2023 PFS final rule (87 FR 69898 through 69915), for renewing and re-entering ACOs beginning January 1, 2024. In the CY 2024 PFS final rule (88 FR 79196 through 79200), we modified the prior savings adjustment to account for changes in savings due to compliance actions or reopenings of prior determinations.

In the CY 2025 PFS final rule (89 FR 61887 through 61892), we introduced the health equity benchmark adjustment (HEBA), which adjusts upward an ACO's historical benchmark based on the number of dually eligible or Low-Income Subsidy (LIS)-enrolled beneficiaries served. With the CY 2026 PFS final rule (90 FR 49831 through 49834), we renamed the HEBA to the ''population adjustment'' to more accurately reflect the nature of the adjustment.

The positive regional adjustment, prior savings adjustment, and population adjustment are all capped at 5 percent of national per capita OM expenditures for the assignable beneficiary population. Further, the population adjustment calculation considers the difference between the 5 percent cap and the higher of regional adjustment, prior savings adjustment, or no adjustment (in the case where the regional adjustment is negative or the ACO is not eligible for the prior savings adjustment) [283]. More generally, the 5 percent cap mitigates the potential risk of CMS paying ACOs shared savings payments that are the result of extreme or outlier positive adjustments to the benchmark.

(2) Proposal

ACOs serving medically complex populations with higher CMS–HCC risk scores (relative to the national assignable population) have expressed concern that the current 5 percent cap applied to the three upward adjustments to the historical benchmark (regional adjustment, prior savings adjustment, and population adjustment) is too restrictive. Specifically, when the cap is applied as a flat percentage without accounting for the degree to which the ACO serves a medically complex population, it imposes a hard ceiling that suppresses the historical benchmark. Rather than allowing the benchmark adjustments to reflect the actual higher costs required to care for these complex patients, the flat 5 percent cap limits the three upward adjustments. These ACOs have requested that the higher clinical complexity, higher CMS–HCC risk scores, and higher cost of providing care to their assigned beneficiary populations be considered when establishing a cap for adjustments to the historical benchmark. Risk adjusting the 5 percent caps accounts for the severity and case mix of each ACO's assigned beneficiary population, allowing a higher positive adjustment ceiling for ACOs serving medically complex populations while still fulfilling the cap's original purpose of safeguarding CMS against extreme or outlier positive

[283] 42 CFR 425.656; 42 CFR 425.658; 42 CFR 425.662.

benchmark adjustments. Beyond addressing ACO concerns, risk adjusting the 5 percent cap would encourage ACOs to enroll and manage higher acuity, higher cost beneficiaries, who stand to benefit most from coordinated care, by allowing the cap to scale upwards with the average CMS–HCC risk scores of their populations relative to the national average.

To better align benchmark adjustments with true clinical complexity and encourage participation among organizations engaged in providing high-needs care, we propose to risk adjust the 5 percent cap on each of the upward adjustments to the historical benchmark: the positive regional adjustment, the prior savings adjustment, and the population adjustment.

(a) Proposal To Risk Adjust the 5 Percent Cap on Positive Regional Adjustments to the Historical Benchmark

We propose to risk adjust the 5 percent cap on positive adjustments to the national per capita dollar amount for each Medicare enrollment type (ESRD, Disabled, Aged/Dual, and Aged/non-dual), used to calculate the regional adjustment to the historical benchmark, according to the following steps:

- Step 1—Identify the national per capita expenditure amount for the enrollment type for BY3.
- Step 2—Identify the ACO's weighted average CMS–HCC risk score for the enrollment type for BY3.[284]
- Step 3—By enrollment type, calculate the product of the amounts identified in Step 1 and Step 2.
- Step 4—By enrollment type, calculate the cap for the enrollment type at 5 percent of the product derived in Step 3.
- Step 5—Apply the risk-adjusted 5 percent cap calculated in Step 4 to the ACO's preliminary regional adjustment for the enrollment type. The preliminary regional adjustment refers to the regional adjustment amount for the enrollment type (that is, the per capita dollar amount) before any caps are applied.[285]

++ Step 5(i)—Identify the ACO's preliminary regional adjustment for the enrollment type.

++ Step 5(ii)—Evaluate whether the value identified in Step 5(i) is greater than the risk-adjusted 5 percent cap determined in Step 4. If yes, set regional adjustment for the enrollment type at the risk-adjusted 5 percent cap calculated in Step 4. If no, set the regional adjustment for the enrollment type as the value identified in Step 5(i).

We illustrate how the proposed calculation methodology would be applied, considering the following hypothetical example in which positive adjustments are applied to the regional adjustment for all enrollment types for the ACO.

[284] For more information on the calculation of the weighted average CMS–HCC risk score, we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

[285] For more information on the calculation of the preliminary regional adjustment for the enrollment type, we refer readers to section 4.1.2 step 5 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

TABLE B-G14: HYPOTHETICAL EXAMPLE OF STEPS FOR RISK ADJUSTING THE 5 percent CAPS ON POSITIVE REGIONAL ADJUSTMENTS TO HISTORICAL BENCHMARKS

	Amount Under Current Policy (No Risk Adjustment Applied to 5 percent Caps)	Amount Under Proposed Policy (Risk Adjustment Applied to 5 percent Caps)
Step 1: Identify the national per capita expenditure amount for the enrollment type for BY3.		
ESRD	$121,092.11	$121,092.11
Disabled	$18,266.87	$18,266.87
Aged/dual	$30,290.30	$30,290.30
Aged/non-dual	$15,943.88	$15,943.88
Step 2: Identify the ACO's weighted average CMS-HCC mean risk score for the enrollment type for BY3.		
ESRD	NA	1.1022
Disabled	NA	0.9249
Aged/dual	NA	1.0648
Aged/non-dual	NA	1.0366
Step 3: By enrollment type, calculate the product of the amounts identified in Step 1 and Step 2.		
ESRD	NA	$133,467.72
Disabled	NA	$16,895.03
Aged/dual	NA	$32,253.11
Aged/non-dual	NA	$16,527.43
Step 4: By enrollment type, calculate the cap for the enrollment type as 5 percent of the product derived in Step 3. (Under current policy, the cap is calculated as 5 percent of the amount identified in Step 1.)		
ESRD	$6,054.61	$6,673.39
Disabled	$913.34	$844.75
Aged/dual	$1,514.51	$1,612.66
Aged/non-dual	$797.19	$826.37
Step 5: Apply the risk-adjusted 5 percent cap calculated in Step 4 to the ACO's preliminary regional adjustment for the enrollment type.		
Step 5(i) Identify the ACO's preliminary regional adjustment for the enrollment type.*		
ESRD	$376.91	$376.91
Disabled	$905.00	$905.00
Aged/dual	$3,036.48	$3,036.48
Aged/non-dual	$883.08	$883.08
Step 5(ii): Evaluate whether the value identified in Step 5(i) is greater than the risk-adjusted 5 percent cap determined in Step 4. If yes, set the regional adjustment for the enrollment type at the risk-adjusted 5 percent cap calculated in Step 4. If no, set the regional adjustment for the enrollment type as the value identified in Step 5(i).		
ESRD	$376.91	$376.91
Disabled	$905.00	$844.75
Aged/dual	$1,514.51	$1,612.66
Aged/non-dual	$797.19	$826.37

*For more information on the calculation of the preliminary regional adjustment for the enrollment type, we refer readers to section 4.1.2 step 5 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.[286]

An average CMS–HCC risk score of 1.000 indicates that the ACO's population risk aligns with the national assignable population average, while scores above 1.000 identify populations with higher-than-average risk and scores below 1.000 identify populations with lower-than-average risk. By risk-adjusting the 5 percent caps for each enrollment group, the caps would become tailored to each ACO's specific risk profile for BY3. In this hypothetical example, the caps for the ESRD, Aged/Dual, and Aged/Non-Dual groups increase to reflect elevated risk levels, while the cap for the Disabled group decreases to reflect a lower risk profile for that group. This hypothetical example illustrates how a single ACO may experience both increased and decreased 5 percent caps across enrollment types, depending on each enrollment type's average risk relative to the national assignable population. Notably, the proposed risk adjustment policy applies exclusively to the 5 percent caps on positive adjustments; caps for negative adjustments remain unchanged under the proposed policy.

We propose to revise and republish § 425.656(c)(3), to include the proposed approach to calculating the caps on regional adjustment amounts applicable for agreement periods beginning on January 1, 2027, and in subsequent years, as well as the existing calculation of the caps on the regional adjustment amounts that would apply for agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

Under new § 425.656(c)(3)(ii), we propose to specify the approach to calculating the cap on regional adjustment amounts, applicable for agreement periods beginning on January 1, 2027, and in subsequent years. Accordingly, we propose to specify that CMS caps the per capita dollar amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under § 425.656(c)(2) at a dollar amount

[286] Refer to the Medicare Shared Savings Program, ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications'' (April 2026, Version #14), available at *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0* (herein for brevity ''Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14'').

as described in the provisions that follow in subparagraphs (A) and (B), inclusive of the provisions included thereunder.

Under new § 425.656(c)(3)(ii)(A), we propose to specify that, for positive adjustments, the per capita dollar amount for a Medicare enrollment type would be capped at a dollar amount calculated as follows:

- As specified in proposed § 425.656(c)(3)(ii)(A)(*1*), we would calculate the product of the following: (i) the amount of national per capita expenditures for Parts A and B services under the OM fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary; and (ii) the ACO's weighted average risk score for the enrollment group for BY3.[287]
- As specified in proposed § 425.656(c)(3)(ii)(A)(*2*), we would calculate 5 percent of the enrollment type-specific product determined in § 425.656(c)(3)(ii)(A)(*1*).

Under new § 425.656(c)(3)(ii)(B), we propose to specify that, for negative adjustments, the per capita dollar amount for a Medicare enrollment type would be capped at a dollar amount equal to negative 1.5 percent of national per capita expenditures for Parts A and B services under the OM program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

The following list summarizes the proposed amendments to the structure and organization of § 425.656(c)(3) (as revised and republished):

- We propose to specify the existing provisions of § 425.656(c)(3), describing the caps on regional adjustment amounts based on a percentage of national per capita expenditures for the assignable beneficiary population for BY3, under new § 425.656(c)(3)(i). Accordingly, we propose to:

++ Add a sentence at the start of the introductory text of new § 425.656(c)(3)(i) specifying the applicability of the calculation for agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

++ Redesignate existing paragraphs (c)(3)(i) and (ii) of § 425.656 (specifying the cap on positive adjustments and negative adjustments, respectively) as paragraphs (c)(3)(i)(A) and (B).

- We propose to specify the proposed caps on regional adjustment amounts, applicable for agreement periods beginning on January 1, 2027, and in subsequent years, in new § 425.656(c)(3)(ii) (previously described in this section).

We seek comment on the proposal to risk adjust the 5 percent caps on positive regional adjustment amounts, applicable for agreement periods beginning on January 1, 2027, and in subsequent years, and related proposed changes to the Shared Savings Program regulations at § 425.656(c)(3) (as revised and republished).

(b) Proposal To Risk Adjust the 5 Percent Cap on the Prior Savings Adjustment to the Historical Benchmark

We propose to risk adjust the 5 percent cap on national per capita dollar amount for each Medicare enrollment type (ESRD, Disabled, Aged/dual, and Aged/non-dual), used in determining the prior savings adjustment to the historical benchmark, according to the following steps:

- Step 1—Identify the national per capita expenditure amount for the enrollment type for BY3.
- Step 2—Identify the ACO's weighted average CMS–HCC risk score by enrollment type for BY3.
- Step 3—By enrollment type, calculate the product of the amounts identified in Steps 1 and 2.
- Step 4—By enrollment type, calculate 5 percent of the product derived in Step 3.
- Step 5—Identify the proportion of the ACO's assigned beneficiaries within each enrollment type by dividing the number of assigned beneficiaries within each enrollment type by the total number of assigned beneficiaries.
- Step 6—To calculate the final risk-adjusted 5 percent national expenditure value by enrollment type, multiply the risk-adjusted 5 percent amounts from Step 4 by the enrollment proportions from Step 5.
- Step 7—Create a single prior savings cap value by summing the products from Step 6 across enrollment types.
- Step 8—Multiply the prorated average per capita prior savings by the 75 percent scaling factor.[288]
- Step 9—If the ACO is eligible for a prior savings adjustment, set the prior savings adjustment as the lesser of: the prior savings cap calculated in Step 7, and the weighted prorated average prior savings calculated in Step 8.

We illustrate how the proposed calculation methodology would be applied, considering the following hypothetical example in which the prior savings adjustment is applied for the ACO.

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[287] For more information on the calculation of the weighted average risk score we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

[288] For more information on the calculation of the prorated average per capita prior savings, we refer readers to step 6c of section 4.1.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

TABLE B-G15: HYPOTHETICAL EXAMPLE OF STEPS FOR RISK ADJUSTING THE 5 percent CAPS ON THE PRIOR SAVINGS ADJUSTMENT TO HISTORICAL BENCHMARKS

	Amount Under Current Policy (No Risk Adjustment Applied to 5 percent Caps)	Amount Under Proposed Policy (Risk Adjustment Applied to 5 percent Caps)
Step 1: Identify the national per capita expenditure amount for the enrollment type for BY3.		
ESRD	$100,000.00	$100,000.00
Disabled	$12,000.00	$12,000.00
Aged/dual	$20,000.00	$20,000.00
Aged/non-dual	$12,000.00	$12,000.00
Step 2: Identify the ACO's weighted average CMS-HCC risk score by enrollment type for BY3.		
ESRD	NA	1.1022
Disabled	NA	0.9249
Aged/dual	NA	1.0648
Aged/non-dual	NA	1.0366
Step 3: By enrollment type, calculate the product of the amounts identified in Step 1 and Step 2.		
ESRD	NA	$110,222.22
Disabled	NA	$11,098.52
Aged/dual	NA	$21,296.18
Aged/non-dual	NA	$12,439.56
Step 4: By enrollment type, calculate 5 percent of the product derived in Step 3. (For the calculation under current policy, calculate 5 percent of the values identified in Step 1.)		
ESRD	$5,000.00	$5,511.11
Disabled	$600.00	$554.93
Aged/dual	$1,000.00	$1,064.81
Aged/non-dual	$600.00	$621.98
Step 5: Identify the proportion of the ACO's assigned beneficiaries within each enrollment type.		
ESRD	0.007	0.007
Disabled	0.052	0.052
Aged/dual	0.055	0.055
Aged/non-dual	0.886	0.886
Step 6: To calculate the final risk-adjusted 5 percent national expenditure value by enrollment type, multiply the risk-adjusted 5 percent amounts from Step 4 by the enrollment proportions from Step 5.		
ESRD	$35.00	$38.58
Disabled	$31.20	$28.86
Aged/dual	$55.00	$58.56
Aged/non-dual	$531.60	$551.07
Step 7: Create a single prior savings cap value by summing the products from Step 6 across enrollment types.		
Prior savings cap	$652.80	$677.07
Step 8: Multiply the prorated average per capita prior savings by the 75 percent scaling factor.*		
Prorated average per capita savings from BY1, BY2, and BY3	$900.00	$900.00
Proposed 75 percent scaling factor (Under current policy, use 50 percent scaling factor)	50%	75%
Weighted prorated average prior savings	$450.00	$675.00
Step 9: If the ACO is eligible for a prior savings adjustment, set the prior savings adjustment as the lesser of: [A] the prior savings cap calculated in Step 7, and [B] the weighted prorated average prior savings calculated in Step 8.		
Prior savings adjustment	$450.00	$675.00

* For more information on the calculation of the prorated average per capita prior savings, we refer readers to step 6c of section 4.1.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

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In this scenario, the ACO's prior savings adjustment would be higher under the proposed risk-adjusted caps than under current policy, driven by

two key changes. First, the risk-adjusted prior savings cap in Step 7 is higher than the non-risk-adjusted cap, reflecting the ACO's higher-than-average risk profile and allowing the ACO to retain a larger share of its prior savings before being capped. Second, the proposed increase to the prior savings adjustment scaling factor from 50 percent to 75 percent further raises the available adjustment amount. Together, these updates ensure that the prior savings adjustment reflects recent patient complexity.

As described in section III.G.5.d.(2) of this proposed rule, we are proposing to specify in revised § 425.658(c)(2) the methodology for calculating the per capita prior savings adjustment applicable for agreement periods beginning on January 1, 2027, and in subsequent years. Under proposed § 425.658(c)(2) (as revised), we would specify the use of a scaling factor of 75 percent (described in section III.G.5.d.(2) of this proposed rule), and the proposed risk adjusted 5 percent cap (described in this section of this proposed rule) in determining the amount of the prior savings adjustment an ACO may receive (if eligible). Specifically, for agreement periods beginning on January 1, 2027, and in subsequent years, if an ACO is eligible for the prior savings adjustment as determined in § 425.658(b)(3), the prior savings adjustment would equal the lesser of the following: (i) 75 percent of the pro-rated average per capita amount computed in § 425.658(b)(3)(ii); or (ii) a single per capita value that would be the result of risk adjusting the 5 percent cap.

With respect to risk adjusting the 5 percent cap, we propose to specify related provisions in revised § 425.658(c)(2)(ii). Specifically, we propose that, for agreement periods beginning on January 1, 2027, and in subsequent agreement periods, CMS calculates a single per capita value as follows:

Under § 425.658(c)(2)(ii)(A), we propose to specify that CMS would calculate the product of the following for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries)—

- The national per capita expenditures for Parts A and B services under the original OM FFS program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary; and
- The ACO's weighted average CMS–HCC risk score for that enrollment type for BY3.[289]

Under § 425.658(c)(2)(ii)(B), CMS would calculate 5 percent of each enrollment type-specific product determined in § 425.658(c)(2)(ii)(A). Under § 425.658(c)(2)(ii)(C), CMS would calculate the single per capita value as a person-year weighted average [290] by multiplying each of these enrollment type-specific values (determined in accordance with § 425.658(c)(2)(ii)(B)) by the proportion of the ACO's assigned beneficiaries within that particular enrollment type and then summing the results.

We also propose a technical and conforming change in § 425.672(c)(2)(iv), describing adjustment of calculation of national per capita OM expenditures for assignable beneficiaries for purposes of capping the prior savings adjustment (among other factors) for SAHS billing activity occurring in CY 2024 or subsequent calendar years. More specifically, in § 425.672(c)(2)(iv), we propose to amend the existing reference to § 425.658(c)(1)(ii), to refer instead to § 425.658(c)(1)(ii) and (c)(2)(ii) (as proposed).

We seek comment on the proposal to risk adjust the 5 percent cap used in calculating the value of the prior savings adjustment to the historical benchmark for agreement periods beginning on January 1, 2027, and in subsequent years. We also seek comment on the proposed calculation of the risk adjusted 5 percent cap as specified in proposed revisions to § 425.658, in paragraph (c)(2)(ii), as well as a proposed technical and conforming change to § 425.672(c)(2)(iv).

(c) Proposal To Risk Adjust the 5 Percent Cap on the Population Adjustment to the Historical Benchmark

We propose to risk adjust the 5 percent cap on national per capita expenditures for each Medicare enrollment type (ESRD, Disabled, Aged/dual, Aged/non-dual), used to calculate the population adjustment, according to the following steps:

- Step 1—Identify the proportion of the ACO's assigned beneficiaries for the performance year who are enrolled in the Medicare Part D Low-Income Subsidy (LIS) or are dually eligible for Medicare and Medicaid. Under existing policy, which we do not propose to change, an ACO with a proportion less than 15 percent is ineligible to receive the population adjustment.
- Step 2—Calculate risk-adjusted 5 percent of the national per capita expenditures for assignable beneficiaries as a single value by employing the following steps:

++ Step 2(i)—Identify the national per capita expenditures for assignable beneficiaries by enrollment type in BY3.

++ Step 2(ii)—Identify the ACO's weighted average CMS–HCC risk score by enrollment type for BY3.[291]

++ Step 2(iii)—By enrollment type, calculate the product of the amounts identified in Step 2(i) and Step 2(ii).

++ Step 2(iv)—By enrollment type, calculate the risk-adjusted, capped national per capita expenditures as 5 percent of the product derived in Step 2(iii).

++ Step 2(v)—Identify the proportion of the ACO's assigned beneficiaries within each enrollment type.

++ Step 2(vi)—To calculate the final risk-adjusted 5 percent national expenditure by enrollment type, multiply the amount from step 2(iv) by the enrollment proportions from Step 2(v).

++ Step 2(vii)—Sum the values in Step 2(vi) to express the risk-adjusted 5 percent of the national per capita expenditures for assignable beneficiaries as a single value.

- Step 3—Calculate population adjustment scaler by employing the following steps:

++ Step 3(i)—Identify the regional adjustment (expressed as a single value) and the prior savings adjustment.[292]

++ Step 3(ii)—Calculate the scaler as the difference between the values in Step 2(vii) and the higher of the regional adjustment and prior savings adjustment identified in Step 3(i).

- Step 4—Calculate the population adjustment as the product of the values derived in Step 1 and Step 3(ii), for an

[289] For more information on the calculation of the weighted average CMS–HCC risk score we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14. *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0.*

[290] For more information on the calculation of the person-year weighted average we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14. *https://www.cms.gov/files/document/medicare-shared-savings-program-shared-savings-losses-assignment-methodology-specifications-version.pdf-0.*

[291] For more information on the calculation of the weighted average CMS–HCC risk score, we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

[292] For more information on the calculation of the regional adjustment (expressed as a single value) and prior savings adjustment, we refer readers to sections 5 and 6 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

ACO eligible for the population adjustment.

We illustrate how the proposed calculation methodology would be applied, considering the following hypothetical example in which the population adjustment is calculated for an ACO with generally higher risk beneficiaries than the national assignable population. Note that by proposing to risk adjust the caps for the regional adjustment and prior savings adjustment, this directly influences the population adjustment an ACO receives; the hypothetical example below (Table B–G16) assumes increased regional and prior savings adjustment amounts under the proposed policy.

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TABLE B-G16: HYPOTHETICAL EXAMPLE OF STEPS FOR RISK ADJUSTING THE 5 percent CAPS ON THE POPULATION ADJUSTMENT TO HISTORICAL BENCHMARKS

	Amount Under Current Policy (No Risk Adjustment Applied to 5 percent Caps)	Amount Under Proposed Policy (Risk Adjustment Applied to 5 percent Caps)
Step 1: Identify the proportion of assigned beneficiaries with LIS or dual status.		
Proportion of LIS or dual beneficiaries for the performance year (if less than 15 percent, ACO is ineligible to receive population adjustment)	0.20	0.20
Step 2: Calculate risk-adjusted 5 percent of the national per capita expenditures for assignable beneficiaries as a single value		
Step 2(i): Identify the national per capita expenditures for assignable beneficiaries by enrollment type in BY3.		
ESRD	$100,000.00	$100,000.00
Disabled	$12,000.00	$12,000.00
Aged/dual	$20,000.00	$20,000.00
Aged/non-dual	$12,000.00	$12,000.00
Step 2(ii): Identify the ACO's weighted average CMS-HCC risk score by enrollment type for BY3.		
ESRD	NA	1.1022
Disabled	NA	0.9249
Aged/dual	NA	1.0648
Aged/non-dual	NA	1.0366
Step 2(iii): By enrollment type, calculate the product of the amounts identified in Step 2(i) and Step 2(ii).		
ESRD	$100,000.00	$110,222.22
Disabled	$12,000.00	$11,098.52
Aged/dual	$20,000.00	$21,296.18
Aged/non-dual	$12,000.00	$12,439.56
Step 2(iv): By enrollment type, calculate the risk-adjusted, capped national per capita values as 5 percent of the product derived in Step 2(iii).		
ESRD	$5,000.00	$5,511.11
Disabled	$600.00	$554.93
Aged/dual	$1,000.00	$1,064.81
Aged/non-dual	$600.00	$621.98
Step 2(v): Identify the proportion of the ACO's assigned beneficiaries within each enrollment type.		
ESRD	0.007	0.007
Disabled	0.052	0.052
Aged/dual	0.055	0.055
Aged/non-dual	0.886	0.886
Step 2(vi): To calculate the final risk-adjusted 5 percent national expenditure by enrollment type, multiply the amount from Step 2(iv) by the enrollment proportions from Step 2(v)		
ESRD	$35.00	$38.58
Disabled	$31.20	$28.86
Aged/dual	$55.00	$58.56
Aged/non-dual	$531.60	$551.07
Step 2(vii): Sum the values in Step 2(vi) to express the risk-adjusted 5 percent of the national per capita expenditures for assignable beneficiaries as a single value.		
Summed, capped BY3 national assignable expenditures.	$652.80	$677.07
Step 3: Calculate the population adjustment scaler.		
Step 3(i): Identify the regional adjustment (expressed as a single value) and the prior savings adjustment.		
Regional adjustment	$375.00	$400.00
Prior savings adjustment	$335.00	$350.00
Step 3(ii): Calculate the scaler as the difference between the values in Step 2(vii) and the higher of the regional adjustment or prior savings adjustment in Step 3(i).		
Population adjustment scaler	$277.80	$277.07
Step 4: Calculate the population adjustment as the product of the values derived in Step 1 and Step 3(ii).		
Population adjustment	$55.56	$55.41

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Because the population adjustment scales based on the difference between 5 percent of risk-adjusted national assignable expenditures and the greater

of the regional adjustment or prior savings adjustment, the proposed risk adjustments to the regional adjustment and prior savings adjustment caps would directly influence the final adjustment value an ACO receives.

For ACOs with higher-risk populations, the regional adjustment and prior savings adjustment will likely increase under the proposed policy, as expressed in the hypothetical example (Table B–G15). On the one hand, these increases reduce the available margin for the population adjustment by increasing the amount being subtracted from the scaler (for example, Steps 3(i) and 3(ii)). On the other hand, the risk-adjusted 5 percent cap for the population adjustment also increases for these ACOs with higher-risk populations, expanding the ceiling for the population adjustment amount (for example, Step 2(vii)). Consequently, the mechanisms of the proposed policy ensure that whichever adjustment an ACO ultimately receives is not limited by a flat 5 percent capped ceiling.

Based on an internal analysis simulating PY 2025 performance for 228 ACOs that entered new agreement periods beginning on January 1, 2025, risk adjusting the 5 percent cap on the regional adjustment, prior savings adjustment, and population adjustment would have the effect of increasing ACO benchmarks by an average of $2.98 (a 0.02 percent aggregate increase).[293] Among ACOs seeing a higher adjustment under this approach, benchmarks increased by an average of $84.18 (0.30 percent), while those ACOs with lower adjustments saw an average decrease of $27.66 (−0.22 percent). About half of ACOs (111 of 228, or 49 percent) had no change in their benchmark value under a risk-adjusted 5 percent cap for all three adjustments. While some ACOs (82 of 228, or 36 percent) had lower benchmarks under this approach, the magnitude of change for these ACOs was smaller than the gains made for ACOs that had an increase in their benchmarks (35 of 228, or 15 percent).

Among 91 ACOs receiving the regional adjustment as their adjustment category, these ACOs would have an average final adjustment that is $16.69 lower or 2.58 percent lower under the proposed policies compared to the current policy. Conversely, for the 8 ACOs that received the prior savings adjustment as their adjustment category, these ACOs would have an average final adjustment that is $142.21 higher or 14.42 percent higher, and 16 ACOs receiving the population adjustment would have an adjustment that is $69.10 higher or 12.61 percent higher. Additionally, 111 ACOs would see no change to their final adjustment under the proposed policy, 98 ACOs would have changes small enough that they ultimately would not impact benchmarks, and 2 ACOs changed the adjustment type received under the proposed policy (one with increased benchmarks and the other with decreased benchmarks as a result of the proposed policy and resultant change in adjustment type).

Ultimately, the simulation suggests that risk adjusting the caps will result in higher caps on positive adjustments for ACOs with above-average risk, which we believe may attract ACOs that serve more clinically complex populations with higher CMS–HCC risk scores or encourage existing ACOs to expand to include ACO providers/suppliers who serve such clinically complex populations.

We propose to revise and republish § 425.662(b)(2), to include the proposed approach to calculating the population adjustment applicable for agreement periods beginning on January 1, 2027, and in subsequent years, as well as the existing calculation of the population adjustment which would apply for agreement periods beginning on January 1, 2025, or January 1, 2026.

We propose to specify the existing provisions of § 425.662(b)(2), describing the calculation of the population adjustment, under new paragraph § 425.662(b)(2)(i). Accordingly, we propose to add a sentence at the start of the introductory text of new § 425.662(b)(2)(i) specifying the applicability of the calculation for agreement periods beginning on January 1, 2025, or January 1, 2026.

Under new § 425.662(b)(2)(ii), we propose to specify the calculation of the population adjustment scaler applicable for agreement periods beginning on January 1, 2027, and in subsequent years. We propose to calculate a scaler as the difference between: § 425.662(b)(2)(ii)(A), specifying a single per capita value that is the risk adjusted 5 percent cap, and § 425.662(b)(2)(ii)(B), specifying the highest among the regional adjustment (expressed as a single value), the per capita prior savings adjustment, or no adjustment (in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment) (specified in new § 425.662(b)(2)(ii)(B)).

We propose the following provisions to state how we would calculate the single per capita value reflecting the risk adjusted 5 percent cap. Under § 425.662(b)(2)(ii)(A)(*1*), we propose to calculate the product of the following bulleted items for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries)—

- The national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary;[294] and
- The ACO's weighted average CMS–HCC risk score for that enrollment type for BY3.[295]

Under proposed § 425.662(b)(2)(ii)(A)(*2*), CMS would calculate 5 percent of each enrollment type-specific product determined in § 425.662(b)(2)(ii)(A)(*1*). Under § 425.662(b)(2)(ii)(A)(*3*), CMS would calculate a single per capita value as a person-year weighted average[296] by multiplying each of these enrollment type-specific products (determined in accordance with § 425.662(b)(2)(ii)(A)(*2*)) by the proportion of the ACO's assigned beneficiaries within that particular enrollment type, then summing the results.

We seek comment on the proposal to risk adjust the 5 percent cap used for calculating the population adjustment to the benchmark applicable for agreement periods beginning on January 1, 2027, and in subsequent years, and related proposed changes to the Shared Savings Program regulations at § 425.662(b)(2) (as revised and republished).

[293] Internal analysis simulating PY 2025 performance for 228 ACOs that entered new agreement periods beginning on January 1, 2025, applying the proposed policy to risk adjust the 5 percent caps on the regional adjustment, prior savings adjustment, and population adjustment. Simulation results were compared to PY 2025 performance on PY 2025 final historical benchmarks to determine the impact of the proposed policies.

[294] We note that in the CY 2025 PFS final rule (89 FR 98158), we explained in detail how we calculate the national assignable expenditure amount used in this calculation, although the provision codified in § 425.662(b)(1) is more general.

[295] For more information on the calculation of the weighted average risk score we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

[296] For more information on the calculation of the person-year weighted average we refer readers to section 3.2 of the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14.

f. Proposal To Incentivize New Participation Through a Growth Adjustment to the Historical Benchmark

(1) Background

(a) Background on Adjusting the Historical Benchmark

Section 1899(d)(1)(B)(ii) of the Act addresses how ACO benchmarks are to be established, updated, and reset at the start of each agreement period under the Shared Savings Program. This provision specifies that the Secretary shall estimate a benchmark for each agreement period for each ACO using the most recent available 3 years of per beneficiary expenditures for Parts A and B services for OM beneficiaries assigned to the ACO. The benchmark shall be reset at the start of each agreement period. Section 1899(d)(1)(B)(ii) of the Act also provides the Secretary with discretion to adjust the historical benchmark by ''such other factors as the Secretary determines appropriate.'' Under this authority, over time we have adopted a variety of methods to adjust the historical benchmark to meet certain policy goals.

Relying on our authority under section 1899(d)(1)(B)(ii) of the Act, we codified benchmarking policies applicable to all ACOs in agreement periods beginning on January 1, 2024, and in subsequent years at § 425.652 (88 FR 79174 through 79208). We refer readers to discussions of the benchmark calculations in earlier rulemaking for details on the development of the current policies (November 2011 final rule, 76 FR 67909 through 67927; June 2015 final rule, 80 FR 32785 through 32796; June 2016 final rule, 81 FR 37953 through 37991; December 2018 final rule, 83 FR 68005 through 68030; CY 2023 PFS final rule, 87 FR 69875 through 69928; CY 2024 PFS final rule, 88 FR 79174 through 79208; CY 2025 PFS final rule, 89 FR 98155 through 98166; and CY 2026 PFS final rule, 90 FR 32690 through 32692).

In the CY 2023 PFS final rule, we adopted policies to modify the regional adjustment under § 425.656 (87 FR 69915 through 69923) and to reinstate a prior savings adjustment under § 425.658 (87 FR 69898 through 69915). The prior savings adjustment policy permits some renewing or re-entering ACOs to receive an adjustment to their benchmarks to account for savings generated in performance years that correspond to the benchmark years of their new agreement periods. The modifications to the regional adjustment limited the impact of negative regional adjustments on ACO historical benchmarks and further incentivized program participation among ACOs serving high-cost beneficiaries.

In the CY 2024 PFS final rule (88 FR 79185 through 79196), we modified the regional adjustment policy further to prevent any ACO from receiving an adjustment that would cause its benchmark to be lower than it would have been in the absence of a regional adjustment. In the CY 2024 PFS final rule (88 FR 79196 through 79200), we also modified the prior savings adjustment policy further to account for the following: a change in savings earned by the ACO in a benchmark year due to compliance action taken to address avoidance of at-risk beneficiaries; or a change in the amount of savings or losses for a benchmark year as a result of a reopening of a prior determination of ACO shared savings or shared losses and the issuance of a revised initial determination under § 425.315.

In the CY 2025 PFS final rule, we finalized provisions in §§ 425.652(a)(8) and 425.662 specifying the methodology for calculating the health equity benchmark adjustment (HEBA) to the historical benchmark, determining an ACO's eligibility for the adjustment, and the applicability of the adjustment (89 FR 61890 and 61891). In the CY 2025 PFS final rule, we noted the limitations of benchmarks based on historically observed spending, as they could be set too low if they are based on the spending of a population of underserved communities. The HEBA was finalized to provide additional financial resources to ACOs serving these populations, and to encourage those ACOs to attract and retain beneficiaries from communities that have faced challenges related to accessing care (89 FR 61887). The adjustment is calculated based on the number of beneficiaries an ACO serves who are either enrolled in the Medicare Part D Low-Income Subsidy (LIS) program or are dually eligible for Medicare and Medicaid, offering a targeted mechanism to reflect the needs of higher-risk populations.

In the CY 2026 PFS final rule, we renamed the HEBA as the ''population adjustment'' for clarity under § 425.662 (90 FR 32683 through 32685). This finalized revision more accurately reflects the nature of the adjustment, which accounts for the proportion of the ACO's assigned beneficiaries who are enrolled in the Medicare Part D LIS program or dually eligible for Medicare and Medicaid.

(b) Methodology for Determining the Applicability of a Regional Adjustment, Prior Savings Adjustment, or Population Adjustment to the ACO's Historical Benchmark, for Agreement Periods Beginning on or After January 1, 2025

We calculate three adjustments to the historical benchmark under the benchmarking methodology for agreement periods beginning on January 1, 2025, and in subsequent years. These adjustments are a regional adjustment (§ 425.656), prior savings adjustment (§ 425.658), and the population adjustment (§ 425.662). We then determine whether to apply one of the three adjustments or no adjustment to the ACO's historical benchmark (§ 425.652(a)(8)(ii)).

The following is an overview of how, under this methodology, we currently calculate the adjustment to apply when establishing benchmarks for ACOs entering an agreement period beginning on January 1, 2025, and in subsequent years:

- *Step 1:* We calculate the capped regional adjustment expressed as a single dollar value as specified in § 425.656. We calculate the regional adjustment to the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

++ Under § 425.656(c)(3), we cap the per capita dollar amount for each Medicare enrollment type at a dollar amount equal to a percentage of national per capita expenditures for Parts A and B services under the OM program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

— Under § 425.656(c)(3)(i), for positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

— Under § 425.656(c)(3)(ii), for negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 1.5 percent of the national per capita expenditure amount for the enrollment type for BY3.

++ Under § 425.656(d)(1), we express the regional adjustment as a single value by taking a person year[297] weighted

[297] To calculate person years: We sum the number of Shared Savings Program-eligible months (beneficiaries are only assigned a monthly enrollment status for months in which they are alive on 1st of the month, enrolled in both Parts A and B, and not enrolled in a Medicare Group Health

Continued

average of the Medicare enrollment type-specific regional adjustment values.

- *Step 2:* For eligible ACOs, we calculate the capped prior savings adjustment as specified in § 425.658. Under § 425.658(c)(1), we calculate an adjustment to the historical benchmark to account for savings an ACO generated in the 3 years prior to the start of the ACO's current agreement period for renewing or re-entering ACOs that were reconciled for one or more PYs in the Shared Savings Program during this period.
- *Step 3:* For eligible ACOs, we calculate the capped population adjustment as specified in § 425.662. Under § 425.662(b), we calculate an adjustment to the historical benchmark to offer a targeted mechanism to reflect the needs of higher-risk populations and account for ACOs with 15 percent or more assigned beneficiaries enrolled in LIS or dually eligible for Medicare and Medicaid during the PY.
- *Step 4:* We determine the final adjustment to the benchmark, as specified in § 425.652(a)(8)(ii). We compare the regional adjustment calculated in accordance with § 425.656, the prior savings adjustment calculated in accordance with § 425.658, and the population adjustment calculated in accordance with § 425.662.

++ Under § 425.652(a)(8)(ii), the ACO receives the highest of the positive adjustments for which it is eligible. The adjustments are calculated as described in § 425.656(c), § 425.658(c), or § 425.662(b), respectively, and applied separately to the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. If an ACO is not eligible to receive a prior savings adjustment under § 425.658(b)(3)(i) or the population adjustment under § 425.662(b)(3), and the regional adjustment, expressed as a single value as described in § 425.656(d), is negative or zero, the ACO does not receive an adjustment to its benchmark.

(c) Background on Incentivizing Growth in the Shared Savings Program

In recent years, we have repeatedly emphasized our interest in promoting growth in the Shared Savings Program through the policies we have established. In the CY 2024 PFS, we stated, ''This rulemaking also seeks to further advance Medicare's overall value-based care strategy of growth [. . .] through the Medicare Shared Savings Program'' (88 FR 78819). We reiterated this aim in the CY 2025 PFS final rule (89 FR 97711) and CY 2026 PFS final rule (90 FR 49768). Many of the Shared Savings Program policies finalized through past rulemaking have either directly or indirectly focused on increasing ACO participants in the program and increasing the number of beneficiaries receiving care from ACOs. For example, in the CY 2024 PFS final rule (88 FR 79139 through 79163) we modified the step-wise beneficiary assignment methodology by adding a new third step that uses an expanded period of time to identify if a beneficiary has received at least one primary care service from an ACO professional. This change, taken with all other changes in the CY 2024 PFS final rule, was designed to enhance program growth (88 FR 78819), making more than 331,000 additional beneficiaries eligible for assignment, and increasing overall participation in the Shared Savings Program. Based on an internal analysis of CY 2024 primary care services, nearly 300,000 active individual practitioners with specialties used in assignment and billing assignment eligible services had not participated in a Shared Savings Program ACO or CMS Innovation Center model initiative involving shared savings during the 6-year period from 2019 through 2024.

We have seen increasing participation in the Shared Savings Program since the start of the program in 2012, with 3 million beneficiaries assigned to Shared Savings Program ACOs in the program's first year and as of January 2026, over 12 million beneficiaries assigned to Shared Savings Program ACOs. We have observed that when participation in the program increases, we see increases in both quality improvements for beneficiaries and increased savings to the Trust Funds. The Shared Savings Program has had 8 consecutive years of generating savings for Medicare relative to benchmarks, with over $12 billion in total savings,[298] and with an upward trend in savings year over year.[299] Additionally, we have observed that Shared Savings Program ACOs have demonstrated improved quality performance over time and higher quality performance relative to other physician groups, suggesting that the Shared Savings Program is achieving savings while improving quality of care. Based on an internal CMS analysis of 87 Shared Savings Program ACOs that participated continuously in the Shared Savings Program between 2014 and 2023, Shared Savings Program ACOs showed statistically significant and substantial improvement across seven comparable CMS Web Interface quality measures used during that period, where quality performance improved across a wide range of clinical practice areas including screening and preventive measures and control of health conditions such as hypertension and diabetes. Please refer to Table B–G16 for details on the quality performance of these 87 Shared Savings Program ACOs. As discussed further in section III.G.3 of this proposed rule, Shared Savings Program ACOs have been transitioning to new quality measure collection types over the last several years and are now being assessed on the APP Plus quality measure set, that can pose limitations on comparing Shared Savings Program ACOs' most recent quality performance to their historical performance. Specifically, Shared Savings Program ACOs have transitioned from reporting on a sampling methodology (for example, web interface) to reporting on a broader patient population, which could impact comparisons on quality performance.

However, there is evidence that Shared Savings Program ACOs perform better than their MIPS counterparts under the new quality reporting collection types. In PY 2024, Shared Savings Program ACOs scored better than comparable MIPS groups on all three electronic clinical quality measures (eCQMs) in the APP Plus quality measure set, with the difference being statistically significant for two of those measures (Quality ID: 134 Preventive Care and Screening: Screening for Depression and Follow-Up Plan ($p < .001$) and Quality ID: 236 Controlling High Blood Pressure ($p < .01$) (90 FR 50002)). Shared Savings Program ACOs also performed better than comparable MIPS groups on two of the three MIPS CQMs in the APP Plus quality measure set and the difference was statistically significant for one measure (Quality ID: 236 Controlling High Blood Pressure ($p < .01$) (90 FR 50002)). Refer to Table B–G17 for an

Plan for the month) for each assigned beneficiary for each Medicare enrollment type; we then divide this number by 12 (the number of months in a calendar year). Refer to the Shared Savings and Losses, Assignment and Quality Performance Standard Methodology Specifications Version 14, Section 3.1 Calculating ACO-Assigned Beneficiary Expenditures.

[298] Additional information on past years Shared Savings Program Performance Year Finance and Quality Results is available at: *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results*.

[299] The Regulatory Impact Analysis reviews evidence that aggregate savings measured by benchmarks have been supported by observation of lower (higher) per capita spending trends in markets with earlier (later) ACO adoption.

overview of Shared Savings Program ACOs' PY 2024 quality performance relative to comparable MIPS Groups. Informed by the historical performance of the Shared Savings Program on savings and quality improvement by health care providers and for beneficiaries assigned to a Shared Savings Program ACO, we are interested in identifying additional incentives to grow participation in the Shared Savings Program and expand the reach of cost savings and improved quality of care.

TABLE B-G17: QUALITY PERFORMANCE AMONG 87 ACOS WHO PARTICIPATED IN THE SHARED SAVINGS PROGRAM CONTINOUSLY FROM PY 2014 to 2013

Quality #	Measure Title (CMS Web Interface)	PY 2014 Mean	PY 2023 Mean	Difference
001	Diabetes: Glycemic Status Assessment Greater Than 9% (Inverse measure)**	20.47	9.21	–11.25*
110	Preventive Care and Screening: Influenza Immunization	58.66	71.64	+12.98*
112	Breast Cancer Screening	62.51	81.53	+19.03*
113	Colorectal Cancer Screening	56.74	78.53	+21.79*
134	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	37.34	82.06	+44.73*
238	Controlling High Blood Pressure	67.32	80.20	+12.88*
318	Falls: Screening for Future Fall Risk	46.80	91.43	+44.62*

*Indicates statistically significant differences between ACOs in PY 2014 and 2023 ($p < .05$). The Difference column represents the mean PY 2023 ACO performance rate minus the mean PY 2014 ACO performance rate.
** This is an inverse measure, and a lower number indicates better quality performance.
Long–participating ACOs N=87.

TABLE B-G18: PY 2024 QUALITY MEASURES THAT SHARED SAVINGS PROGRAM ACOs PERFORMED BETTER ON THAN COMPARABLE MIPS GROUPS

Quality #	Measure Title	Difference in Mean ACO and MIPS Group Performance Rates for PY 2024 (%)*
	eCQMs	
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-3.75**
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	9.11****
236	Controlling High Blood Pressure	3.39***
	MIPS CQMs	
001	Diabetes: Hemoglobin A1c (HbA1c) Poor Control (>9%)	-7.63**
236	Controlling High Blood Pressure	8.59***
321	**CAHPS for MIPS**	0.08
CAHPS-1	Getting Timely Care, Appointments, and Information	2.47***
CAHPS-5	Health Promoting and Education	0.84
CAHPS-6	Shared Decision Makin	0.08
CAHPS-7	Health Status and Functional Status	0.11
CAHPS-11	Stewardship of Patient Resources	0.17
	Administrative Claims	
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	-0.59**

*The numbers in this column represent the mean ACO performance rate minus the mean MIPS group performance rate for each measure.
**This is an inverse measure, and a lower number indicates better quality performance.
***Indicates statistically significant differences between ACOs and comparable MIPS groups ($p < 0.01$).
****Indicates statistically significant differences between ACOs and comparable MIPS groups ($p < 0.001$).

As described previously, we have observed substantial evidence that the Shared Savings Program both generates savings and improves quality of care for beneficiaries. We also have observed there are still health care providers and beneficiaries not yet in accountable care relationships, and there is additional potential to increase participation in the Shared Savings Program and thereby continue to grow savings to the Medicare Trust Funds while improving the quality of care for beneficiaries. Although the number of primary care practitioners participating in a Shared Savings Program ACO has steadily grown over time, a targeted incentive that encourages ACOs to recruit new practitioners and the beneficiaries they serve may help offset some of the initial investment costs associated with first time participation. As of PY 2024, there were 12.3 million beneficiaries that were eligible to be assigned to a Shared Savings Program ACO but were not assigned to an ACO. Approximately 11.1 million of these beneficiaries were not part of any shared savings initiative in PY 2023 or PY 2024, 6.7 million of which were primarily served by one of the aforementioned 300,000 practitioners who had no shared savings experience during the 6-year period from 2019 through 2024. ACOs may seek to recruit these practitioners and in turn provide care for their beneficiary populations if a well-designed incentive could help reduce certain financial barriers to recruitment and initial participation.

(d) Background on Determining Risk Experience

In the December 2018 final rule (83 FR 67894 through 67899), we finalized the definitions of performance-based risk Medicare ACO initiative, and what it means for an ACO to be deemed experienced and inexperienced with performance-based risk Medicare ACO initiatives under § 425.20. Under paragraph (1) of the definition of ''experienced with performance-based risk Medicare ACO initiatives,'' an ACO is considered experienced if the ACO (or a plurality of its ACO participants) has participated in a CMS initiative that requires an ACO to participate under a two-sided model (with shared savings and losses) such as Level E of the BASIC track and the ENHANCED track of the Shared Savings Program or other Innovation Center ACO models such as ACO REACH.[300] Under paragraph (2) of the definition, an ACO is also considered experienced if forty percent or more of the ACO's participants participated in a performance-based risk Medicare ACO initiative in any of the 5 most recent performance years. This means either the ACO itself (as a legal entity) has participated in such a program, or 40 percent or more of its participating provider groups (TINs) participated in such a program during any of the five performance years prior to the start of the ACO's agreement period. An ACO is considered inexperienced with performance-based risk Medicare ACO initiatives if its legal entity has never participated in a Medicare program with shared savings and shared losses and if less than 40 percent of its participating provider groups (TINs) participated in such programs during each of the 5 performance years prior to the start of the ACOs agreement period. ACOs that are inexperienced with performance-based risk Medicare ACO initiatives can typically qualify for certain participation options in the Shared Savings Program that are not otherwise available.

(2) Proposed Growth Adjustment to the Historical Benchmark

Relying on our authority under section 1899(d)(1)(B)(ii) of the Act, we are proposing a growth adjustment to the historical benchmark applicable to ACOs in agreement periods beginning on January 1, 2027, and in subsequent years. The proposed growth adjustment would offer a method of upwardly adjusting an ACO's historical benchmark that would be applied in addition to the existing regional adjustment, prior savings adjustment, and population adjustment, up to the proposed cap of 5 percent of ACO risk-adjusted national per capita expenditures, if finalized; otherwise, it will remain as the existing 5 percent of national per capita expenditures. The intent of the growth adjustment is to directly target those ACOs that are actively engaged in expanding their beneficiary population and provide a financial incentive to reward growth above what we typically observe. To promote growth in the Shared Savings Program, this upward adjustment to the historical benchmark is designed to reward ACOs for recruiting ACO professionals inexperienced with value-based care arrangements who are also serving beneficiaries new to value-based care. Through the growth adjustment, we intend to provide a greater financial incentive for ACOs to recruit ACO professionals who are inexperienced with value-based care arrangements and serve more beneficiaries new to value-based care by increasing the likelihood that an ACO would earn shared savings and by potentially increasing the amount of shared savings earned.

Under proposed § 425.652(a)(8)(iii), an ACO would receive a growth adjustment, if applicable, in addition to the highest of the positive adjustments for which it is eligible, either the regional adjustment, prior savings adjustment, or population adjustment to the benchmark § 425.652(a)(8)(ii)(B). An ACO would be required to meet the eligibility criteria as described elsewhere in this section of this proposed rule to receive the growth adjustment to the historical benchmark. We note that the proposed risk-adjustment of the 5 percent cap (see section III.G.5.e. of this proposed rule), if finalized, would operate synergistically with the proposed growth adjustment, in that ACOs that are eligible for a growth adjustment may receive a greater adjustment with a risk-adjusted cap if the beneficiaries newly assigned to their ACO through newly recruited ACO professionals are also medically complex and high-risk beneficiaries.

Additionally, we note that, if finalized, the proposed modifications to the prior savings adjustment to increase the scaling factor (described in section III.G.5.d. of this proposed rule) would complement the proposed growth adjustment. Specifically, ACOs that receive a growth adjustment could generate larger performance year gross savings that would be accounted for in the calculation of future prior savings adjustments, thereby carrying a portion of the growth adjustment forward to a subsequent agreement period. Additionally, should we finalize our proposal to increase the prior savings adjustment scaling factor from 50 percent to 75 percent, ACOs that receive a growth adjustment and generate gross savings would then be able to carry a larger portion of that growth adjustment forward to the subsequent agreement period through the larger prior savings adjustment. The use of a proration factor, which is not subject to modifications under this proposed rule, to calculate the prior savings adjustment based on changes in the assigned beneficiary population size also helps ensure that growth adjustments that might be awarded in the prior agreement period are only carried forward to the subsequent agreement period if the ACO maintains its overall size. If the ACO were to decrease in size, the ACO would receive a smaller prior savings adjustment and thus carry forward a smaller portion of the growth adjustment from the prior agreement period.

We propose to calculate the growth adjustment as the product of the ACO's ''new growth'' share described in section III.G.5.f.(2)(a) of this proposed rule and the incentive factor described in section III.G.5.f.(2)(b) of this proposed rule.

(a) Determine the ACO's ''New Growth'' Share of Assigned Beneficiary Person Years

To identify the ACO's new growth share of assigned beneficiary person years, CMS would first need to identify the ACO's new growth. By new growth, we mean the number of beneficiaries (in person year terms) that are new to the Shared Savings Program that are brought into the program by ACO professionals who are inexperienced in shared savings initiatives. We propose to identify shared savings initiatives for the purpose of determining the growth adjustment (as defined at § 425.664(b)(1)) as an initiative implemented by CMS, including the Shared Savings Program (as defined at § 425.664(b)(1)(i)), the Innovation Center ACO models ((as defined at § 425.664(b)(1)(ii)) (for example, ACO REACH, LEAD, etc.), or other initiatives that may be specified by CMS ((as defined at § 425.664(b)(1)(ii)).[301]

We specify the proposed criteria to meet this proposed definition throughout this section of this proposed

[300] Refer to the Participation Options Report available to applicant ACOs on the Accountable Care Organization-Management System (ACO–MS) for other Innovation Center ACO models including ACO REACH.

[301] We will monitor for other similar models and initiatives in the future.

rule under § 425.664. To identify the ACO's new growth, we must first identify the ACO professionals who are inexperienced in shared savings initiatives. The second step is then to determine the number of beneficiaries (in person year terms) that are new to the Shared Savings Program that are brought into the program by these inexperienced ACO professionals.

Therefore, we first propose to define ACO professionals inexperienced with shared savings initiatives under § 425.664(b)(2) similar to the way we define how ACOs are ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' in § 425.20. Under § 425.664(b)(2), we propose that for an ACO professional to be considered inexperienced in a shared savings initiative for the growth adjustment (as defined at § 425.664(b)(1)), the ACO professional must not have billed primary care services through a participant in the Shared Savings Program, or participated in an Innovation Center ACO model, or other initiative specified by CMS for one or more performance years in any of the 5 performance years directly preceding the start of the ACO's current agreement period. In other words, for an ACO professional to be considered experienced in a shared savings initiative, described as follows, the ACO professional must have billed primary care services through a participant in the Shared Savings Program, or participated in an Innovation Center ACO model, or other initiative specified by CMS, for one or more performance years of any of the 5 performance years directly preceding the start of the ACO's current agreement period.

Among the ACO professionals who we determine to be inexperienced in a shared savings initiative under § 425.664(b)(2), we then determine the number of beneficiaries (in person year terms) that are new to the Shared Savings Program that are brought into the program by these inexperienced ACO professionals under § 425.664(b)(3). To determine the number of these beneficiaries (in person year terms), we first need to determine an assigned beneficiary's experience in shared savings initiatives. To do so, we propose applying a similar definition as used to identify inexperienced ACO professionals to determine beneficiary experience in shared savings initiatives under § 425.664(b)(2). Thus, under § 425.664(b)(3) we propose that for an ACO assigned beneficiary to be considered inexperienced with a shared savings initiative, the ACO assigned beneficiary was not included in assignment in financial reconciliation to a Shared Savings Program ACO, Innovation Center ACO model, or other initiative specified by CMS in the performance year that corresponds to the ACO's BY3[302] under § 425.664(b)(3). In other words, for an ACO assigned beneficiary to be considered experienced with a shared savings initiative, the beneficiary would have to have been assigned to a Shared Savings Program ACO, Innovation Center ACO model, or other initiative specified by CMS and included in financial reconciliation for the performance year that corresponds to the ACO's BY3.

Under § 425.664(b)(4), we propose to measure new growth for each ACO in a given performance year as: (1) the number of assigned beneficiary person years inexperienced with a shared savings initiative; that (2) have an ACO professional who is inexperienced with a shared savings initiative as the ACO professional who provided the highest number of primary care services (as defined at § 425.20) at the ACO within the assignment window, or to whom the beneficiary was voluntarily aligned. To qualify as new growth, both characteristics must be present. Under § 425.664(b)(4), we propose to determine which ACO professional provided the highest number of primary care services (as defined at § 425.20) included in assignment for each assigned beneficiary at the ACO during the assignment window for the relevant performance year, or to whom the beneficiary voluntarily aligned. Refer to the example provided in Step 1.

TABLE B-G19: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 1

Step 1: Calculate an ACO's new growth for the applicable performance year	New Growth = Number of assigned beneficiary person years inexperienced with a shared savings initiative that have an ACO professional inexperienced with shared savings initiatives as the primary ACO professional that provided the highest count of primary care services. New Growth = 3,000 assigned beneficiary person years.

As a guardrail to ensure that measured new growth is contributing to overall growth in the program, only ACOs that grow and maintain their size, as measured by the count of assigned beneficiary person years, are eligible to receive an incentive, we propose to cap new growth. We propose to cap new growth to ensure ACOs are not only recruiting inexperienced ACO professionals and beneficiaries but additionally are maintaining their existing practitioner and beneficiary populations over the course of their agreement period, thus contributing to overall growth in the program. Under § 425.664(c), the first step to determine whether the cap on new growth applies, is to determine the overall growth as the difference between the number of beneficiary person years assigned to the ACO during final assignment in the performance year and the number of beneficiary person years assigned to the ACO during final assignment in the PY that corresponds to the ACO's BY3. If the ACO is a new entrant or re-entering ACO, the overall growth is equal to the number of assigned beneficiary person years in the performance year.

For re-entering ACOs, defined under § 425.20, overall growth will also be set equal to the number of assigned beneficiaries in the performance year. We propose to handle re-entering ACOs in this way because they may have had a multi-year gap in participation since their prior participation agreement, be heavily comprised of ACO participants

[302] Throughout this section, the assignment associated with the performance year that corresponds to the ACO's BY3 refers to the point in time from which to determine growth in assigned beneficiaries. For example, for an ACO that may begin an agreement period on January 1, 2027, we mean the final assignment list for PY 2026; we do not mean the benchmark year assignment list for BY 2026, which is the ACO's BY3. We use this as the point of comparison, so that we can determine the growth in assignment that occurred prior to the start of the agreement period relative to the applicable performance year, which will not be as clearly reflected if we used the current agreement period's participant list and BY3 assignment.

from multiple prior ACOs, or may have split off from another ACO. Therefore, for ACOs that are new or re-entering, we would not have a comparable way to measure overall growth as we do for ACOs that are not new or re-entering (for example, using the performance year that corresponds to the ACO's BY3 from which to calculate the ACO's overall growth for the performance year). In an analysis of all re-entering ACOs between PY 2022 and PY 2026, two-thirds of re-entering ACOs had a smaller assigned beneficiary population than in their prior participation agreement. The complex nature of re-entering ACOs' composition makes it difficult to determine a fair and accurate beneficiary count to be used in determining a baseline for capped new growth. Only providing the incentive to inexperienced ACO professionals and beneficiary who have not been assigned to an ACO in the final assignment for the PY that corresponds to the ACO's BY3 ensures that only the new growth is counted toward the incentive and acts as a guardrail to mitigate any unintended incentives created by the treatment of re-entering ACOs as new entrants. For example, any currently participating ACOs that terminate and immediately re-enter, or that split into multiple new re-entering ACOs would still need to add additional inexperienced ACO professionals and beneficiaries to their organization to receive the growth adjustment. ACO professionals and beneficiaries added during the previous agreement period, prior to terminating and re-entering would not be considered inexperienced, and therefore would not count towards the incentive. This mitigates against the possibility that an ACO might terminate and re-enter to set their baseline count of beneficiaries to zero.

TABLE B-G20: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 2

Step 2: Determine overall growth	overall growth = Number of assigned beneficiary person years in the PY minus the number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 (if applicable). If the ACO is a new entrant or re-entering, the overall growth is equal to the number of assigned beneficiary person years in the PY Continuing ACO Example: Number of assigned beneficiary person years in the PY = 11,000 Number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 = 5,000 overall growth = 11,000 - 5,000 = 6,000 assigned beneficiary person years New Entrant or Re-Entering ACO Example: Number of assigned beneficiary person years in the PY = 11,000 Number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 = 0 overall growth = 11,000 - 0 = 11,000 assigned beneficiary person years

The third step to determine the cap on the new growth is to take the lesser of the new growth and the overall growth under § 425.664(d) (refer to Example Tables 1 through 4 for examples of this calculation). For new entrant ACOs that did not participate prior to the current agreement period, assuming zero assigned beneficiary person years for the performance year corresponding to the ACO's BY3, the overall growth in the number of assigned beneficiary person years, which will determine the cap on the new growth, will be equivalent to the total number of assigned beneficiary person years in the current performance period. As described elsewhere in this section of this proposed rule, we propose to treat re-entering ACOs the same as new entrant ACOs for the purposes of this calculation as well. We note as proposed, the cap effectively would not apply for new entrant ACOs and re-entering ACOs because new growth and the total number of assigned beneficiaries in a performance year will always be the same. Refer to the example provided in Step 3.

TABLE B-G21: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 3

Step 3: Determine capped new growth	Capped new growth = the lesser of the new growth determined in Step 1 and the overall growth determined in Step 2. overall growth = 6,000 assigned beneficiary person years new growth = 3,000 assigned beneficiary person years capped new growth = 3,000 assigned beneficiary person years

We recognize that there are typically new ACO professionals who join Shared Savings Program ACOs annually, as well as new beneficiaries assigned to Shared Savings Program ACOs annually. The intent of the growth adjustment is to provide a financial incentive to reward growth above what we typically observe. Accordingly, under § 425.664(e), we propose to apply the minimum new growth thresholds in Table B–G22 for each performance year of an agreement period above which the ACO would need to grow with ACO professionals that have not previously participated in shared savings initiatives and beneficiaries that have not previously been assigned to an ACO to receive the growth adjustment.

Under § 425.664(e), we propose determining the minimum new growth

threshold on a relative basis, defined as the person years of the minimum new growth divided by total assigned beneficiary person years, and on an absolute basis, defined as the number of person years of the minimum new growth for the PY according to Table B–G22. We propose to determine the threshold on both an absolute and relative basis to ensure parity and equal opportunity for ACOs of various sizes to receive the incentive. For example, the relative threshold creates an incentive for ACOs that are smaller, in which small additions in assigned beneficiaries would substantially impact the ACO's relative size. Whereas, the absolute threshold creates an incentive for ACOs that are larger to recruit practices that may not otherwise substantially impact the relative size of those ACOs. We propose the following absolute and relative minimum new growth thresholds for PY1 through PY5:

TABLE B-G22: ABSOLUTE AND RELATIVE MINIMUM "NEW GROWTH" THRESHOLDS OVER AN AGREEMENT PERIOD

	PY 1	PY 2	PY 3	PY 4	PY 5
Absolute Minimum New Growth Threshold	100	300	600	900	1200
Relative Minimum New Growth Threshold	0.5%	1.5%	3.5%	5.5%	7.5%

We identified these proposed minimum thresholds by analyzing Shared Savings Program ACO program data from 2017 through 2026. To identify a proposed minimum threshold for each performance year, we looked at ACOs that began their second or subsequent agreement period (that is, not new or re-entering ACOs) on or before January 1, 2022 that were still participating through the start of 2026 and experienced new growth (as we now propose to define it). CMS then set the threshold at the 25th percentile of new growth, based on the observed inflection point in the distribution of new growth for each performance year. While we understand that many ACOs experience some natural growth, we intend the growth adjustment as an incentive for ACOs to actively engage in expanding their beneficiary population that is inexperienced and expand their ACO participants who are inexperienced. We determined that setting the threshold at the 25th percentile [303] was sufficient to make the distinction between natural population variation and those ACOs that were actively recruiting new participants and growing their ACOs, while maintaining reasonable growth rates for ACOs of all sizes, as demonstrated by ACOs in this analysis. We propose that only ACOs that exceed this threshold in a given year would qualify for the growth adjustment.

This analysis showed that new growth steadily increased among ACOs in this sample in each year relative to the PY that corresponds to the ACO's BY3, but the rate of increase was not consistent or linear. The proposed thresholds approximately matched observed rates of growth year to year among the ACOs in this sample. The proposed thresholds increase in each subsequent performance year to account for natural changes in the assigned beneficiary and ACO professional populations.[304] Thus we propose to measure new growth relative to the performance year that corresponds to the ACO's BY3. The larger thresholds in later performance years ensures that measured new growth is primarily the result of ACOs targeting intentional growth and not natural composition changes. We propose that we will periodically re-evaluate the determined thresholds, and if changes to these thresholds are needed we would expect the updates to be on a performance year basis (rather than agreement period basis). We would propose changes to the minimum new growth thresholds in rulemaking. We expect that updates to these thresholds will be infrequent to provide additional predictability in the proposed growth adjustment.

Under § 425.664(e), we propose to determine which minimum new growth threshold is applied to an ACO by taking the lesser of the absolute and relative thresholds after we convert the relative threshold to beneficiary person years by multiplying the relative threshold by the ACO's total assigned beneficiary person years in the PY. Refer to the example provided in Step 4.

TABLE B-G23: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 4

Step 4: Determine which minimum new growth threshold is applied	Minimum new growth threshold applied = the lesser of the relative minimum new growth threshold and the absolute minimum new growth threshold. Absolute minimum new growth threshold = 100 assigned beneficiary person years. Relative minimum new growth threshold = 0.5% assigned beneficiary person years x total assigned beneficiary person years (11,000) = 55 assigned beneficiary person years. Minimum new growth threshold applied = 55 assigned beneficiary person years.

[303] The absolute and relative distribution of new growth among all ACOs *and* ACOs experiencing growth was a right-skewed L-shaped distribution with many ACOs experiencing little to no growth, a few experiencing extreme growth, and the middle set experiencing some growth. The first slope change (that is, inflection point) distinguished the majority of ACOs who experienced little to no new growth as defined in this proposed rule and in § 425.664(b)(4) from those who may have made composition changes to increase their ACO size. Among ACOs who participated for a full agreement period and experienced new growth, the first inflection point occurred at approximately the 25th percentile.

[304] In other words, the composition of ACOs' beneficiary and ACO professional populations are not static. ACOs experience population changes as time passes. As more time passes, more changes will occur. These changes are the natural result of employment changes among ACO professionals, and changes in care patterns among beneficiaries—both of which occur even in organizations not engaged in actively expanding. Since growth is measured against a fixed time period, and the number of changes increases over time, the thresholds need to increase as the time relative to the PY corresponding to the ACO's BY3 increases.

The new growth above the minimum and below the cap is the amount of newly assigned beneficiary person year growth eligible for the growth incentive. Under § 425.664(f), we propose to calculate new growth above the minimum and below the cap, which is the portion of new growth for which ACOs may be eligible to receive a growth adjustment, as the difference between the new growth and the minimum new growth threshold, or 0, if negative. We propose to calculate new growth above the minimum and below the cap in this way so that ACOs are rewarded for contributing to overall growth in the Shared Savings Program. The minimum thresholds in conjunction with the cap ensures CMS is rewarding ACOs engaged in actively expanding their assigned population with beneficiaries not currently in an accountable care relationship. Refer to the example provided in Step 5.

TABLE B-G24: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 5

Step 5: Determine new growth above minimum and below the cap	New growth above the minimum and below the cap = the difference of capped new growth determined in Step 3 and the minimum new growth threshold applied in Step 4. Capped New Growth = 3,000 assigned beneficiary person years Minimum new growth threshold applied = 55 assigned beneficiary person years New growth above the minimum and below the cap = 3,000 - 55 = 2,945 assigned beneficiary person years.

To facilitate the calculation of a per capita growth adjustment to be applied to the historical benchmark, we must first calculate this new growth as a proportion of the ACO's total assigned beneficiary person years. Therefore, we propose to determine an ACO's new growth share. Under § 425.664(g), we propose to determine the new growth share as the ratio of the new growth above the minimum and below the cap divided by the ACOs number of assigned beneficiary person years for the PY. This value will be multiplied by the incentive factor to determine the growth adjustment to the historical benchmark. Refer to the example provided in Step 6.

TABLE B-G25: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 6

Step 6: Calculate new growth share	New Growth Share = new growth above the minimum and below the cap determined in Step 5 divided by the number of assigned beneficiary person years in the PY. New growth above the minimum and below the cap = 2,945 Number of assigned beneficiary person years in the PY = 11,000 New growth share = 2,945 / 11,000 = 0.268.

We provide four example scenarios for determining the new growth share for hypothetical ACOs over an agreement period to illustrate the multiple steps of the calculation, using the minimum new growth thresholds established in Table B–G22.

EXAMPLE 1: NEW GROWTH CAPPED BY OVERALL GROWTH OVER AN AGREEMENT PERIOD

		Base	PY1	PY2	PY3	PY4	PY5
	Total assigned person years	5000	11000	11000	12000	13000	7000
Step 1	New growth person years		3000	1500	2000	2500	3000
Step 2	Overall growth [Total assigned person years in PY - Base]		6000	6000	7000	8000	2000
Step 3	Capped new growth [Step 1 ≤ Step 2]		3000	1500	2000	2500	2000
Step 4	Minimum new growth threshold applied		55	165	420	715	490
Step 5	New growth above the minimum and below the cap [Step 3 – Step 4]		2945	1335	1580	1785	1510
Step 6	New growth share [Step 5 ÷ Total assigned person years in PY]		0.268	0.121	0.132	0.137	0.216

EXAMPLE 2: LARGE ACO WITH ABSOLUTE THRESHOLD APPLIED OVER AN AGREEMENT PERIOD

		Base	PY1	PY2	PY3	PY4	PY5
	Total assigned person years	50000	55000	56000	57000	58000	56000
Step 1	New growth person years		1000	1500	2000	2500	3000
Step 2	Overall growth [Total assigned person years in PY - Base]		5000	6000	7000	8000	6000
Step 3	Capped new growth [Step 1 ≤ Step 2]		1000	1500	2000	2500	3000
Step 4	Minimum new growth threshold applied		100	300	600	900	1200
Step 5	New growth above the minimum and below the cap [Step 3 – Step 4]		900	1200	1400	1600	1800
Step 6	New growth share [Step 5 ÷ Total assigned person years in PY]		0.016	0.021	0.025	0.028	0.032

EXAMPLE 3: NEW ENTRANT OR RE-ENTERING ACO WHERE BASE EQUALS ZERO OVER AN AGREEMENT PERIOD

		Base	PY1	PY2	PY3	PY4	PY5
	Total assigned person years	0	10000	11000	12000	13000	11000
Step 1	New growth person years		1000	1500	2000	2500	3000
Step 2	Overall growth [Total assigned person years in PY - Base]		10000	11000	12000	13000	11000
Step 3	Capped new growth [Step 1 ≤ Step 2]		1000	1500	2000	2500	3000
Step 4	Minimum new growth threshold applied		50	165	420	715	770
Step 5	New growth above the minimum and below the cap [Step 3 – Step 4]		950	1335	1580	1785	2230
Step 6	New growth share [Step 5 ÷ Total assigned person years in PY]		0.095	0.121	0.132	0.137	0.203

EXAMPLE 4: SLOW "NEW GROWTH" AND GROWTH DECLINED IN LATER PY OVER AN AGREEMENT PERIOD

		Base	PY1	PY2	PY3	PY4	PY5
	Total assigned person years	5000	5000	6000	7000	8000	6000
Step 1	New growth person years		100	150	250	50	0
Step 2	Overall growth [Total assigned person years in PY - Base]		0	1000	2000	3000	1000
Step 3	Capped new growth [Step 1 ≤ Step 2]		0	150	250	50	0
Step 4	Minimum new growth threshold applied		25	90	245	440	420
Step 5	New growth above the minimum and below the cap [Step 3 – Step 4]		0	60	5	0	0
Step 6	New growth share [Step 5 ÷ Total assigned person years in PY]		0	0.01	0.001	0	0

(b) Determine the ACO's Incentive Factor

To determine a dollar amount for the proposed adjustment to the historical benchmark, under § 425.664(h), we propose to establish an incentive factor, which would be the per capita dollar amount that would convert the new growth share into dollar terms. The proposed incentive factor would be based on a percentage of the ACO's per capita historical benchmark and when multiplied against the new growth share will determine the dollar amount added to an ACO's historical benchmark. We propose to determine an ACO's incentive factor as an ACO-specific per capita dollar amount. We propose to calculate this per capita dollar amount as 5 percent of the per capita historical benchmark before the regional adjustment, prior savings adjustment, or population adjustment is applied, expressed as a single value. The CMS Office of the Actuary (OACT) provided information to support that 5 percent of the ACO's unadjusted historical benchmark is sufficient to incentivize recruitment of inexperienced ACO professionals while balancing savings in the program, and is described in the Regulatory Impacts Analysis, in section VII. of this proposed rule. Calculating the incentive factor as a percentage of the ACO's unique historical benchmark ensures the adjustment is specific to the ACO and provides a greater incentive, especially for ACOs caring for medically complex high-cost beneficiaries, than just a flat dollar for all ACOs. Refer to the example of the determination of the Incentive Factor provided in Step 7.

TABLE B-G26: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 7

Step 7: Determine the incentive factor	Incentive factor = 5% of historical benchmark before adjustment is applied historical benchmark before adjustment is applied = $13,000 incentive factor = $13,000 x 5% = $650

To follow is an example scenario of determining the ACO's incentive factor for a hypothetical ACO over an agreement period.

TABLE B-G27: CALCULATION OF THE INCENTIVE FACTOR OVER AN AGREEMENT PERIOD

		PY1	PY2	PY3	PY4	PY5
	Historical Benchmark before Adjustments are Applied ($)	13,000	15,500	14,500	16,000	15,750
	Percentage Applied to the Historical Benchmark	5%	5%	5%	5%	5%
Step 7	Incentive Factor ($)	650.00	775.00	725.00	800.00	787.50

(c) Determine the ACO's Growth Adjustment to the Historical Benchmark

Under § 425.664(I)(1), we propose to calculate the growth adjustment as the product of the ACO's new growth share, defined in section III.G.5.f.(2)(a) of this proposed rule, and the ACO's incentive factor, defined in section III.G.5.f.(2)(b) of this proposed rule. Refer to the example provided in Step 8.

TABLE B-G28: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 8

Step 8: Determine the growth adjustment to the historical benchmark	Determine the growth adjustment to the historical benchmark = new growth share determined in Step 6 and the incentive factor determined in Step 7 new growth share = 0.268 incentive factor = $650 growth adjustment to the historical benchmark = $174.02

Under § 425.652(a)(8)(iii), we propose that the growth adjustment amount would be added to the highest of the positive regional adjustment, prior savings adjustment, and population adjustment, or no adjustment, and the total amount could not exceed 5 percent of national per capita OM expenditures, adjusted for risk (if finalized), as discussed in section III.G.5.e of this proposed rule, otherwise if not finalized, the total amount could not exceed the existing 5 percent of national per capita OM expenditures, not adjusted for risk. Refer to the example provided in Step 9.

TABLE B-G29: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1, STEP 9

Step 9: Determine the final adjustment to the historical benchmark	Final adjustment to the historical benchmark = sum of the growth adjustment to the historical benchmark determined in Step 8 and the highest of the regional adjustment, prior savings adjustment, and the population adjustment, not to exceed 5% of the risk-adjusted national assignable FFS expenditures expressed as a single value; otherwise, the existing 5% of national per capital OM expenditures, not adjusted for risk. growth adjustment to the historical benchmark = $174.02 highest of the regional, prior savings, or population adjustment if applicable = $125 5% of the national FFS expenditures expressed as a single value = $350 final adjustment to the historical benchmark = $299.02

To follow is an example scenario of determining an ACO's growth adjustment and Final Adjustment to the Historical Benchmark.

TABLE B-G30: DETERMINATION OF THE GROWTH ADJUSTMENT AND FINAL ADJUSTMENT TO THE BENCHMARK OVER AN AGREEMENT PERIOD

		PY1	PY2	PY3	PY4	PY5
Step 6	"New Growth" Share	0.268	0.121	0.132	0.137	0.216
Step 7	Incentive Factor ($)	650.00	775.00	725.00	800.00	787.50
Step 8	Growth Adjustment ($)	174.02	94.06	95.46	109.85	169.88
	Regional, Prior Savings, or Population Adjustment, if Applicable ($)	125.00	230.00	75.00	350.00	410.00
	Growth Adjustment + Highest Applicable Adjustment ($)	299.02	324.06	170.46	459.85	579.88
	Risk-Adjusted Cap on Adjustments to the Benchmark, not to exceed 5% of National Assignable FFS Expenditures, expressed as a Single Value, if finalized. Otherwise, the Existing 5% National Assignable FFS Expenditures, expressed as a Single Value Not Adjusted for Risk. ($)	350.00	400.00	475.00	500.00	500.00
Step 9	Final Adjustment to the Benchmark ($)	299.02	324.06	170.46	459.85	500.00

We summarize the proposed steps of the calculation of the growth adjustment as follows in Table B–G31.

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TABLE B-G31: HYPOTHETICAL ACO GROWTH ADJUSTMENT CALCULATION FOR PY1

Step 1: Calculate an ACO's new growth for the applicable performance year	new growth = number of assigned beneficiary person years inexperienced with a shared savings initiative that have an ACO professional inexperienced with shared savings initiatives as the primary ACO professional that provided the highest count of primary care services new growth = 3,000 assigned beneficiary person years
Step 2: Determine overall growth	overall growth = number of assigned beneficiary person years in the PY minus the number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 (if applicable). If the ACO is a new entrant or re-entering, the overall growth is equal to the number of assigned beneficiary person years in the PY Continuing ACO Example: Number of assigned beneficiary person years in the PY = 11,000 Number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 = 5,000 overall growth = 11,000 - 5,000 = 6,000 assigned beneficiary person years New Entrant or Re-Entering ACO Example: Number of assigned beneficiary person years in the PY = 11,000 Number of assigned beneficiary person years in the PY that corresponds to the ACO's BY3 = 0 overall growth = 11,000 - 0 = 11,000 assigned beneficiary person years
Step 3: Determine capped new growth	Capped new growth = the lesser of the new growth determined in Step 1 and the overall growth determined in Step 2. overall growth = 6,000 assigned beneficiary person years new growth = 3,000 assigned beneficiary person years capped new growth = 3,000 assigned beneficiary person years
Step 4: Determine which minimum new growth threshold is applied	Minimum new growth threshold applied = the lesser of the relative minimum new growth threshold and the absolute minimum new growth threshold absolute minimum new growth threshold = 100 assigned beneficiary person years relative minimum new growth threshold = 0.5% assigned beneficiary person years x total assigned beneficiary person years (11,000) = 55 assigned beneficiary person years minimum new growth threshold applied = 55 assigned beneficiary person years
Step 5: Determine new growth above minimum and below the cap	New growth above the minimum and below the cap = the difference of capped new growth determined in Step 3 and the minimum new growth threshold applied in Step 4 capped new growth = 3,000 assigned beneficiary person years minimum new growth threshold applied = 55 assigned beneficiary person years new growth above the minimum and below the cap = 3,000 - 55 = 2,945 assigned beneficiary person years
Step 6: Calculate new growth share	New growth share = new growth above the minimum and below the cap determined in Step 5 divided by the number of assigned beneficiary person years in the PY new growth above the minimum and below the cap = 2,945 number of assigned beneficiary person years in the PY = 11,000 new growth share = 2,945 / 11,000 = 0.268
Step 7: Determine the incentive factor	Incentive factor = 5% of historical benchmark before adjustment is applied historical benchmark before adjustment is applied = $13,000 incentive factor = $13,000 x 5% = $650
Step 8: Determine the growth adjustment to the historical benchmark	Determine the growth adjustment to the historical benchmark = new growth share determined in Step 6 and the incentive factor determined in Step 7 new growth share = 0.268 incentive factor = $650 growth adjustment to the historical benchmark = $174.02

Step 9: Determine the final adjustment to the historical benchmark	Final adjustment to the historical benchmark = sum of the growth adjustment to the historical benchmark determined in Step 8 and the highest of the regional adjustment, prior savings adjustment, and the population adjustment, not to exceed 5% of the risk-adjusted national assignable FFS expenditures expressed as a single value; otherwise, the existing 5% of national per capital OM expenditures, not adjusted for risk. growth adjustment to the historical benchmark = $174.02 highest of the regional, prior savings, or population adjustment if applicable = $125 5% of the national FFS expenditures expressed as a single value = $350 final adjustment to the historical benchmark = $299.02

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We seek comment on the proposal to apply a growth adjustment to the historical benchmark in addition to the existing regional, prior savings and population adjustments, up to the existing 5 percent cap on upward adjustments to the historical benchmark, or if finalized, the risk-adjusted 5 percent cap described in section III.G.5.e. of this proposed rule for agreement periods beginning on January 1, 2027, and in subsequent years.

(3) Timing of Applicability

We propose to apply the growth adjustment proposal for agreement periods beginning on January 1, 2027, and in subsequent years. If finalized, for ACOs with agreement periods beginning on January 1, 2027, we would use CY 2021 through CY 2026 as the 5-year period used to determine whether ACO professionals are inexperienced with shared savings initiatives. For ACOs with agreement periods beginning on January 1, 2027, we would use CY 2026 as the 1-year period to determine whether beneficiaries are inexperienced with shared savings initiatives for ACOs.

We seek comment on this proposal.

g. Proposal To Reform the Accountable Care Prospective Trend (ACPT) Component of the Benchmark Update Factor

(1) Background

As finalized in the December 2018 final rule (83 FR 68024 through 68030), we used our statutory authority under section 1899(i)(3) of the Act to adopt the policy under which we update the historical benchmark using a blend of national and regional growth rates, rather than the projected absolute amount of growth in national per capita expenditures for Parts A and B services under the original Medicare FFS program as required under section 1899(d)(1)(B)(ii) of the Act. In accordance with § 425.601(b), applicable for agreement periods beginning on or after July 1, 2019, and before January 1, 2024,[305] we update the historical benchmark for an ACO for each performance year using a blend of national and regional growth rates between BY3 and the performance year. To update the benchmark, we make separate calculations for expenditure categories for each of the following populations of beneficiaries based on Medicare enrollment type: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, aged/non-dual eligible for Medicare and Medicaid (§ 425.601(b)(1)).

The national-regional blend is a weighted average of national FFS and regional growth rates between BY3 and the performance year for the applicable Medicare enrollment type (§ 425.601(b)(4)). The national growth rates are computed using CMS Office of the Actuary national Medicare expenditure data for BY3 and the performance year for assignable beneficiaries (as defined at § 425.20) identified for the 12-month calendar year corresponding to each year (§ 425.601(b)(2)). Regional growth rates are computed using expenditures for the ACO's regional service area for BY3 and the performance year (§ 425.601(b)(3)). To calculate regional expenditures, we determine the counties included in the ACO's regional service area based on the ACO's assigned beneficiary population for the year and determine the ACO's regional expenditures as specified under § 425.601(c) and (d) and § 425.601(b)(3)(i) (ii).

As noted, the national and regional growth rates are blended together by taking a weighted average of the two. The weight assigned to the national component of the national-regional blend for a given Medicare enrollment type is calculated as the share of assignable beneficiaries in the ACO's regional service area that are assigned to the ACO for the applicable performance year (as calculated in § 425.601(a)(5)(v) and (§ 425.601(b)(4)(i)). The weight assigned to the regional component of the national-regional blend for a given Medicare enrollment type is equal to 1 minus the weight applied to the national growth rate (§ 425.601(b)(4)(ii)). Under this approach, as an ACO's penetration in its regional service area increases, the weight applied to the national component of the national-regional blend increases and the weight applied to the regional component decreases.

The national and regional growth rates are blended together by taking a weighted average of the two. Specifically, for each Medicare enrollment type, the national-regional blended growth rate is equal to the sum of the following: (1) the growth rate for national assignable FFS expenditures for BY3 to the performance year multiplied by the weight assigned to the national component; and (2) the average growth rate for regional FFS expenditures for BY3 to the performance year based on the ACO's regional service area multiplied by the weight assigned to the regional component (87 FR 69881). In accordance with § 425.601(a)(5), we also use blended national-regional growth rates to trend forward expenditures for each benchmark year (BY1 and BY2) to BY3 dollars, making separate calculations for each Medicare enrollment type.

We summarized commenters' concerns about using the blended national-regional growth rates for benchmarking in the CY 2023 PFS final rule (87 FR 69879 through 69881). Specifically, ACOs and other interested parties expressed concerns regarding the dynamic under which an ACO that reduces costs for its own assigned beneficiaries also reduces its average regional costs, resulting in a relatively lower benchmark for the ACO under the blended national-regional growth rates used to trend and update the ACO's historical benchmark. As summarized in

[305] § 425.652 applies to ACOs that started agreement periods in 2025 and 2026. However, for simplicity, we have cited the provisions in § 425.601 in this background section to describe how the ACPT fits into the bigger picture of benchmark adjustments, and the same policies apply to ACOs to which § 425.652 applies.

the CY 2022 PFS final rule, ACOs and other interested parties also have suggested that this dynamic particularly disadvantages ACOs with high market penetration in their regional service areas, which may tend to be ACOs operating in rural areas (86 FR 65296 through 65299).

In the CY 2023 PFS final rule, we implemented new policies effective beginning with performance year 2024 to address these concerns by incorporating a prospectively set projected administrative growth factor, a variant of the modified United States Per Capita Cost (USPCC) called the Accountable Care Prospective Trend (ACPT), into a three-way blend with national and regional growth rates to update an ACO's historical benchmark for each performance year in the ACO's agreement period (87 FR 69882 through 69898). Incorporating this prospective trend in the update to the benchmark insulates a portion of the annual update from any savings occurring as a result of the actions of ACOs participating in the Shared Savings Program and helps to address the impact of increasing market penetration by ACOs in a regional service area on a growth factor that only uses blended national-regional rates. Because the ACPT is set prospectively at the outset of an agreement period, any savings generated by ACOs during the agreement period are not reflected in the ACPT. Accordingly, incorporation of the ACPT allows for benchmarks to increase beyond actual spending growth rates as ACOs slow spending growth. We noted that the use of the three-way blend to update ACOs' benchmarks should incentivize both greater savings by ACOs and greater program participation. We also noted that we believed that because incorporating the ACPT into the update would reduce the degree to which an ACO's savings negatively impact its benchmark through the regional trend component of the update, the ACPT would help to address the disproportionate impact of an ACO's savings on the benchmark update for ACOs with a high market share (87 FR 69882).

In addition, as discussed in the Regulatory Impact Analysis for the CY 2023 PFS proposed rule (87 FR 46427), we projected that this proposed approach for use of an ACPT/national-regional three-way blended update factor, in combination with other proposed changes to the statutory payment model in the CY 2023 PFS proposed rule, as well as then-current policies established using the authority of section 1899(i)(3) of the Act (87 FR 46403 through 46404), would not increase program expenditures relative to those under the statutory payment model. Since we have established the three-way blended update factor, we have continued to reexamine this projection to ensure that the requirement under section 1899(i)(3)(B) of the Act that an alternative payment model not result in additional program expenditures continues to be satisfied, and we have found continue compliance with section 1899(i)(3)(B) of the Act.

Under § 425.660, the three-way blend is calculated as the weighted average of the ACPT (one-third) and the existing national-regional blend (two-thirds) for use in updating an ACO's historical benchmark between BY3 and the performance year. We calculate the ACPT component of the blended annual update using an annualized growth rate based on 5-year projections in per capita spending as of the start of an ACO's agreement period as specified in § 425.660(b)(2)(ii). We use an annualized growth rate based on 5-year projections in per capita spending as of the start of an ACO's agreement period to align the ACPT with the 5-year agreement periods used under the Shared Savings Program. The CMS Office of the Actuary projects the ACPT, which is a modification of the FFS United States Per Capita Cost (USPCC) growth trend projections used annually for establishing Medicare Advantage rates. We set the ACPT growth factors for an ACO's entire 5-year agreement period near the start of the agreement period (87 FR 46163). The ACPT factors remain unchanged throughout the ACO's agreement period, providing a degree of certainty to ACOs.

Similar to the production of FFS USPCCs, for a given agreement period cohort (that is, ACOs with the same agreement period start date) and performance year, OACT produces two separate, modified USPCC values for ESRD and non-ESRD aged/disabled populations (as described in § 425.660(b)(2)). In the CY 2023 PFS final rule (87 FR 69882), we described the modified USPCC values as reflecting an exclusion of payments for indirect medical education (IME), disproportionate share hospitals (DSH), and supplemental payment for IHS/Tribal Hospitals and hospitals located in Puerto Rico, and including payments associated with hospice claims (87 FR 69882). Subsequently, for a given ACO and performance year, the two modified USPCCs serve as inputs into the calculation of four separate ACPT values, one for each of four Medicare enrollment types: ESRD, disabled, aged/dual eligible for Medicare and Medicaid, and aged/non-dual eligible for Medicare and Medicaid (87 FR 69882). In turn, each of these enrollment-type specific ACPT values is used to calculate an ACO's four enrollment-type specific three-way blended update factors (as described in § 425.652(b)(4)).

As we have previously noted (87 FR 69896), we expect in any year the ACPT could overestimate or underestimate the actual growth rate of expenditures of the national assignable population. In the CY 2023 PFS final rule (87 FR 69882–69888), we included the following factors in the design of the three-way blended update factor to mitigate impacts in differences between the ACPT and the actual growth rate of expenditures for the national assignable population:

- The ACPT is one-third of the three-way blended update factor; the remaining two-thirds of the blend are based on the national-regional trend, which reflects actual national and regional spending growth.
- As part of the ACPT calculation, the ACPT is expressed as a flat dollar amount and is risk-adjusted, which may benefit low growth/low spending ACOs and ACOs serving medically complex populations.
- We established a guardrail policy where, if an ACO generates losses for a performance year that meet or exceed its minimum loss rate (MLR) (for two-sided model ACOs) or negative minimum savings rate (MSR) (for one-sided model ACOs) under the three-way blended update factor, we will recalculate the ACO's updated benchmark using the two-way national-regional blended update factor. If the ACO generates a smaller amount of losses using the two-way blend, we will use this smaller amount to determine the ACO's responsibility for shared losses, if applicable.
- If we determine that expenditure growth has differed significantly from projections made at the start of the agreement period due to unforeseen circumstances, such as an economic recession, pandemic, or other factors, a reduction in the weight placed on the ACPT may be considered. We have sole discretion to determine whether an unforeseen circumstance exists that warrants a reduction to the weight of the ACPT and the reduced weight that will apply to the ACPT.

The CY 2024 modified USPCC cumulative growth rates (2023 to 2024) that were corrected and posted in July 2026 and used to calculate ACPT values for ACOs with an agreement period starting on January 1, 2024, were 5.5 percent for the aged/disabled population and 5.1 percent for the ESRD

population.[306] [307] However, the CY 2024 actual cumulative growth rate of expenditures for the national assignable population was 8.4 percent for the aged/disabled population (2.9 percentage points higher than projected) and 6.9 percent for the ESRD population (1.8 percentage points higher than projected).[308] When the ACPT is lower than the actual national FFS expenditure growth, it could reduce or eliminate shared savings for ACOs. For CY 2024, we determined that unforeseen circumstances occurred, as it was observed that there were unanticipated billing patterns and unexpectedly high increases in multiple categories of Part A and B spending, most notably Part B drugs. This represented a substantial discrepancy between projected and actual growth rates for CY 2024, and it materialized in the context of the COVID–19 Public Health Emergency that imparted material and complex effects on Medicare trend experience over a multi-year period extending into the first half of 2023. This difference between the projected and actual growth rates for CY 2024 represented a material impact across the Shared Savings Program and led to our decision to reduce the ACPT's weight in the three-way blend from one-third (⅓) to one-sixth (⅙) in CY 2024. In CY 2024, the three-way blend for the growth factor was based on 5/6th weight of the national-regional trend and 1/6th weight on the ACPT.[309] [310]

(2) Proposed Revisions

(a) Performance Year-Specific Modified USPCC Annualized Growth Rates Used To Construct ACPT Values

For agreement periods beginning on or after January 1, 2027, we propose to establish performance year-specific modified USPCC annualized (year-over-year) growth rates used to construct ACPT values, that would apply to the performance year regardless of an ACO's agreement period start date. This would replace the current approach under which the modified USPCC annualized growth rates used to construct ACPT values are established on an agreement period-specific basis, as illustrated in Table B–G32. This proposal would not change the methodology by which CMS would calculate the modified USPCC annualized growth rates for any given performance year. This proposal would only change the timing of the calculation and publicly reporting of modified USPCC annualized growth rates.

TABLE B-G32: STATUS QUO AND PROPOSED BASES FOR CALCULATING ANNUALIZED GROWTH RATES

Approach	Agreement Period Start Year	Basis for Calculating Modified USPCC Annualized Growth Rates
Status Quo	2024	Agreement Period
	2025	
	2026	
Proposed	2027	Performance Year
	2028	
	2029	

Specifically, for agreement periods beginning on or after January 1, 2027, and in subsequent years, we are proposing that CMS would no longer calculate a fixed five-year schedule of annualized growth rates at the start of an ACO's agreement period. Instead, in the summer of the year preceding a given performance year, CMS would calculate and publicly report the modified USPCC annualized growth rates applicable to that performance year. This means that, although ACOs would no longer receive a five-year set of enrollment type-specific ACPT values near the beginning of the agreement period, they would still receive advance notice of the modified USPCC annualized growth rate used to calculate enrollment type-specific ACPT values for a given performance year in the year preceding that performance year. As illustrated in Table B–G33, in the late spring or early summer preceding the start of the first performance year of an agreement period, an ACO would be able to review the performance year-specific modified USPCC annualized growth rates publicly reported, applicable to the first performance year. For example, ACOs entering agreement periods in 2027 would receive their 2027 ACPT (PY 1 ACPT) in the late spring or early summer of 2026. Then, during each subsequent performance year through the remainder of the agreement period, the ACO would receive a newly calculated set of ACPT values based on the performance year-specific modified USPCC annualized growth rates calculated and published in the summer preceding that performance year. For example, ACOs entering agreement periods in 2027 would receive their 2028 ACPT (PY 2 ACPT) in the late spring or early summer of 2027.

[306] Shared Savings and Losses, Assignment and Quality Performance Standard Methodology: Specifications of the Accountable Care Prospective Trend (ACPT) and Three-Way Blended Benchmark Update Factor (Version 5). Page 16. *https://www.cms.gov/files/document/medicare-ssp-acpt-specifications.pdf*. Centers for Medicare and Medicaid Services (2026).

[307] Centers for Medicare and Medicaid Services (2026). Announcement of Calendar Year (CY) 2026 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies. Page 14–15. [2026 Announcement]. *https://www.cms.gov/medicare/payment/medicare-advantage-rates-statistics/announcements-and-documents/2026*.

[308] Observed cumulative growth in national assignable expenditures for the aged/disabled population and ESRD populations applicable to financial reconciliation for PY 2024 were determined in an internal analysis conducted by CMS.

[309] Information regarding the announcement for the CY 2024 actual cumulative growth rates and the determination that unforeseen circumstance occurred resulting in the decision to reduce ACPT's weight in the three-way blend was disseminated to Accountable Care Organizations via the June 30, 2025, Issue 7 Spotlight Article, an internal communication distributed by the Centers for Medicare & Medicaid Services (CMS) to ACOs.

[310] CY 2024 Projected ESRD Modified USPCC Annualized Growth Rates and Aged/Disabled Modified USPCC Annualized Growth Rates are available at: Shared Savings and Losses, Assignment and Quality Performance Standard Methodology: Specifications of the Accountable Care Prospective Trend (ACPT) and Three-Way Blended Benchmark Update Factor. Pages 6–7. *https://www.cms.gov/files/document/medicare-ssp-acpt-specifications.pdf*. Centers for Medicare and Medicaid Services (2025).

TABLE B-G33: APPLICATION OF PERFORMANCE YEAR-SPECIFIC MODIFIED USPCC ANNUALIZED GROWTH RATES FOR ACOS ENTERING AGREEMENT PERIODS BEGINNING ON JANUARY 1, 2027, AND IN SUBSEQUENT YEARS

Year rate is published[1]	Performance year to which rate applies	ACOs entering agreement periods in 2027	ACOs entering agreement periods in 2028	ACOs entering agreement periods in 2029
2026	CY 2027: Values based on 2027 modified USPCC annualized growth rates	Receives PY1 ACPT	-	-
2027	CY 2028: Values based on 2028 modified USPCC annualized growth rates	Receives PY2 ACPT	Receives PY1 ACPT	-
2028	CY 2029: Values based on 2029 modified USPCC annualized growth rates	Receives PY3 ACPT	Receives PY2 ACPT	Receives PY1 ACPT
Under this approach, overlapping agreement period cohorts would use the same modified USPCC annualized growth rate for the same calendar year corresponding to a performance year. Note 1: Modified USPCC would be published in late spring or early summer of the year the rate is published.				

As illustrated in Table B–G34, under the current approach, modified USPCC annualized growth rates calculated on an agreement period basis may differ across agreement period cohorts.

TABLE B-G34: SUMMARY OF PROJECTED ESRD AND AGED/DISABLED MODIFIED USPCC ANNUALIZED GROWTH RATES, CORRESPONDING TO AGREEMENT PERIODS BEGINNING ON JANUARY 1, 2024, AND JANUARY 1, 2025

Population	Agreement Period Start Year	PY1	PY2	PY3	PY4	PY5
ESRD	2024	5.1%	7.5%	5.5%	5.5%	8.0%
	2025	7.5%	5.7%	5.5%	5.2%	5.6%
Aged/Disabled	2024	5.5%	4.8%	5.7%	5.8%	4.3%
	2025	5.6%	5.7%	6.0%	5.0%	6.1%

Notes: The projected ESRD and Aged/Disabled modified USPCC annualized growth rates that are planned to be updated in July 2026.
Source: Shared Savings and Losses, Assignment and Quality Performance Standard Methodology, Specifications of the Accountable Care Prospective Trend (ACPT) and Three-Way Blended Benchmark Update Factor, Version 5

Establishing performance year-specific modified USPCC annualized growth rates would improve consistency across agreement periods by ensuring that, for a given performance year, the same modified USPCC annualized growth rates for that year would apply to all ACOs regardless of agreement period start date. For example, at reconciliation for PY 2028, the same modified USPCC annualized growth rates would apply to ACOs that entered agreement periods on January 1, 2027, and January 1, 2028. That is, neither cohort of ACOs would face different modified USPCC annualized growth rates for that performance year solely because their agreement periods began in different years.

We continue to believe that the prospective character of the ACPT is an important feature that benefits ACOs by providing a degree of certainty regarding their annual benchmark updates. However, as we acknowledged in the CY 2023 PFS final rule, establishing modified USPCC annualized growth rates at the start of an ACO's agreement period means that ACOs entering agreement periods in different years could be subject to higher or lower updates based on how projections differ across agreement periods. Thus, the current approach poses a tradeoff between long-term predictability (over a 5-year agreement period) and inconsistency across agreement period cohorts. Under the proposed approach, our goal is to thoughtfully recalibrate the balance of that tradeoff by forgoing some predictability in favor of greater consistency and, in turn, fairness across agreement period cohorts. Specifically, although ACOs would no longer receive a fixed five-year schedule of modified USPCC annualized growth rates near the beginning of the agreement period, they would receive advance notice of the modified USPCC annualized growth rates in the late spring or early summer of the year preceding a given performance year, thus preserving the ACPT's core design as a prospectively-set external factor that provides ACOs with a degree of certainty regarding their annual benchmark update, as originally intended, albeit on a shorter time horizon (1 year rather than 5 years). At the same time, applying a consistent modified USPCC annualized growth rate to all ACOs reconciled for a given performance year, regardless of their agreement period start date, would promote greater fairness by reducing the disparities that currently arise when different start dates result in different growth rates, which can advantage or disadvantage certain ACOs. Lastly, the proposed approach may reduce operational complexity by ensuring that, in a given performance year, there is a single set of underlying modified USPCC annualized growth rates used to

calculate ACPT values, rather than a unique set of modified USPCC annualized growth rates that are specific to each agreement period cohort of ACOs being reconciled for that performance year.

(b) Guardrail on the Difference Between the Modified USPCC Cumulative Growth Rate and the Actual Cumulative Growth Rate of Expenditures for the National Assignable Population for Agreement Periods Beginning on or After January 1, 2027

For agreement periods beginning on or after January 1, 2027, we propose to establish a guardrail on instances in which the modified USPCC cumulative growth rates used to construct ACPT values differ substantially from observed cumulative growth in national assignable expenditures. Specifically, we propose to establish a guardrail that would not allow the modified USPCC cumulative growth rate for each of the ESRD population and the Aged/Disabled population to be more than 1.0 percentage point below or 1.5 percentage points above the corresponding observed cumulative growth in national assignable expenditures for that population, respectively (where the percentage point thresholds are rounded to the nearest tenth of a percentage point). We would apply the guardrail at reconciliation for a given performance year. Hereafter, we refer to the difference between the modified USPCC cumulative growth rate and observed cumulative growth in national assignable expenditures as ''delta modified USPCC.''

Establishing guardrail thresholds that are fixed over an agreement period, rather than thresholds that widen or narrow, acknowledges that the realized path of delta modified USPCC over an agreement period cannot be known in advance with sufficient certainty. That is, the extent to which delta modified USPCC widens or narrows over an agreement period depends on the extent to which projection errors in a given year offset the projection error that's accumulated over prior years. This is an outcome that can only be known at financial reconciliation for a given performance year. Therefore, whereas establishing thresholds that widen or narrow reflects a prospective assumption about the trajectory that delta modified USPCC will take over an agreement period, establishing fixed thresholds applies a consistent tolerance for delta modified USPCC to each performance year in recognition of the fact that delta modified USPCC may widen or narrow over an agreement period.

Proposing to set the guardrail threshold levels asymmetrically at −1.0 percentage point and +1.5 percentage points, as opposed to a tighter, wider, or symmetrical guardrail range, primarily reflects a policy judgment about the appropriate approach to limit the effects of unusually large delta modified USPCC at financial reconciliation for a given performance year. The proposed threshold levels are not based on predictions of the path that delta modified USPCC will take over an agreement period. Rather, they establish the bounds within which delta modified USPCC would be addressed. In proposing these levels, we aim to balance several considerations: protection of ACOs from the financial consequences of unusually large cumulative under-projection (substantially negative delta modified USPCC); protection of the Medicare Trust Funds from the financial consequences of unusually large cumulative over-projection (substantially positive delta modified USPCC); and preservation of the original policy aims of the ACPT (that is, to allow for benchmarks to increase beyond actual spending growth even as ACOs slow spending growth).

In proposing these levels, we also considered alternative approaches. For example, a tighter guardrail threshold would provide greater protection to ACOs and the Medicare Trust Funds from delta modified USPCC. However, it could also undermine the prospective design of the ACPT if it results in the frequent application of the guardrail. Conversely, a wider guardrail was also considered and such a guardrail could be applied less frequently than a tighter guardrail and, in turn, may preserve the prospective design of the ACPT to a greater degree, but the wider guardrail could also potentially expose the Medicare Trust Funds and ACOs to harms associated with substantially positive or substantially negative delta modified USPCC. We also considered a symmetrical guardrail that would apply equally in cases of both substantially positive and substantially negative delta modified USPCC. However, we believe that an asymmetric guardrail that imposes a tighter bound on substantially negative delta modified USPCC and a wider bound on substantially positive delta modified USPCC would more directly protect ACOs from the harms associated with substantially negative delta modified USPCC while still allowing ACOs to benefit from modestly positive delta modified USPCC, consistent with the prospective design of the ACPT. Lastly, while historical delta modified USPCC values have informed the reasonableness of the proposed thresholds, they have not determined the threshold levels themselves, as the path that delta modified USPCC takes over any agreement period cannot be known in advance and may differ across agreement periods. Taken together, the proposed threshold levels of −1.0 percentage point and +1.5 percentage points are best understood as reasonable policy calibrations that, we believe, strike an acceptable balance of the considerations discussed previously. We also believe that the guardrail as proposed would be consistent with the original policy aims of the ACPT, as well as program goals of predictability, fairness, and administrative feasibility. We seek comment on the proposed threshold levels, including whether a tighter guardrail, a wider guardrail, or a modification of any of the approaches discussed in this paragraph, would represent a better balance of the considerations discussed previously.

The following steps illustrate how the proposed guardrail on delta modified USPCC would operate in practice at reconciliation for a given performance year for agreement periods beginning on or after January 1, 2027:

Step 1: Calculate the Applicable Delta Modified USPCC Values

As illustrated in Table B–G35, at reconciliation for a given performance year, CMS would calculate two delta modified USPCC values for each agreement period cohort: one for the ESRD population, and one for the Aged/Disabled population. For a given population, delta modified USPCC would be equal to the modified USPCC cumulative growth rate minus the observed cumulative growth in national assignable expenditures. Because delta modified USPCC values are constructed at the agreement period cohort, performance year, and population levels, they apply uniformly to all ACOs within a given cohort for a given performance year.

TABLE B-G35: HYPOTHETICAL EXAMPLE OF STEP 1 (CALCULATE THE APPLICABLE DELTA MODIFIED USPCC VALUES)

Population	Modified USPCC Cumulative[1] Growth Rate	Observed Cumulative[1] Growth in National Assignable Expenditures	Delta Modified USPCC[2]
ESRD	4.0%	4.5%	-0.5 percentage points
Aged / Disabled	3.0%	5.0%	-2.0 percentage points

Notes:
[1] – "Cumulative" reflects the period from a given ACO's BY3 to the applicable performance year.
[2] – At reconciliation for a given performance year, delta modified USPCC for each population and agreement period cohort equals the modified USPCC cumulative growth rate minus observed cumulative growth in national assignable expenditures.

Step 2: Determine Whether Each Delta Modified USPCC Falls Outside the Guardrails

As illustrated in Table B–G36, once calculated, each population-specific delta modified USPCC value would then be compared with the previously mentioned guardrail thresholds (−1.0 percentage point and +1.5 percentage points). If delta modified USPCC for either population falls within the guardrail thresholds (that is, greater than or equal to −1.0 percentage point and less than or equal to +1.5 percentage points), no guardrail adjustment would apply for a population, and the corresponding enrollment type-specific ACPT values initially calculated for that performance year would remain unchanged. If delta modified USPCC falls outside the guardrail thresholds (that is, less than −1.0 percentage point or greater than +1.5 percentage points) for one or both of the populations, a guardrail adjustment would apply.

TABLE B-G36: HYPOTHETICAL EXAMPLE OF STEP 2 (DETERMINE WHETHER EACH DELTA MODIFIED USPCC FALLS OUTSIDE THE GUARDRAILS)

Population	Delta Modified USPCC	Guardrails[1]		Does Guardrail Adjustment Apply?
		Lower Bound	Upper Bound	
ESRD	-0.5 percentage points	-1.0 percentage point	+1.5 percentage points	No (delta modified USPCC falls inside bounds)
Aged / Disabled	-2.0 percentage points	-1.0 percentage point	+1.5 percentage points	Yes (delta modified USPCC falls outside bounds)

Notes:
[1] - The lower and upper bounds shown here reflect fixed thresholds of -1.0 percentage point (lower bound) and +1.5 percentage points (upper bound) applied to both the ESRD delta modified USPCC and the Aged/Disabled delta modified USPCC.

Step 3. Calculate the Guardrail-Adjusted Modified USPCC Cumulative Growth Rate, as Applicable

As illustrated in Table B–G37, for a given population, if delta modified USPCC falls below the lower guardrail threshold, the applicable modified USPCC cumulative growth rate would be replaced with a guardrail-adjusted value equal to the observed cumulative growth in national assignable expenditures minus 1.0 percentage points. If delta modified USPCC falls above the upper guardrail threshold, the applicable modified USPCC cumulative growth rate would be replaced with a guardrail-adjusted value equal to the observed cumulative growth in national assignable expenditures plus 1.5 percentage points.

TABLE B-G37: HYPOTHETICAL EXAMPLE OF STEP 3 (CALCULATE THE GUARDRAIL-ADJUSTED MODIFIED USPCC CUMULATIVE GROWTH RATE)

Population	Delta Modified USPCC (Step 1)	Applicable Guardrail (Step 2)	Observed Cumulative Growth in National Assignable Expenditures	Original Modified USPCC Cumulative Growth Rate	Guardrail-Adjusted Modified USPCC Cumulative Growth Rate
ESRD[1]	-0.5 percentage points	Not Applicable	4.5%	4.0%	No adjustment (4.0% used)
Aged / Disabled[2]	-2.0 percentage points	-1.0 percentage point	5.0%	3.0%	4.0%

Notes:
1 – For the ESRD population, there would be no guardrail adjustment because the ESRD delta modified USPCC calculated in Step 1 would have been determined to fall within the guardrail thresholds in Step 2. Therefore, the ESRD-specific ACPT values initially calculated for that performance year would still apply.
2 – For the Aged/Disabled population, the guardrail-adjusted modified USPCC cumulative growth rate would equal 4.0 percent, or the observed cumulative growth in national assignable expenditures minus 1.0 percentage points because the Aged/Disabled delta modified USPCC calculated in Step 1 would have been determined to fall below the lower guardrail threshold in Step 2. In turn, the ACPT values for the Disabled, Aged/Dual, and Aged/Non-Dual populations initially calculated for that performance year would be recomputed in Step 4 using the guardrail-adjusted modified USPCC cumulative growth rate.

Step 4. Recompute ACPT Values, as Applicable

If a guardrail adjustment applies (as determined in Step 2), the corresponding enrollment type-specific ACPT values initially calculated for that performance year would be recomputed using the guardrail-adjusted modified UPSCC cumulative growth rate (calculated in Step 3) rather than the original modified USPCC cumulative growth rate. For the ESRD population, the guardrail-adjusted modified USPCC cumulative growth rate would be used to recompute ACPT values applicable to the ESRD enrollment type. For the Aged/Disabled population, the guardrail-adjusted modified USPCC cumulative growth rate would be used to recompute ACPT values applicable to the Disabled, Aged/Dual-Eligible, and Aged/Non-Dual-Eligible enrollment types. The recomputed ACPT values would then be used to construct the three-way blended update factors, updated historical benchmarks, and, in turn, shared savings and losses calculations for the applicable performance year.

The procedures described previously would be applied at financial reconciliation for each performance year of an ACO's agreement period. The application of a guardrail on delta modified USPCC in a given performance year would affect only the ACO-level ACPT values and downstream shared savings and losses calculations applicable to that performance year. This is appropriate because delta modified USPCC is, by definition, a comparison of the cumulative modified USPCC growth rate to the cumulative observed growth in national assignable expenditures. Thus, the guardrail calculation of each performance year already accounts for projection error accumulated through prior years by construction. For example, in Table B–G38, the delta modified USPCC for PY3 reflects cumulative projection error through PY3. As a result, any guardrail adjustment applied in PY1 or PY2 would not need to be carried forward into PY3 because the cumulative structure of the guardrail calculation for PY3 would have incorporated the cumulative effect of projection errors from PY1 and PY2.

TABLE B-G38: ILLUSTRATIVE APPLICATION OF THE PY-SPECIFIC GUARDRAIL APPLICATION (EFFECTS IN ONE PY DO NOT CARRY OVER TO SUBSEQUENT PYS)

Performance Year	Modified USPCC Annualized Growth Rate	Modified USPCC Cumulative Growth Rate	Observed Cumulative Growth in National Assignable Expenditures	Delta Modified USPCC	Does Guardrail Adjustment Apply?	Guardrail-Adjusted Modified USPCC Cumulative Growth Rate Used to Recompute PY ACPT
PY1	5.7%	5.7%	6.8%	-1.1%	Yes, lower bound	5.8%
PY2	5.4%	11.4%	12.3%	-0.9%	No	No adjustment (11.4% used)
PY3	5.4%	17.4%	14.0%	3.4%	Yes, upper bound	15.5%

Notes:
The guardrail applies in PY1 and PY3, but not in PY2. The PY1 adjustment affects only the PY1 ACPT and does not carry forward into PY2. Instead, the guardrail is reassessed independently in each performance year using the delta modified USPCC applicable to that performance year.

We seek comments on this proposal.

(c) Retroactive Guardrail on Substantially Negative Delta Modified USPCC for Agreement Periods Beginning on January 1, 2024, and Before January 1, 2027

For agreement periods beginning on or after January 1, 2024, and before January 1, 2027, we propose to establish a guardrail on instances in which the modified USPCC cumulative growth rates used to construct ACPT values are substantially lower than observed cumulative growth in national assignable expenditures. Specifically, beginning at reconciliation for PY 2025 for ACOs currently in an agreement period, and for future performance years in their agreement periods, we propose to establish a guardrail that would not allow the modified USPCC cumulative growth rate to be more than 1.0 percentage point below the corresponding observed cumulative growth in national assignable expenditures (where the percentage point threshold is rounded to the nearest tenth of a percentage point). In other words, this proposed retroactive guardrail would be applied at reconciliation for any remaining performance years for agreement periods that began on January 1, 2024 (that is, PY 2025 through 2028), January 1, 2025 (that is, PY 2025 through 2029), and January 1, 2026 (that is, PY 2026 through 2030).

We propose to apply this proposal retroactively because it adjusts the methodology used in determining shared savings and losses for a performance year and for agreement periods that have already started. Applying this proposal retroactively would either have no effect or a positive effect on an ACOs' determinations of shared savings and losses, and no ACOs would be harmed by retroactively applying this proposed policy. Section 1871(e)(1)(A) of the Act prohibits substantive changes in regulations, manual instructions, interpretive rules, statements of policy, or guidelines of general applicability under Title XVIII of the Act from being applied retroactively to items and services furnished before the effective date of the change unless, as permitted under paragraph (ii), the Secretary determines that failing to apply the change retroactively would be contrary to the public interest. We believe it is appropriate to extend this retroactive applicability to PY 2025 for consistency with future performance years and for the reasons described in the subsequent paragraph.

Failing to apply this proposed policy retroactively for agreement periods beginning on January 1, 2024, and before January 1, 2027, would be contrary to the public interest. Some ACOs may feel unfairly punished by forcing them to assume financial risk when the modified USPCC is a substantial under-projection compared to actual growth, and no ACO would experience reduced shared savings or increased shared losses by retroactively applying this proposed policy. This is especially the case in comparison to ACOs with agreement periods beginning on or after January 1, 2027, that would be protected from financial risk if the delta modified USPCC is substantially negative simply because their agreement period would start after the potential implementation date of the proposed policy. A substantially negative delta modified USPCC would cause greater harm to ACOs with agreements starting January 1, 2024, January 1, 2025, or January 1, 2026, than for ACOs with agreement periods beginning on or after January 1, 2027, especially because of the potential for these negative projection and mis-estimation errors to compound over multiple years. Specifically, for a given ACO, substantially negative delta modified USPCC would result in corresponding lower ACPT values, which would, in turn, potentially result in lower shared savings or greater shared losses than would occur for a similar ACO with an agreement period beginning on or after January 1, 2027. Such a consequence would be outside an ACO's control, potentially undermining both participation in and the sustainability of the Shared Savings Program and the public's faith in CMS as a fair partner. We are compelled to propose a retroactive remedy for a substantially negative delta modified USPCC because all ACOs covered by this proposed policy will either benefit from it or will be unaffected by it. Also, the proposed policy likely will not place additional administrative burden upon ACOs, CMS, or other interested parties.

ACOs participating in the Shared Savings Program and other ACOs that may be considering joining the Shared Savings Program may be less likely to join or continue to participate in a program where applications of policy based on agreement period start date, which such ACOs may perceive to be arbitrary, can reduce shared savings or increase shared losses. Having more ACOs than what is typical terminating their participation in the Shared Savings Program could negatively affect the sustainability of the program. The Shared Savings Program financial methodology and the procedures we have utilized in the past to address projection errors in the ACPT provide a means to account for instances of substantially negative delta modified USPCC. However, these remedies to address projection errors under our current policies can only be used if an unforeseen circumstance occurs and we determine the negative effects of an under-projected delta modified USPCC to be substantial enough to affect ACOs. As a result, this can create uncertainty for ACOs on whether CMS would address projection errors with delta modified USPCC. The delta modified USPCC is a factor that directly affects whether an ACO receives shared savings, and ACOs can easily measure the impact of the delta modified USPCC on their shared savings. In recognition of the differing circumstances that could warrant accounting for errors, we have not established a set amount of difference between the modified USPCC and national expenditure trends that we consider to be a substantial enough under-projection to implement a remedy. This uncertainty can create challenges for ACOs to be able to plan what their benchmark could be and how they will achieve savings against such benchmark.

For some ACOs, the uncertainty in the difference between the modified USPCC and national expenditure trends may either discourage new ACOs from joining the Shared Savings Program or cause some ACOs to leave the program, which goes against our goal to encourage more ACOs to participate in the Shared Savings Program. If we do not remedy projection errors in update factors that directly affect the amount of shared savings earned by ACOs, this could cause a loss of faith by ACOs, health care providers, and the public in CMS's ability to effectively administer the Shared Savings Program, substantially reducing ACO and health care provider participation in the program. Reduced participation, in turn, would significantly diminish the savings to the Medicare Trust Funds, the quality of care improvements for Medicare beneficiaries resulting from ACOs participants in the Shared Savings Program, and reduce the coordination of care performed for Medicare beneficiaries when obtaining items and services from ACO providers and suppliers. For these reasons, it would be contrary to the public interest for CMS to fail to retroactively apply our proposed policy mitigating this issue. With our proposed policy, ACOs will know the lower-bound limit on the

difference between the modified USPCC and national expenditure trends for the duration of their entire agreement period and have more confidence participating in the Shared Savings Program.

The following steps illustrate how the proposed guardrail on substantially negative delta modified USPCC would operate in practice at reconciliation for a given performance year, beginning with reconciliation for PY 2025, for agreement periods beginning on or after January 1, 2024, and before January 1, 2027. Note that Step 1 and Step 4 (with the exception of calculating benchmark-based loss sharing limits for ACOs participating in a two-sided risk track) would be operationally identical to those applied to agreement periods beginning on or after January 1, 2027. Moreover, in Steps 2 and 3, the only methodological difference relative to Steps 2 and 3 applied to agreement periods beginning on or after January 1, 2027, is that we would not apply an upper guardrail threshold of 1.5 percentage points on delta modified USPCC for agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

For completeness and clarity, all four steps are illustrated.

Additionally, similar to the two-sided guardrail on delta modified USPCC in a given performance year for agreement periods beginning on or after January 1, 2027, the application of a guardrail on substantially negative delta modified USPCC in a given performance year for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, would only impact the ACPT values and downstream shared savings and losses calculations applicable to that performance year. The effects of applying a guardrail on substantially negative delta modified USPCC in one performance year would not carry over into subsequent performance years.

Step 1: Calculate the Applicable Delta Modified USPCC Values

As illustrated in Table B–G39, at reconciliation for a given performance year, beginning with PY 2026, CMS would calculate two delta modified USPCC values for each agreement period cohort: one for the ESRD population, and one for the Aged/Disabled population. For a given population, the delta modified USPCC would be equal to the modified USPCC cumulative growth rate minus the observed cumulative growth in national assignable expenditures. Because delta modified USPCC values are constructed at the agreement period cohort, performance year, and population levels, they apply uniformly to all ACOs within a given cohort for a given performance year.

TABLE B-G39: HYPOTHETICAL EXAMPLE OF STEP 1 (CALCULATE THE APPLICABLE DELTA MODIFIED USPCC VALUES)

Population	Modified USPCC Cumulative[1] Growth Rate	Observed Cumulative[1] Growth in National Assignable Expenditures	Delta Modified USPCC[2]
ESRD	6.5%	4.5%	+2.0 percentage points
Aged / Disabled	3.0%	5.0%	-2.0 percentage points

Notes:
[1] – "Cumulative" reflects the period from a given ACO's BY3 to the applicable performance year.
[2] – At reconciliation for a given performance year, delta modified USPCC for each population and agreement period cohort equals the modified USPCC cumulative growth rate minus observed cumulative growth in national assignable expenditures.

Step 2: Determine Whether Each Delta Modified USPCC is Less Than −1.0 Percentage Point

As illustrated in Table B–G40, once calculated, each population-specific delta modified USPCC value would then be compared with the previously mentioned guardrail threshold (−1.0 percentage point). If delta modified USPCC is greater than or equal to −1.0 percentage point, no guardrail adjustment would apply, and the corresponding enrollment type-specific ACPT values initially calculated for that performance year would remain unchanged. If delta modified USPCC is less than −1.0 percentage point, a guardrail adjustment would apply.

TABLE B-G40: HYPOTHETICAL EXAMPLE OF STEP 2 (DETERMINE WHETHER EACH DELTA MODIFIED USPCC IS LESS THAN -1.0 PERCENTAGE POINT)

Population	Delta Modified USPCC	Guardrails[1]		Does Guardrail Adjustment Apply?
		Lower Bound	Upper Bound	
ESRD	+2.0 percentage points	-1.0 percentage point	None	No (Upper bound guardrail does not apply for ACOs that began an agreement period prior to January 1, 2027)
Aged / Disabled	-2.0 percentage points	-1.0 percentage point	None	Yes (delta modified USPCC less than lower bound)

Notes:
1 - The lower and upper bounds shown here reflect a fixed threshold of -1.0 percentage point applied to both the ESRD delta modified USPCC and the Aged/Disabled delta modified USPCC.

Although the ESRD delta modified USPCC of +2.0 percentage points is greater than the upper guardrail threshold of +1.5 percentage points for agreement periods beginning on or after January 1, 2027, this threshold would not apply for ACOs in agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

Step 3. Calculate the Guardrail-Adjusted Modified USPCC Cumulative Growth Rate, as Applicable

As illustrated in Table B–G41, for a given population, if delta modified USPCC is less than the lower guardrail threshold, the applicable modified USPCC cumulative growth rate would be replaced with a guardrail-adjusted value equal to the observed cumulative growth in national assignable expenditures minus 1.0 percentage point.

TABLE B-G41: HYPOTHETICAL EXAMPLE OF STEP 3 (CALCULATE THE GUARDRAIL-ADJUSTED CUMULATIVE GROWTH RATE)

Population	Delta Modified USPCC (Step 1)	Applicable Guardrail (Step 2)	Observed Cumulative Growth in National Assignable Expenditures	Original Modified USPCC Cumulative Growth Rate	Guardrail-Adjusted Modified USPCC Cumulative Growth Rate
ESRD[1]	+2.0 percentage points	Not Applicable	4.5%	6.5%	No adjustment (6.5% used)
Aged / Disabled[2]	-2.0 percentage points	-1.0 percentage points	5.0%	3.0%	4.0%

Notes:

1 - For the ESRD population, there would be no guardrail adjustment because the ESRD delta modified USPCC calculated in Step 1 would have been determined to fall above the guardrail threshold in Step 2. Therefore, the ESRD-specific ACPT values initially calculated for that performance year would still apply.

2 - For the Aged/Disabled population, the guardrail-adjusted modified USPCC cumulative growth rate would equal 4.0 percent, or the observed cumulative growth in national assignable expenditures minus 1.0 percentage points because the Aged/Disabled delta modified USPCC calculated in Step 1 would have been determined to fall below the guardrail threshold in Step 2. In turn, the ACPT values for the Disabled, Aged/Dual, and Aged/Non-Dual populations initially calculated for that performance year would be recomputed in Step 4 using the guardrail-adjusted modified USPCC cumulative growth rate.

Step 4. Recompute ACPT Values, as Applicable

If a guardrail adjustment applies (as determined in Step 2), the corresponding enrollment type-specific ACPT values initially calculated for that performance year would be recomputed using the guardrail-adjusted MUPSCC cumulative growth rate (calculated in Step 3) rather than the original modified USPCC cumulative growth rate. For the ESRD population, the guardrail-adjusted modified USPCC cumulative growth rate would be used to recompute ACPT values applicable to the ESRD enrollment type. For the Aged/Disabled population, the guardrail-adjusted modified USPCC cumulative growth rate would be used to recompute ACPT values applicable to the Disabled, Aged/Dual-Eligible, and Aged/Non-Dual-Eligible enrollment types.

The recomputed ACPT values would then be used to construct the three-way blended update factors, updated historical benchmarks, and, in turn, shared savings and losses calculations for the applicable performance year. However, in calculating the benchmark-based loss recoupment limit for a given ACO participating in a two-sided risk track, we would use as its basis the lesser of the two updated benchmarks calculated before and after application of the retroactive guardrail. This would be done to account for the unlikely scenario in which an ACO's benchmark-based loss recoupment limit increases under the retroactive guardrail and, as a result of that increase, the ACO is rendered liable for greater shared losses than would otherwise occur in the absence of the retroactive guardrail. This would ensure that no ACO could be harmed as a result of implementing this proposed policy.

We seek comments on this proposal.

(d) Delay in Financial Reconciliation for Performance Year 2025

Proposing to implement this guardrail to take effect starting with PY 2025, including PY 2025 financial reconciliation, will result in a delay in PY 2025 financial reconciliation and delay providing financial results and shared savings payments to ACOs, pending the issuance of the CY 2027 PFS final rule and confirmation that we ultimately finalize the proposal for the lower bound guardrail policy. CMS plans to issue PY 2025 financial results and distribute shared savings payments in November 2026 and December 2026, respectively, in accordance with the finalized policy. This is necessary because, to complete the reconciliation process, we need to have a final value established for the ACPT for PY 2025.

Under our proposed retroactive, lower-bound guardrail policy, the ACPT for ACOs with agreement periods starting in PY 2024 would be 15.3 percent for ESRD beneficiaries and 14.7 percent for Aged/Disabled beneficiaries. For ACOs with agreement periods starting in PY 2025 under our proposed policy, the ACPT would be 7.7 percent for ESRD beneficiaries and 5.7 percent for Aged/Disabled beneficiaries. As described in section III.G.5.g.(2)(c). of this proposed rule, all of the ACOs covered by our proposed policy for PY 2025 financial reconciliation would either benefit from it or would be unaffected by it.

If our proposed policy is not implemented and no other action is taken to adjust the ACPT, the unadjusted ACPT for ACOs with agreement periods starting in PY 2024 would be 13.0 percent for ESRD beneficiaries and 10.6 percent for Aged/Disabled beneficiaries. For ACOs with agreement periods starting in PY 2025 if the ACPT is not changed, the unadjusted ACPT would be 7.5 percent for ESRD beneficiaries and 5.6 percent for Aged/Disabled beneficiaries. If we do not implement our proposed policy, ACOs with agreement periods starting in either 2024 or 2025 would otherwise receive less shared savings or have no change in their shared savings payments.

The goal of this proposed policy is to address the under-estimate of the modified USPCC compared to national expenditure trends. The proposal also would ensure that as soon as PY 2025 financial reconciliation occurs, ACOs would not be subject to the risk of modified USPCC values being included in the three-way blended growth factor that are substantially lower than the national assignable expenditure trends solely because of the starting date of an ACO's agreement period. The proposed ACPT lower bound policy also can be applied in the same manner for ACOs with agreement periods starting either January 1, 2024, or January 1, 2025, which would lead to a consistent ACPT lower bound policy regarding the relationship between the ACPT and the

national assignable expenditures, if we finalize our proposal to establish a guardrail as described in section III.G.5.g.(2)(b). of this proposed rule. For the reasons noted in this section, we believe that a delay to financial reconciliation is necessary so that ACOs that participated in PY 2025 can immediately benefit if this proposed lower bound guardrail policy is finalized.

(e) Proposed Amendments to Shared Savings Program Regulation

We propose the following amendments to § 425.605:

- Revise paragraph (i)(2)(i) introductory text to remove the phrase ''paragraph (i)(2)(ii) of this section'' and add in its place the phrase ''paragraph (i)(2)(ii) or (i)(2)(iii) of this section, as applicable''.
- Add new paragraph (i)(2)(iii) to specify that for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, applicable to performance years 2025 and subsequent performance years remaining in these agreement periods, CMS calculates the benchmark-based loss recoupment limit as follows:

++ Calculates the value for total benchmark expenditures as the product of an ACOs per capita updated benchmark expenditures for the performance year prior to the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

++ Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year after the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

++ Calculates the product of the percentage specified in paragraph (d)(1)(iii)(D)(2), (d)(1)(iv)(D)(2), and (d)(1)(v)(D)(2) of this section, as applicable, and the lesser of the ACO's total benchmark expenditures calculated according to paragraphs (i)(2)(iii)(A) and (i)(2)(iii)(B) of this section.

We propose the following amendments to § 425.610:

- In paragraph (l)(2) introductory text, remove the phrase ''paragraph (l)(3) of this section'' and add in its place the phrase ''paragraphs (l)(3) or (l)(4) of this section, as applicable'';
- Add new paragraph (l)(4) to specify that for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, applicable to performance years 2025 and subsequent performance years remaining in these agreement periods, the amount of shared losses for which an eligible ACO is liable may not exceed 15 percent of the lesser of the following:

++ Total benchmark expenditures calculated as the product of an ACO's per capita updated benchmark expenditures for the performance year prior to the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

++ Total benchmark expenditures calculated as the product of an ACO's per capita updated benchmark expenditures for the performance year after the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

We propose to revise the entirety of § 425.660 with provisions on the ACPT. In summary, we propose the following amendments to § 425.660:

Revise paragraph (a) to provide a general explanation of the ACPT and specify that the methodology by which CMS calculates and adjusts a projected growth rate called the Accountable Care Prospective Trend (ACPT) is described in § 425.660. We would also specify that CMS incorporates the ACPT into the blended update factor described in § 425.652(b) when updating an ACO's benchmark for each performance year of the agreement period, for agreement periods beginning on January 1, 2024, and in subsequent years.

Revise paragraph (b) on the determination of the ACPT to specify in the introductory text that an ACPT is a flat dollar amount calculated using one or more annualized growth rates based on national FFS Medicare expenditures projected by the CMS Office of the Actuary. We would specify in paragraphs (b)(1) through (b)(6), the provisions on CMS' determination of the ACPT for a Medicare enrollment type for each performance year, as follows:

Proposed paragraph (b)(1) of § 425.660 specifies provisions on CMS' calculation of annualized projected growth rates. This provision explains that the annualized projected growth rates are calculated as an annual rate of growth in projected expenditures relative to the prior year. Further, CMS projects annualized per capita growth in Parts A and B FFS expenditures for each performance year of the ACO's agreement period. In calculating the annualized projected growth rates, CMS would do all of the following:

- Exclude IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals;
- Make separate expenditure calculations for the ESRD and Aged/Disabled populations; and
- Calculate one or more annualized projected growth rates for the ESRD population of beneficiaries, and one or more annualized growth rates for the Aged/Disabled population of beneficiaries, as follows:

++ Using a uniform annualized projected rate of growth over each of the 5 performance years of the 5-year agreement period (for agreement periods beginning on or after January 1, 2024, and before January 1, 2027), or for each performance year (for agreement periods beginning on January 1, 2027, and in subsequent years), as applicable; or

++ If using an uniform annualized projected rate of growth is determined not to reasonably fit the anticipated growth curve (for example, if growth is expected to be above- or below-average in the short-run and return to more typical levels later in the agreement period), We would apply an alternative annualization technique using two or more annualized growth rates reflecting the projected rates of growth during the 5 performance years comprising the 5-year agreement period (for agreement periods beginning on or after January 1, 2024, and before January 1, 2027), or for each performance year (for agreement periods beginning on January 1, 2027, and in subsequent years), as applicable.

Proposed paragraph (b)(2) of § 425.660 specifies that, for each performance year, CMS calculates cumulative projected growth rates relative to the ACO's benchmark year (BY) 3, using the annualized projected growth rates, determined in accordance with proposed paragraph (b)(1) of § 425.660, for each population of beneficiaries: the ESRD population and the Aged/Disabled population.

Proposed paragraph (b)(3) of § 425.660 specifies provisions on CMS' calculations to express a cumulative projected growth rate as a flat dollar amount. Accordingly, for each performance year, CMS would multiply the applicable cumulative projected growth rate described in proposed paragraph (b)(2) of § 425.660 by BY3 truncated national per capita FFS Medicare expenditures for assignable beneficiaries for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) identified for the 12-month calendar year corresponding to BY3 to express the cumulative projected

growth rate as a flat dollar amount as follows:

- The ESRD cumulative projected growth rate would be used for the ESRD population.
- The Aged/Disabled cumulative projected growth rate would be used for the following populations: disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

Under proposed paragraph (b)(4) of § 425.660, we would maintain the existing provision on risk adjusting the flat dollar amount but add a related description to serve as a heading for clarity and consistency.

Under proposed paragraph (b)(5) of § 425.660, we would maintain the existing provision on calculating ACO-specific ACPT growth rates but add a related description to serve as a heading and make other revisions for clarity and consistency.

Under proposed new paragraph (b)(6) of § 425.660, we would specify provisions on the timing of calculations, which include the following:

- Under new paragraph (b)(6)(i), with provisions applicable for agreement periods beginning on or after January 1, 2024, and before January 1, 2027, we would specify the following:

++ At the beginning of the ACO's agreement period, CMS calculates the annualized projected growth rates for all performance years of the ACO's agreement period in accordance with proposed paragraph (b)(1) of § 425.660. These annualized projected growth rates remain fixed over the ACO's agreement period.

++ For a given performance year, CMS calculates an ACO-specific ACPT value, in accordance with proposed paragraphs (b)(2) through (b)(5) of § 425.660, using the annualized projected growth rates calculated at the beginning of the ACO's agreement period.

- Under new paragraph (b)(6)(ii), with provisions applicable for agreement periods beginning on January 1, 2027, and in subsequent years, we specify the following:

++ In the calendar year preceding a given performance year, CMS calculates the annualized projected growth rates in accordance with proposed paragraph (b)(1) § 425.660 for that performance year.

For a given performance year, CMS calculates an ACO-specific ACPT value, in accordance with proposed paragraphs (b)(2) through (b)(5) of § 425.660, using the annualized projected growth rates calculated in the preceding calendar year.

Under proposed new paragraph (c) of § 425.660, we would specify provisions on the recomputation of the ACPT based on the guardrail policies described in sections III.G.5.g.(2).(b)and III.G.5.g.(2).(c) of this proposed rule. Specifically, at financial reconciliation for a given performance year, CMS may recompute the ACO-specific ACPT value for a Medicare enrollment type initially determined at proposed paragraph (b)(5) of § 425.660 for that performance year, to address under-projection or over-projection of the ACPT (as applicable), as follows:

- In paragraph (c)(1), for agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

++ For performance year 2025, and any subsequent performance years of the ACO's agreement period, CMS separately calculates for the ESRD and Aged/Disabled populations the difference between the cumulative projected growth rates calculated in proposed paragraph (b)(2) of § 425.660 and the cumulative observed growth in per capita expenditures for the national assignable FFS population.

++ For the ESRD and Aged/Disabled populations separately, if this difference is less (more negative) than −1.0 percentage point (for example, −1.5, −2.0, −3.0), CMS would recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at proposed paragraph (b)(5) of § 425.660. CMS would calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with proposed paragraphs (b)(3) through (b)(5) of § 425.660, using the cumulative observed growth in expenditures for the national assignable FFS population minus 1.0 percentage point.

++ If this difference is greater than (less negative) or equal to -1.0 percentage point (for example, −0.9, −0.5, 0.5), CMS would not recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at proposed paragraph (b)(5) of § 425.660.

- In paragraph (c)(2) of § 425.660, for agreement periods beginning on January 1, 2027, and in subsequent years.

++ CMS separately calculates for the ESRD and Aged/Disabled populations the difference between the cumulative projected growth rates calculated in proposed paragraph (b)(2) of § 425.660 and the cumulative observed growth in per capita expenditures for the national assignable FFS population.

++ For the ESRD and Aged/Disabled populations separately, if this difference is less (more negative) than −1.0 percentage point (for example, −1.5, −2.0, −3.0), CMS would recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at proposed paragraph (b)(5) of § 425.660. CMS would calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with proposed paragraphs (b)(3) through (b)(5) of § 425.660, using the cumulative observed growth in expenditures for the national assignable FFS population minus 1.0 percentage point.

++ If this difference is greater than or equal to +1.5 percentage points, CMS would recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at proposed paragraph (b)(5) of § 425.660. CMS would calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with proposed paragraphs (b)(3) through (b)(5) of § 425.660, using the cumulative observed growth in expenditures for the national assignable FFS population plus 1.5 percentage point.

++ If this difference is greater than (less negative) or equal to −1.0 percentage point and less than or equal to +1.5 percentage points (for example, between −1.0 and +1.5, inclusive), CMS would not recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at proposed paragraph (b)(5) of § 425.660.

We seek comment on our proposed revisions to § 425.660.

6. Beneficiary Engagement

a. Proposal To Allow ACOs To Reduce or Eliminate Part B Cost Sharing

(1) Background

We believe that ACOs play a key role in strengthening beneficiary engagement in their care; accordingly, we intend to continue expanding the tools available to ACOs to support this work. Improving beneficiary engagement allows the benefits of receiving care from providers who are part of an ACO be more tangible and may ultimately result in improved quality and efficiency of care for beneficiaries, helping us meet our goals of improving beneficiary outcomes and reducing unnecessary spending.

As part of the effort to strengthen beneficiary engagement, in the CY 2025 Physician Fee Schedule final rule, CMS finalized the prepaid shared savings option (89 FR 98132). This payment option is available to current Shared Savings Program ACOs with a history of earning shared savings and is intended to expand access to performance year

savings that encourages investment in staffing, healthcare infrastructure, and additional services for beneficiaries. Under § 425.640(e)(1), ACOs participating in the prepaid shared savings option are required to spend a specific portion of the prepaid shared savings amount on direct beneficiary services, improving the quality of care beneficiaries receive. As discussed elsewhere in section III.G.6. of this proposed rule, ACO interest in receiving prepaid shared savings has been limited, and CMS is proposing to discontinue the participation option in future years. However, we believe a component of prepaid shared savings, providing ACOs the ability to reduce or eliminate cost sharing for certain Part B items and services, is a valuable tool to offer eligible ACOs. Cost sharing support for Part B items and services was offered in the ACO REACH model and allows ACO participants not to collect cost sharing amounts (in whole or in part) from eligible beneficiaries for eligible Part B items and services. In the ACO REACH model, ACOs and ACO participants enter into cost sharing support arrangements for the ACO to reimburse the ACO participant for beneficiary cost sharing amounts not collected. In the ACO REACH model, ACOs have wide flexibility to determine the beneficiaries and items and services that will be eligible for cost sharing support, but ACOs are prohibited from waiving Part B cost sharing support for items that may have a higher risk of fraud, waste, or abuse, such as durable medical equipment, prosthetics, orthotics, prescription drugs or supplies.

Part B cost sharing support is the third most used Beneficiary Engagement Incentive in the ACO REACH model with 41 percent of ACOs reporting that they had implemented it by 2025 or were planning to implement in 2026.[311] Additionally, interested parties have identified Part B cost sharing support as a valuable tool for ACOs to engage beneficiaries in their care.[312]

In 2026, the standard Medicare Part B monthly premium is $202.90, with a $283 annual deductible.[313] After the deductible is met, beneficiaries generally pay 20 percent of the Medicare-approved amount for items and services, such as doctor visits and durable medical equipment, with no limit on out-of-pocket costs. While most beneficiaries have supplemental insurance that covers the 20 percent cost sharing, including Medigap plans, employer sponsored plans, and Medicaid, some beneficiaries do not. In 2023, 3.5 million Medicare FFS beneficiaries (13 percent) lacked additional supplemental coverage.[314] These beneficiaries were more likely to have modest incomes (between $20,000 and $40,000 per person) compared to all Medicare FFS beneficiaries in 2023.[315] Beneficiaries with higher out of pocket costs receive less medical care than those with supplemental coverage.[316] While not all of this difference in care may be due to financial concerns, higher out of pocket costs may cause patients to skip or postpone necessary care and result in worsening health outcomes.[317] Offering Part B cost sharing support would allow ACOs to remove cost barriers for beneficiaries to receive items and services that will positively impact their health, which is consistent with the goals of the Shared Savings Program of improved quality and efficiency of care for beneficiaries.

While only one Shared Savings Program ACO receiving prepaid shared savings chose to reduce or eliminate Part B cost sharing support in the first year, that experience may not reflect future demand for this flexibility, given that only four ACOs elected to receive prepaid shared savings. Based on the ACO REACH model experience and the number of Medicare FFS beneficiaries without supplemental insurance, Shared Savings Program ACOs may be very interested in using this flexibility, were it available, simple to administer, and easy to implement. Additionally, we think providing ACOs the ability to reduce or eliminate Part B cost sharing support would better enable them to bill the new modifiers where appropriate as described in section II.D of this proposed rule, should they be finalized, without increasing costs for ACO beneficiaries. These modifiers are intended to better account for the complexity of visits in the ACO context, including the cognitive work of providing longitudinal care and accountability for a beneficiary's total cost of care.

As discussed in section III.G.6.a.(2)(f) of this proposed rule, if this proposal is finalized, CMS expects to make a determination that the anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§§ 1001.952(ii)(1) and (2) of this title) is available to protect remuneration exchanged under Part B cost sharing support arrangements and patient incentives in the form of Part B cost sharing support furnished to beneficiaries under the Shared Savings Program that meets the requirements of this section and the anti-kickback statute safe harbor requirements set forth at § 1001.952(ii) of this title.

(2) Proposed Revisions

(a) Eligibility, Application Procedure and Contents

To establish the ability for ACOs to offer Part B cost sharing support, we propose in § 425.304(e)(1) that eligible ACOs may, subject to certain conditions and safeguards, enter into Part B cost sharing support agreements with ACO participants, under which ACO participants reduce or eliminate cost sharing for those categories of eligible Part B items and services and eligible beneficiaries identified by the ACO. This cost sharing support could include both Medicare FFS deductible and coinsurance amounts, or either of the two.

To help ensure that only ACOs capable of complying with program requirements have the ability to offer cost sharing support, we propose to limit the ability to reduce or eliminate Part B cost sharing support to those eligible ACOs that have submitted a Part B cost sharing support application and for which CMS has approved their application to participate for that agreement period or the remainder of that agreement period.

In addition to the eligibility requirement, CMS would design application criteria to collect information important for determining ACO compliance with the requirements of new § 425.304(e) while minimizing administrative burden to ACOs. ACOs would be required to submit an implementation plan in their

[311] CMS Innovation Center. December 2025. ACO REACH Pulse Check Survey Preliminary Results. Internal Analysis.

[312] HCTTF and NAACOS: Reimagining Beneficiary Engagement in Accountable Care Models. 2026. Available at *https://www.naacos.com/wp-content/uploads/2026/03/Reimagining-Beneficiary-Engagement-in-Accountable-Models_2026.pdf.*

[313] 2026 Medicare Parts A & B Premiums and Deductibles, Fact Sheet, November 14, 2025. Available at *https://www.cms.gov/newsroom/fact-sheets/2026-medicare-parts-b-premiums-deductibles.*

[314] Cubanski J, Neuman T and Ochieng N, KFF. A Snapshot of Sources of Coverage Among Medicare Beneficiaries. 2025. Available at: *https://www.kff.org/medicare/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/.*

[315] Ibid.

[316] Roberts E, Glynn A, Donohue J, et al. Consequences of Health Insurance Cost Sharing Among Low-Income Medicare Beneficiaries: Evidence from Benefit Cliffs in Medicaid and Medicare's Prescription Drug Subsidy Program. Health Serv Res. 2020;55(Suppl 1):98–99. *https://doi.org/10.1111/1475-6773.13470.*

[317] Hamel L, Lopes L, Montero A, Presiado M, and Sparks G. Americans' Challenges with Health Care Costs. KFF. 2026. Available at *https://www.kff.org/health-costs/americans-challenges-with-health-care-costs/.*

application to provide Part B cost sharing support. ACOs will have substantial flexibility to design a Part B cost sharing support implementation plan that will be operationally and financially feasible for the ACO. As long as ACOs follow CMS procedures and accurate information is submitted to CMS, ACOs may independently determine the categories of beneficiaries and items and services for which they will reduce or eliminate Part B cost sharing.

We propose to establish the application procedures in § 425.304(e)(3)(i). An ACO must submit a Part B cost sharing support implementation plan in the form and manner and by a deadline specified by CMS. The implementation plan must include the following:

- The categories of eligible beneficiaries for which the ACO plans to make Part B cost sharing support available.
- The categories of eligible Part B items and services for which the ACO plans to make Part B cost sharing support available.
- A description of how the ACO's planned Part B cost sharing support strategy meets at least one of the clinical goals in § 425.304(e)(4)(iii).
- The procedures the ACO will implement to ensure that ACO participants that have entered into a Part B cost sharing support arrangement with the ACO have access to the most current list of beneficiaries eligible to receive Part B cost sharing support.
- A requirement for the ACO to submit to CMS a complete and accurate list of ACO participants that have entered into a Part B cost sharing support arrangement according to paragraph (e)(5)(i) of this section.
- An attestation that, in any marketing or communications regarding the availability of Part B cost-sharing support, the ACO and its ACO participants will not represent such support as a substitute for supplemental insurance coverage or encourage beneficiaries to reduce or terminate such coverage. Of note, this requirement would not prohibit ACOs from communicating the availability of Part B cost-sharing support, provided such communication complies with this limitation and those outlined at § 425.310.
- Such other information as may be specified by CMS.

We intend this application process to ensure that ACOs have a fully developed strategy that complies with § 425.304(e) prior to implementing a strategy for reducing or eliminating Part B cost sharing support for eligible beneficiaries. To allow ACOs to participate as quickly as possible, if this proposal is finalized, CMS plans to collect applications in early 2027 and approve participation by the second quarter of 2027, with a target date of April 1, 2027. After the first application review period, CMS would conduct the application cycle for ACOs to reduce or eliminate Part B cost sharing as part of, and in conjunction with, the Shared Savings Program application process under § 425.202, with instructions and timelines published on the Shared Savings Program's website.[318] We would provide further information regarding the process, including the application format and specific requirements, such as the deadline for submitting applications, through sub-regulatory guidance. The Part B cost sharing support application review process will provide an ACO with feedback and an opportunity to clarify or revise their application. In conjunction with the application process laid out at § 425.202, ACOs would have their next opportunity (after the first application review period) to apply to provide beneficiaries with Part B cost sharing support in the summer of 2027 with an effective start date of January 1, 2028. CMS posts the annual Application and Change Request Cycle on the Shared Savings Program website annually, which would be updated to include information regarding the timing for submitting an application to provide Part B cost sharing support to beneficiaries for the remainder of an ACO's agreement period.

We propose at § 425.304(e)(3)(ii) that CMS would evaluate an ACO's application to determine whether the ACO satisfies the requirements of § 425.304 and would approve or deny the application. CMS could reject the ACO's application to reduce or eliminate Part B cost sharing on the basis of one or more of the following:

- The ACO's and the ACO participant's history of noncompliance in the Shared Savings Program.
- The ACO's history of noncompliance in CMS Innovation Center ACO models.
- Whether the implementation plan complies with the requirements of § 425.304.
- Such other factors as we deem reasonable to protect the integrity of the Shared Savings Program, including concerns that the use of Part B cost sharing support may contribute to fraud, waste or abuse.

[318] *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos.*

Part B cost sharing support can impact beneficiaries and ACO participants financially and therefore requires an ACO to maintain compliance with the requirements and guardrails laid out in this section to protect beneficiaries and ACO participants. We believe historical compliance with Shared Savings Program requirements and CMS Innovation Center model requirements is important for establishing experience that suggests the ACO is capable of providing Part B cost sharing support in alignment with program requirements. For example, if an ACO or an ACO participant has a history of noncompliance and we therefore issued pre-termination actions under § 425.216, we would want to review the facts of those actions to determine whether the ACO's application to provide Part B cost sharing support should be approved. Additionally, if CMS receives additional information through claims analysis or other avenues that suggest that particular usage patterns of the Part B cost sharing support may be contributing to fraud, waste or abuse, CMS may not accept an ACO's application that proposes similar strategies.

In the event that an ACO wants to make a change to its implementation plan, we propose at § 425.304(e)(3)(iii) that the ACO must submit a description of the change to CMS in a form and manner and by a deadline or deadlines specified by CMS. CMS would evaluate the proposed change and either approve or reject it based on whether it complies with the factors outlined at proposed § 425.304(e)(3)(ii). CMS intends to provide further information regarding the process for updating the implementation plan through sub-regulatory guidance.

We seek comments on these proposals.

(b) Part B Cost Sharing Support Requirements

We propose in § 425.304(e)(4) to specify the program requirements for reducing or eliminating Part B cost sharing. We intend our proposal to allow ACOs to reduce or eliminate Part B cost sharing to improve the quality and efficiency of items and services furnished to Medicare beneficiaries by giving ACOs additional tools to encourage beneficiaries to utilize high value care. We recognize that there are a multitude of strategies that could be successful when reducing or eliminating Part B cost sharing for beneficiaries, and these strategies will likely differ by ACO. Our goal with this proposal is to provide ACOs with significant

flexibility to design a strategy that works for their organization while still maintaining safeguards for beneficiaries, health care providers, and CMS.

In § 425.304(e)(4)(i), we propose the basic eligibility requirements for a beneficiary to receive Part B cost sharing support for a specific item or service. An eligible beneficiary must be an assignable beneficiary as defined at § 425.20 and must not have secondary insurance that covers the associated Part B cost sharing support obligation. Examples of secondary insurance could include a Medigap plan, Medicaid coverage, or other supplemental coverage through a beneficiary's employer or union. A beneficiary's eligibility may vary based on the item or service for which the ACO intends to reduce or eliminate cost sharing, based on their secondary insurance coverage. If a beneficiary's secondary insurance covers cost sharing support for some items and services but not all, ACOs may reduce or eliminate cost sharing support reductions for items and services that are not covered by the secondary insurance. This requirement would ensure the beneficiaries receive the benefits of reducing or eliminating cost sharing, and not insurers. To ensure that Part B cost sharing support is focused on improving the quality and efficiency of items and services beneficiaries receive, ACOs may only reduce or eliminate Part B cost sharing for beneficiaries whose overall health is expected to be improved or maintained by receiving the associated Part B item or service. This requirement is in place to reiterate that ACOs and ACO participants may not reduce or eliminate Part B cost sharing simply to increase reimbursements to health care providers through the provision of unnecessary items and services to beneficiaries.

Proposed § 425.304(e)(4)(ii) would allow ACOs to reduce or eliminate beneficiary cost sharing for all Medicare FFS Part B items and services except durable medical equipment, prosthetics, orthotics, supplies, and prescription drugs. We believe these excluded items have a higher risk potential for fraud, waste and abuse related to reducing or eliminating cost sharing, and this proposed policy aligns with the excluded items in the ACO REACH model. We intend to continue monitoring potential high-risk items and services and may add or remove items and services from this list in future years through notice and comment rulemaking.

While ACOs would have significant flexibility to determine the groups of beneficiaries and items and services for which they intend to reduce or eliminate Part B cost sharing, we propose in § 425.304(e)(4)(iii) that an ACO's Part B cost sharing support must meet one or more of the following clinical goals for each beneficiary:

- Adherence to a treatment regime.
- Adherence to a drug regime.
- Adherence to a follow-up care plan.
- Management of a chronic disease or condition.

This is intended to focus ACO use of cost sharing support on goals that will improve or maintain the overall health of eligible beneficiaries. While ACOs would have substantial flexibility to design their strategy for reducing or eliminating Part B cost sharing, CMS believes it is important that these strategies focus on a clear theory of action for meeting certain clinical goals.

Additionally, we seek comment on whether CMS should make information regarding beneficiaries' supplemental health insurance coverage available to ACOs to assist them with determining beneficiary eligibility for and implementing Part B costs sharing support in accordance with the proposed requirements discussed above. We also seek comment on the specific data elements ACOs would need for this purpose, how frequently such information should be provided and any appropriate limitations or safeguards governing its use.

CMS currently shares certain beneficiary-identifiable data with ACOs under our regulations at 42 CFR part 425, subpart H. We believe the disclosure of this additional information would be consistent with our existing data sharing framework, which is based on HIPAA Privacy Rule provisions governing disclosures for ''health care operations,'' provided the relevant regulatory conditions are satisfied. Under 45 CFR 164.506(c)(4), a covered entity may disclose protected health information to another covered entity for the recipient's health care operations when each entity has or had a relationship with the individual who is the subject of the information, the information pertains to that relationship, and the disclosure is for a health care operations activity described in paragraphs (1) or (2) of the definition of ''health care operations'' at 45 CFR 164.501. Those activities include quality assessment and improvement activities, population-based activities relating to improving health or reducing health care costs, and evaluating practitioner or provider performance. CMS would offer only the information reasonably necessary to support implementation of Part B cost-sharing support and would establish appropriate limitations and safeguards governing its use and redisclosure.

We seek comment on whether supplemental coverage information would help enable ACOs to administer Part B cost-sharing support effectively; the particular data elements, level of detail and frequency of updates needed; and whether additional data would be necessary for ACOs to operationalize this flexibility. After consideration of comments on this topic, CMS may finalize policy to share supplemental coverage information with ACOs.

We propose to add § 425.304(e)(4), to establish standards for the implementation of Part B cost sharing support. We seek comments on these proposals.

(c) Part B Cost Sharing Support Arrangements

When an ACO chooses to reduce or eliminate Part B cost sharing, it must partner with ACO participants to implement this reduction or elimination of cost sharing for beneficiaries. In practice, the ACO would reduce or eliminate the cost sharing for an eligible beneficiary in partnership with the ACO participant, which would not collect cost sharing amounts (in whole or in part) from eligible beneficiaries for certain eligible Part B items and services. As this may have significant financial implications for practitioners, ACOs may only establish Part B cost sharing support arrangements with their ACO participants on a voluntary basis, as described below. ACOs must also communicate the relevant implementation information, including how ACO participants will be reimbursed for reduced or waived Part B cost sharing, prior to ACO participants agreeing to participate. In § 425.304(e)(5)(i), we propose that ACOs must have a written agreement with each ACO participant that has agreed to reduce or eliminate Part B cost sharing for eligible beneficiaries under a Part B cost sharing support arrangement with the ACO. The terms of the cost sharing support agreement must specify all of the following:

- The categories of eligible beneficiaries and eligible Part B items and services for which the ACO participant may reduce or eliminate cost sharing.
- A requirement that the ACO participant reduce or eliminate cost sharing in accordance with the ACO's approved implementation plan.
- The amount and frequency with which the ACO will reimburse the ACO participant for the cost sharing amounts not collected.

• A requirement for ACO participants to maintain copies of records that identify each beneficiary who received a reduction or elimination of Part B cost sharing, the type and date of service for which cost sharing support was provided, and the dollar amount of the cost sharing support.

• The ability for the ACO or ACO participant to terminate the Part B cost sharing support agreement if the ACO or ACO participant fails to comply with the requirements of this section.

• A requirement that the ACO or ACO participants will not market to beneficiaries the availability of the Part B cost sharing support as a substitute for their supplemental insurance coverage.

All cost sharing support provided to beneficiaries must be provided in accordance with the ACO's implementation plan and the cost sharing support agreement between the ACO and ACO participant. We propose in § 425.304(e)(5)(ii)(A) and (B) that an ACO participant cannot be required by an ACO to participate in an ACO's Part B cost sharing support arrangement and, alternatively, an ACO can participate in Part B cost sharing support, under an approved implementation plan, even if not all of its ACO participants agree to participate. While we believe reducing or eliminating Part B cost sharing is an important tool to offer ACOs, ACOs should not pressure their ACO participants into providing Part B cost sharing support. ACOs would be required to permit ACO participants to choose whether they wish to participate. CMS expects that some ACO participants would decide not to participate and that ACOs would be able to implement a reduction or elimination of Part B cost sharing for eligible beneficiaries if only a portion of their ACO participants were to opt in.

Additionally, to avoid inappropriate conflicts of interest, we propose in § 425.304(e)(5)(iii) that the ACO would be required to finance all payments made to ACO participants under the cost sharing support agreements from the ACO's own funds. For example, ACOs may not partner with local businesses outside the ACO to fund copay reimbursements to health care providers.

We propose to add § 425.304(e)(5) to establish the standards discussed previously in this section for the cost sharing support agreements ACOs must develop for ACO participants that choose to reduce or eliminate Part B cost sharing. We seek comments on these proposals.

(d) Record Retention

To maintain the ability for CMS to monitor the implementation of the reduction or eliminating Part B cost sharing and resolve any identified compliance issues, we propose to require that ACOs must keep detailed records on the reduction or elimination of Part B cost sharing for beneficiaries. We propose in § 425.304(e)(6)(i) that the ACO must maintain copies of the written cost sharing support agreements with ACO participants, as well as the following records.

• Records that identify each beneficiary who received a reduction or elimination of Part B cost sharing.

• Records that document the type and date of the Part B item or service for which Part B cost sharing was reduced or eliminated.

• Records that document the dollar amount of Part B cost sharing that was reduced or eliminated; and

• Records that document the ACO participant that furnished the item or service for which cost sharing support was reduced or eliminated.

Additionally, we propose at § 425.304(e)(6)(ii) that the ACO must provide the records specified in paragraph (e)(6)(i) upon CMS' request. For example, CMS may request these records if disputes arise that are elevated to CMS or if CMS has any reason to believe there may be non-compliance with a cost sharing support requirement. We may also conduct periodic audits to ensure compliance with this requirement.

We propose to add § 425.304(e)(6) to establish the standards discussed previously in this section for the record retention related to the reduction or elimination of Part B cost sharing. We seek comments on these proposals.

(e) Addressing Compliance Problems

To protect both beneficiaries and health care providers, CMS proposes in § 425.304(e)(7) that at any time, CMS may suspend or prohibit the ACO or any ACO participant from participating in a Part B cost sharing support arrangement if CMS determines that the ACO or ACO participant has failed to comply with any of the requirements of Part 425. This suspension or prohibition will be effective, in CMS's discretion, regardless of whether the ACO has corrected or otherwise resolved the noncompliance.

We propose to add § 425.304(e)(7) to establish the standards discussed previously in this section for compliance and enforcement policies related to the reduction or elimination of Part B cost sharing. We seek comments on these proposals.

(f) OIG Safe Harbor Authority

We expect to make a determination, if this rule is finalized, that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§§ 1001.952(ii)(1) and (2) of this title) is available to protect remuneration exchanged under certain financial arrangements and patient incentives that may be permitted under the final rule. Specifically, we expect to determine that the CMS-sponsored models safe harbor would be available to protect the following: remuneration exchanged under Part B cost sharing support arrangements between the ACO and ACO participant and patient incentives in the form of Part B cost sharing support furnished to eligible beneficiaries.

We propose to add new § 425.304(e)(2) that notes that CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§§ 1001.952(ii)(1) and (2) of this title) is available to protect remuneration exchanged under Part B cost sharing support arrangements between ACOs and ACO participants, and patient incentives in the form of Part B cost sharing support furnished to eligible beneficiaries under the Shared Savings Program that meet all of the requirements of this section and the anti-kickback statute safe harbor requirements set forth at § 1001.952(ii) of this title.

We seek comments on this proposal to allow ACOs to reduce or eliminate Part B cost sharing beginning in 2027, with a target date of April 1, noting that the application process for this first performance year will occur during early 2027.

b. Proposal to Discontinue Availability of the Option for Prepaid Shared Savings

(1) Background

In the CY 2025 PFS final rule (89 FR 97710), CMS finalized prepaid shared savings, a payment option for ACOs that meet the eligibility criteria under § 425.640 (89 FR 98134). This new payment option provides prepaid shared savings to ACOs with a history of earning shared savings while participating in the Shared Savings Program (89 FR 98134). These payments would be distributed on a quarterly basis and would be recouped from shared savings CMS determines the ACO to have earned during the annual financial reconciliation cycle (89 FR 98134). Prepaid shared savings are the

advanced payment of shared savings that are expected to be earned by the ACO and are covered under the Shared Savings Distribution Waiver (89 FR 98134 referencing 80 FR 66726).

In the CY 2025 PFS final rule, certain policies, including both existing policies and new policies adopted in the final rule, relied upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determined would improve the quality and efficiency of items and services furnished under the Medicare program, and that would not result in program expenditures greater than those that would result under the statutory payment model (89 FR 98085). This included allowing eligible ACOs to receive prepaid shared savings, as described in the final rule (89 FR 98085). Such a change to our payment methodology for prepaid shared savings was expected to improve the quality and efficiency of care and was not expected to result in a situation in which the payment methodology resulted in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act (89 FR 98085). As described in the Regulatory Impact Analysis in the CY 2025 PFS final rule, the impact of prepaid shared savings alone was projected to be nominal. Both at the mean and at the 90th percentile the projected net impacts on Medicare spending rounded to zero (89 FR 98526). We noted at the time that there was a high degree of uncertainty regarding whether (a) a meaningful number of ACOs would choose this option given the requirements for how prepayments must be spent, and (b) the potential impact (if any) that participation in this option would have on the cost of care (89 FR 98525).

Uptake of this payment option has been very low. Only four ACOs participated in prepaid shared savings in 2026, the first year the payment option was available. This is likely due to a number of factors, many of which were raised by commenters during CY 2025 PFS rulemaking (89 FR 98136).

As part of the prepaid shared savings option under § 425.640(e)(1)(ii), ACOs participating in prepaid shared savings must spend at least 50 percent of prepaid shared savings on direct beneficiary services in each performance year. These include, but are not limited to: cost-sharing support for Part B beneficiaries; certain vision, hearing and dental services; beneficiary meals; nutrition support; tenancy support and sustaining services, housing assistance, utility support, caregiver support services; services to address social isolation, home visits; and transportation services.[319] Under § 425.640(e)(1)(i), ACOs may also elect to spend up to 50 percent of their prepaid shared savings on staffing (for example, hiring physicians or mid-level providers or staff education) and healthcare infrastructure investments (for example, improving practice management or electronic health record systems) in each performance year. ACOs participating in prepaid shared savings are prohibited from using prepaid shared savings for any expense other than those allowed under § 425.640(e)(1), including but not limited to the following: management company or parent company profit; performance bonuses; provision of medical services covered by Medicare; cash or cash equivalent payments to patients; and items or activities unrelated to ACO management and operations of an ACO or beneficiary care (§ 452.640(e)(2)). In the CY 2025 PFS final rule (89 FR 98141), we stated that the prepaid shared savings policy was developed to improve the quality and efficiency of items and services furnished to Medicare beneficiaries. We explained that the requirement that ACOs spend at least 50 percent of their prepaid shared savings on direct beneficiary services is important for meeting those goals. Direct beneficiary services like vision, hearing and dental, and other services that are evidence-based and medically appropriate for the beneficiary based on clinical risk factors, have the potential to improve beneficiary health outcomes, reduce costs, and improve beneficiary engagement and willingness to receive care from a provider affiliated with an ACO. We believed financially successful ACOs are likely to have already made significant investments in staffing and healthcare infrastructure, as they are necessary for the functioning of an ACO. We also noted the restriction on using prepaid shared savings for expenses like provider bonuses is important for ensuring that prepaid shared savings are used for expenses that directly improve beneficiary care (89 FR 98141).

Additionally, to monitor compliance with ACO use of the prepaid shared savings, CMS requires ACOs to submit an annual spend plan under § 425.640(d) detailing their planned use of prepaid shared savings to CMS as well as publicly report the total amount of prepaid shared savings received, investments made, beneficiary groups served, changes to ACO's spend plan, and an itemization of how prepaid shared savings were spent during the performance year (§ 425.308(b)(10) and § 452.640(i)). In the CY 2025 PFS final rule (89 FR 98138), we noted that we understood that submitting a detailed spend plan on the use of prepaid shared savings requires administrative work for participating ACOs. However, detailed spend plans which include information on (1) direct beneficiary services that would be provided to ACO beneficiaries; and (2) investments that would be made in the ACO with prepaid shared savings are important for monitoring that ACOs use prepaid shared savings consistent with the requirements for use and management of prepaid shared savings under § 425.640(e) (89 FR 98138). CMS expressed that it was particularly important for us to ensure ACOs use prepaid shared savings consistent with those use and management requirements because prepaid shared savings are advances of shared savings to ACOs prior to ACOs actually earning the shared savings, and should be focused on improving beneficiary outcomes and quality of care, reducing costs, improving ACO efficiency, and improving beneficiary engagement and willingness to receive care from a provider affiliated with an ACO. Those requirements also promote transparency in how ACOs are using prepaid shared savings. That transparency improves the coordination and quality of care provided by participating ACOs by facilitating their efforts to share information with each other, CMS, and the public about how they effectively used prepaid shared savings to improve the quality and efficiency of the care they provided to their beneficiaries (89 FR 98138).

In the CY 2025 PFS final rule (89 FR 98141), commenters noted that the restrictions on use of prepaid shared savings and the amount of documentation required would create significant administrative burden beyond what is already required by the Shared Savings Program. Many commenters asserted that the restrictions on the use of prepaid shared savings are unnecessary and likely to negatively impact ACO participation in prepaid shared savings (89 FR 98141). Most of the commenters disagreed with the requirement that ACOs spend at least 50 percent of prepaid shared savings on direct beneficiary services (89 FR 98141). They also commented that providing written spend plans would generate additional burden for ACOs (89 FR 98138). CMS acknowledged commenter concerns but

[319] See Prepaid Shared Savings Guidance, May 2025 Version 1 *https://www.cms.gov/files/document/prepaid-shared-savings-guidance.pdf.*

implemented the policy largely as proposed. CMS subsequently heard similar feedback from ACOs during the first application period for prepaid shared savings, PY 2026, including that the requirement to spend at least 50 percent of prepaid shared savings on direct beneficiary services is unrealistic as there is a lack of evidence that services identified as ''direct beneficiary services'' generates sufficient return on investment for ACOs.

We continue to believe that these guardrails on the use and reporting of prepaid shared savings are important for ensuring ACOs direct these funds in a way that improves the quality and efficiency of items and services furnished to Medicare beneficiaries; however, we believe that commenters were also correct that these guardrails significantly limited participation. In CY 2025 PFS final rule (89 FR 98141), CMS anticipated that the restrictions in prepaid shared savings could reduce the number of ACOs that ultimately decide to participate in prepaid shared savings. During the PY 2026 application cycle, 23 ACOs submitted an application for prepaid shared savings and only 4 were ultimately approved to participate. The majority of applicants withdrew from consideration or were denied participation due to deficiencies with their applications. Examples of the deficiencies included submitted spend plans that did not align with the requirement that 50 percent of the funding be spent on direct beneficiary services. We believe the low participation rate reflects the administrative burden and limited financial incentive of the prepaid shared savings option for ACOs. At this time, we believe we can achieve similar outcomes with less burden and less financial risk to CMS through an alternative approach that offers ACOs the ability to reduce or eliminate Part B cost sharing as described in section III.G.6.a. of this proposed rule, as ACOs are already permitted to use their earned shared savings to invest in staffing and healthcare infrastructure.

(2) Proposed Revisions

Based on our experience with the prepaid shared savings option to date, we are proposing to remove the prepaid shared savings option from the Medicare Shared Savings Program. Although our prior analysis assumed up to 30 ACOs per year might elect the option,[320] actual uptake has been significantly lower with only four ACOs currently participating.

We believe this limited uptake constrains the option's ability to meaningfully advance the goals for which it was established, including improving beneficiary engagement and outcomes and reducing unnecessary expenditures. At the same time, maintaining the option requires CMS to maintain annual application cycles for the prepaid shared savings option, monitor ACO participation under prepaid shared savings, distribute payments, and assume the risk of unpaid debt.

Furthermore, based on early experience with the program with few ACOs opting to participate and feedback from eligible ACOs, we anticipate that participation in the prepaid shared savings option as currently written is likely to remain limited, as we do not believe we can resolve the ACOs' concerns with the payment option while meeting the option's original goals and safeguards. For example, the requirement that ACOs spend at least 50 percent of the funding on direct beneficiary services is necessary for impacting beneficiary health outcomes and reducing costs. Similarly, spend plan requirements are necessary for monitoring and transparency purposes. Removing or substantially weakening these requirements would materially change the purpose and expected effects of the option. Given the very limited participation to date as well as limited anticipated future participation, we do not believe continuing to maintain this option is an effective and efficient use of CMS program resources.

As such, we plan to sunset the prepaid shared savings option over the course of currently participating ACOs' agreement periods.

We propose to revise § 425.640(b) to end ACO eligibility for prepaid shared savings beginning on January 1, 2027. Section 425.640(b)(1)(i) will be revised to read, the ACO is a renewing ACO as defined under § 425.20 entering an agreement period beginning on January 1, 2026 or January 1, 2027. We will accept one final cohort of ACOs during the PY 2027 application cycle but will no longer accept applications for this prepaid shared savings payment option after this year. We propose to revise § 425.640(c)(1) to read, ''For an ACO renewing to enter into an agreement period beginning on January 1, 2026 or January 1, 2027, to obtain a determination regarding whether the ACO may receive prepaid shared savings, the ACO must submit a complete supplemental application with its application to renew for a new agreement period in the Shared Savings Program (submitted under § 425.224) in the form and manner and by a deadline specified by CMS.''

Additionally, we propose to revise § 425.640(f)(1) to no longer distribute prepaid shared savings to ACOs after December 31, 2027. Section 425.640(f)(1)(i) will be revised to state, ''An eligible ACO entering an agreement period beginning on January 1, 2026, or January 1, 2027 will receive quarterly prepaid shared savings payments through December 31, 2027, unless the payment is withheld or terminated under paragraph (h) of this section.'' A similar change will be made to § 425.640(f)(1)(ii), which will be revised to read, ''An eligible ACO participating in an agreement period beginning on January 1, 2025, will receive quarterly prepaid shared savings payments starting with the performance year beginning on January 1, 2026, through December 31, 2027, unless the payment is withheld or terminated under paragraph (h) of this section. The ACO will not receive additional or catch-up payments for performance year 2025.'' Currently participating ACOs who receive payments for 2026 and 2027 will not receive prepaid shared savings payments beginning in 2028. Any ACO who begins participating in 2027 will receive one year of payments in 2027 and will not receive payments beginning in 2028. We intend to provide further information regarding the timing of final quarterly payments through sub-regulatory guidance.

We do not anticipate significant disruption among ACOs participating in the option or their beneficiaries due to (1) the low number of participants, (2) the ample notice we propose giving ACOs to plan for the sunsetting of the prepaid shared savings option and (3) the ability of ACOs to continue to provide any ''direct beneficiary services'' through their earned shared savings. With the exception of beneficiary cost sharing support, ACOs are currently permitted to use their earned shared savings to pay for anything that is currently being covered by prepaid shared savings as both funding sources qualify for protection under the Shared Savings Program ACO Final Waivers (80 FR 66726). As discussed in section III.G.6.a. of this proposed rule, CMS is proposing to allow ACOs to offer beneficiary cost sharing support outside of prepaid shared savings in early 2027 so there will be no gap in an ACO's ability to offer beneficiary cost sharing support if they opt to offer it under earned prepaid shared savings.

Those ACOs who participate in the prepaid shared savings participation option in 2026 or 2027 will not see

[320] 89 FR 98525.

changes to the requirements of the program for the prepaid shared savings they receive. Specifically, ACOs that receive prepaid shared savings in 2026 or 2027 will continue to be able to spend the funding as outlined in § 425.640(e). ACOs will be required to continue to participate in the monitoring and reporting requirements of prepaid shared savings until all prepaid shared savings have been repaid to CMS.

We still believe there is value in encouraging ACOs to engage beneficiaries with strategies and tools designed to support their health and believe there is value in supporting cash flow mechanisms for ACOs. However, the combination of these two goals in prepaid shared savings does not appear viable. We are proposing under § 425.304(e) to allow all eligible ACOs to offer cost sharing support to beneficiaries beginning early 2027 as noted previously in this section. We are interested in feedback on tools ACOs would find valuable for engaging beneficiaries in hopes to expand policies in this area in future years. We are also interested in additional ways to support ACO cash flow and are looking for feedback on this topic as outlined in the Request for Information on primary care capitation in section II.E. of this proposed rule.

We seek comments on the proposal to eliminate the prepaid shared savings option as of January 1, 2028, noting that the last opportunity for a cohort to elect to participate in the option will be for PY 2027.

7. Proposal To Modify the Methodology and Use Description for Advance Investment Payments

(a) Background

In the CY 2023 PFS final rule (87 FR 69782 through 87 FR 69805), we finalized the availability of the advance investment payment option, beginning on January 1, 2024. Advance investment payments are available to eligible low revenue ACOs inexperienced with performance-based risk Medicare ACO initiatives and that are new to the Shared Savings Program. These ACOs may receive an up-front, one-time fixed payment of $250,000 and per beneficiary quarterly payments for the first two performance years of their agreement period. Eligible ACOs that apply for and receive advance investment payments receive payments determined under the methodology described in § 425.630(f)(2). Furthermore, ACOs' use of advance investment payments is subject to the requirements set forth in § 425.630(e). ACOs are permitted to use the advanced investment payments to invest in increased staffing, healthcare infrastructure, and the provision of accountable care for underserved beneficiaries. Advance investment payments are intended to reduce upfront costs that prevent providers and suppliers from forming ACOs, caring for beneficiaries in underserved communities, and achieving long-term success in the Shared Savings Program. For more information about the history and development of the advance investment payment option and goals for the program, refer to the CY 2023 PFS final rule (87 FR 69782 through 87 FR 69805).

(1) Area Deprivation Index

In the CY 2023 PFS final rule (87 FR 69792 through 69800), we finalized that the amount of advance investment payments that eligible ACOs can receive over the two years of quarterly payments was based on assigned beneficiaries' area deprivation index (ADI) score, Medicare Part D Low Income Subsidy (LIS) status, and dual eligibility for Medicare and Medicaid. The maximum amount was finalized as $45 per eligible beneficiary per quarter and there was a 10,000-beneficiary cap for the calculation of quarterly payments. LIS/dual eligibility grants an ACO the maximum $45 per eligible beneficiary, whereas ADI scores provide a range of payment amounts for beneficiaries without LIS/dual eligibility.

The quarterly advance investment payment calculation methodology finalized in the CY 2023 PFS final rule (87 FR 69792 through 69800) results in an increase in payments when more beneficiaries who are LIS/dually eligible or who live in areas with high deprivation (measured by ADI), or both, are assigned to the ACO. Regarding ADI, the risk factors-based score was set to the ADI national percentile rank of the census block group in which the beneficiary resides, and higher risk factors-based scores resulted in ACOs receiving higher payment amounts for assigned beneficiaries (87 FR 69794 and 69795). ADI scores range in payment amounts from $0 for those with a risk factors-based score between 1 and 24 to the maximum $45 for those with a risk factors-based score between 85 and 100 (§ 425.630(f)(2)(iii)). The quarterly payments intend to compensate for variable ongoing operating costs that are related to the provision of care for the ACO's assigned beneficiaries.

We stated in the CY 2023 PFS final rule (87 FR 69793 and 69794) that we believed using ADI was a method for indicating beneficiaries with high needs, specifically to capture local socioeconomic factors correlated with medical disparities and underservice. We stated that the inclusion of ADI as a criterion for quarterly advance investment payments furthered CMS's goal to reduce financial barriers for new, low revenue, and inexperienced ACOs. Since the option became available January 1, 2024, we have reviewed the characteristics of ACOs electing to participate in the advance investment payment option and how ADI as well as LIS/dual eligibility are impacting ACOs' quarterly advance investment payments.

(2) Advance Investment Payment Program Post-Implementation

In PY 2024, 19 newly formed ACOs in the Shared Savings Program were participating in the new advance investment payment option, receiving more than $25.7 million in advance investment payments in their first performance year.[321] Analysis of ACOs receiving advance investment payments show that the payment option is encouraging ACOs to form in areas where ACOs may not have otherwise formed and where other Medicare payment and delivery innovations were less likely to be present. In its first year of implementation, the advance investment payment option appeared to attract new ACOs in these communities. Compared to non-advance investment payment ACO starters in 2024, the advance investment payment ACOs were caring for more beneficiaries residing in a health provider shortage area (51.2 percent versus 34 percent) and residing in a rural location (42.1 percent versus 27.0 percent).[322] Our analysis of the advance investment payments made in PYs 2025 and 2026 also investigated which beneficiary characteristics were impacting the quarterly payment amount received by ACOs receiving advance interest payments. This analysis showed that the average share of quarterly payments attributed to ADI beneficiaries, as opposed to LIS/dual eligible beneficiaries, fluctuated by 13 percentage points between PY 2025 and PY 2026.[323]

After publication of the CY 2023 PFS final rule for the advance investment payment option, we were made aware of

[321] Counts based on internal analysis of ACOs participating in the Advance Investment Payment option in PY 2024.

[322] Counts based on internal analysis of ACOs participating in the Advance Investment Payment model in PY 2024.

[323] Counts based on internal analysis of ACOs participating in the Advance Investment Payment model in PYs 2025 and 2026.

concerns with the lack of standardization of ADI: Scores were heavily influenced by the median home value indicator, which is one out of the 17 indicators included in the calculation of ADI.[4] The 17 indicators are combined directly and, as such, the median home value indicator, which a combination of being in large dollar units and having large variance, impacts ADI scores more than other indicators, in particular, the percent-based indicators (for example, percent living in poverty). Cost-of-living when primarily captured by a region's median home value is incomplete and not perfectly aligned with area deprivation, as current research testing ADI indicates. For example, analyses have shown that many regions with high median home values were flagged as low deprivation based on their ADI scores, but these areas were experiencing deprivation when looking at other ADI variables such as poverty and unemployment rates.[324] [325] We do not believe it is appropriate to continue using an indicator that is not meeting its stated goals of identifying area deprivation, and propose to revise the advance investment payment methodology to simplify and refocus on the intended outcome of reducing upfront costs that prevent providers and suppliers from forming ACOs, caring for beneficiaries in underserved communities, and achieving long-term success in the Shared Savings Program.

(b) Proposed Revisions

(1) Proposed Removal of the Area Deprivation Index From the Advance Investment Payment Methodology

We propose to remove ADI from the advance investment payments methodology at § 425.630(f)(2). Our proposal to remove ADI from the quarterly payment amount methodology and remove the risk factors-based score (as described below in section III.G.7.2.b) necessitates adjustments to § 425.630(f)(2)(ii) and is intended to better meet the objectives of the advance investment payment option policy.

(2) Proposed Addition of the Rural Criterion to the Advance Investment Payment Methodology

While we are proposing to remove ADI, we want to continue to encourage low-revenue ACOs that are inexperienced with risk to participate in the Shared Savings Program, including rural ACOs as noted previously in this section. Rural ACOs are currently underrepresented in the Shared Savings Program, with only 14.5 percent of TINs participating in Shared Savings Program ACOs located in rural areas in comparison to 20 percent of non-Shared Savings Program TINs.[326] This analysis of FY 2024 assigned beneficiaries, provided in section III.G.7.1.b. of this proposed rule, highlights a smaller proportion of these beneficiaries live in rural communities. We propose adding a rural component to the payment amount calculation for determining quarterly advance investment payments and believe this addition, in conjunction with the current components targeting beneficiaries enrolled in the Medicare Part D LIS or dually eligible for Medicare and Medicaid, will contribute to the advance investment payment option's increasing ACO's population health management capabilities, including the provision of accountable care for underserved beneficiaries, while simplifying the calculation (87 FR 69788). This also aligns with work CMS is carrying out through the Rural Health Transformation Program that was authorized by section 71401 of the Working Families Tax Cut legislation (Pub. L. 119–21, July 4, 2025).

Through the Rural Health Transformation Program, CMS is working to strengthen rural communities across America by improving healthcare access, quality, and outcomes by transforming healthcare delivery. Encouraging ACO formation in rural areas directly supports these goals.[327] Primary residence in rural areas can be associated with barriers to accessing care, including geographic isolation, provider shortages, transportation challenges, limited broadband or technology infrastructure, and fewer locally available health care resources. We had hoped to address some of these access-related challenges through the inclusion of ADI in the advance investment payments methodology. However, rural residence captures a distinct set of geographic and infrastructure-related barriers.

Our internal analysis of ACO beneficiaries indicates there is limited overlap between LIS/duals eligibility and beneficiaries living in a rural area. As a result, adding a rural residence component would allow the methodology to better identify and direct the maximum quarterly payment amount to additional underserved beneficiaries who may face access-related barriers that are not otherwise captured by LIS/dual eligibility status.

As noted, we believe rurality is an appropriate geographic proxy for access-related challenges, including differences in health care infrastructure and workforce availability. These factors may affect an ACO's ability to form, participate, and succeed in rural areas and therefore ACOs therefore may need a higher amount of advance investment payments to consider participating. We seek to encourage formation of ACOs in areas experiencing medical disparities and underservice, and have recognized through internal analysis of assigned beneficiary characteristics that the LIS/dual eligibility statuses do not fully capture rural beneficiaries. Therefore, we propose introducing a rural component to the advance investment payments methodology.

To calculate the advance investment payment for an eligible ACO based on the number of their rural assigned beneficiaries, we propose establishing a beneficiary's rural residence from their latest mailing address in the CMS data systems at the time of determining advance investment payments. Furthermore, we propose using the most recently available version of the United States Census Bureau Delineation File to determine whether a beneficiary resides in a rural county.[328] The Office of Management and Budget (OMB) makes the delineation file publicly available on the Census.gov website. OMB provides the delineation file and other reference files as a reliable standard for academic research and public policy development. The delineation file defines an area as micropolitan or metropolitan as having a population of 10,000 to 50,000 individuals or a population greater than 50,000 individuals, respectively. Areas where the population is less than 10,000 are considered noncore. Noncore areas are defined by identifying Federal Information Processing Standards State

[324] Edward L. Hannan, Yifeng Wu, Kimberly Cozzens, and Brett Anderson, Health Affairs 2023. Available at *https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.01406*.

[325] Alexander M, Azar K, Smits K, Tio A, deGhetaldi L. Health Affairs Forefront. February 2023. ACO Benchmarks Based On Area Deprivation Index Mask Inequities. Available at *https://www.healthaffairs.org/content/forefront/aco-benchmarks-based-area-deprivation-index-mask-inequities*.

[326] Counts based on internal analysis of ACOs participating in the Shared Savings Program in PY 2026.

[327] CMS Rural Health Transformation (RHT) Program. 2026 Available at *https://www.cms.gov/priorities/rural-health-transformation-rht-program/overview*.

[328] Refer *to https://www.census.gov/geographies/reference-files/time-series/demo/metro-micro/delineation-files.html*.

and County codes that are not included in the delineation file. OMB does not characterize counties as rural or urban, and we propose to use the Federal Office of Rural Health Policy (FORHP), in the Health Resources and Services Administration, interpretation of these county designations, which considers all non-metro counties as rural.[329] We propose that beneficiaries will be considered to be residing in a rural county for the purposes of the advance investment quarterly payment calculation, if they are non-metro, that is residing in a micropolitan or noncore area. As of July 2023, 13.8 percent of the U.S. population is living in the micropolitan or noncore areas.[330]

For the purpose of implementing changes to the advance investment payments, the use of county level data would allow for timelier implementation and sharing of data with ACOs since the delineation file is readily available and already used by CMS for internal analyses of ACOs by region. Counties are also well understood by providers and stable over time, which reduces complexity and burden for ACOs working to understand the methodology. We believe that this rural definition, in combination with the maximum payments based on beneficiary LIS/dual eligibility status, will support ACOs in caring for beneficiaries in underserved communities.

(3) Proposed Amount for All Beneficiaries to the Advance Investment Payment Methodology

We intend for these changes to the advance investment payments methodology to encourage the formation of new ACOs in underserved communities and describe the proposed rural criteria for determining advance investment payments above. However, as we stated in the CY 2023 PFS final rule (87 FR 69785), we do not believe in limiting advance investment payment option eligibility only to ACOs serving rural areas or areas with a high proportion of beneficiaries dually eligible for Medicaid and Medicare or Part D LIS is in line with the policy's goals. We recognize that there are beneficiaries who reside in other areas who could also benefit from the high-quality coordinated care an ACO provides. With the removal of ADI and its tiered scoring structure using risk factors-based scores, we propose an alternative payment methodology that also accounts for non-rural beneficiaries who are not LIS/dually eligible and whose assignment may have resulted in some payment under the current advance investment payments methodology. Our experience implementing the advance investment payment option over the last few years leads us to believe ACO participation in the payment option could be more attractive with the addition of a lower flat payment amount for all beneficiaries assigned to the ACO, up to the 10,000 beneficiaries cap. Therefore, we propose that all non-rural beneficiaries who are not LIS/dually eligible beneficiaries would result in ACOs receiving a flat rate of $25 per beneficiary as part of setting each ACO's quarterly payments.

We anticipate that the proposed change to remove ADI and add rurality as well as a payment amount for all beneficiaries not identified as LIS/dual eligible or rural will provide similar aggregate quarterly payment amounts to new advance investment payment option participants and, in keeping in line with the intent of the advance investment payment option, any new methodology developed should encourage ACOs serving populations that need financial support to begin participation in value-based care. We conducted an analysis that compared the quarterly advance investment payments for PY 2024 using the existing methodology utilizing ADI and the proposed methodology using a rural component. Results indicated that, compared to the current methodology, the proposed methodology will provide the vast majority (89.5 percent) of advance investment payment ACOs with slightly higher payments (totaling about $889,000 more per quarter or $3.6 million more per year distributed among all ACOs), which align with payment goals outlined previously in this section.[331] While we believe these proposed policy adjustments will increase support for ACO formation in rural areas, this analysis demonstrates that our proposed policies maintain support for ACOs regardless of location.

Section 1899(i)(3)(A) of the Act requires CMS to determine that advance investment payments would improve the quality and efficiency of items furnished to Medicare to make such payments. We believe that the updated methodology will meet this standard and improve our ability to target the populations that CMS seeks to support.

Section 1899(i)(3)(B) of the Act requires CMS to determine that advance investment payments, when implemented in combination with existing modifications made to the Shared Savings Program specified in section 1899(d) of the Act, will not result in additional program expenditures. In evaluation of current program performance, the structure of advance investment payment program is successful in not increasing program expenditures, and the changes to the methodology will not affect this outcome as the overarching structure the advance investment payment option remains the same. In accordance with section 1899(i)(3) of the Act authorizing the use of alternative payment models, we propose to update the steps at § 425.630(f)(2) to allow ACOs participating in the advance investment payment option will receive a maximum payment of $45 if the assigned beneficiary is enrolled in the Medicare Part D LIS or is dually eligible for Medicare and Medicaid or is residing in a Micropolitan or ''Noncore'' Census Status (henceforth ''rural''). Additionally, for beneficiaries outside of these categories, ACOs will receive a flat rate of $25 per beneficiary as part of setting each ACOs quarterly payments.

(4) Implementation Timeline for Revisions to the Advance Investment Payments Methodology

We propose that changes to remove ADI and to add rurality to the quarterly payment methodology would be implemented for ACOs who apply for the advance investment payment option with an effective date of January 1, 2028, as well as for the second year of payments for ACOs who began receiving advance investment payments in 2027. This timeline allows ACOs planning to apply to the Shared Savings Program to understand the proposed methodology for the advance investment payment option prior to applying to the program in the summer of 2027. We believe that as the vast majority of the ACOs will receive slightly higher payments under the new methodology, it is a more efficient use of agency resources to move to using the updated methodology for all ACOs at the same time, instead of running two separate methodologies simultaneously.

We seek public comment on the proposed timeline for implementing changes to the advance investment payments methodology effective January 1, 2028. Specifically, we are seeking public comment on the following proposed revisions to the regulation text at § 425.630:

[329] Health Resources and Services Administration. How we Define Rural. Available at *https://www.hrsa.gov/rural-health/about-us/what-is-rural.*

[330] US Census Bureau. Metropolitan and Micropolitan. Available at *https://www.census.gov/programs-surveys/metro-micro.html.*

[331] Based on internal analysis of ACOs participating in the Advance Investment Payment model in PY 2024.

• At paragraph (f)(2)(ii) add the introductory phrase ''For performance years 2023 through 2027.''

• At paragraph (f)(2)(iii), we propose to specify how CMS determines the amount each assigned beneficiary adds to an ACOs quarterly payment amount. At new paragraph (f)(2)(iii)(A), we describe the existing requirements on how we determine the payment amount that corresponds to the beneficiary's risk factors-based score, and related table, which we propose to specify would be applicable for PYs 2023 through 2027. In new paragraph (f)(2)(iii)(B), we are proposing to specify how we would determine the quarterly payment amount for PY 2028 and subsequent PYs. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS determines the quarterly payment amount for two categories of beneficiaries. First, an ACO will receive a quarterly payment of $45 for each beneficiary that meets any of the following criteria:

• Is enrolled in the LIS.

• Is dually eligible for Medicare and Medicaid.

• Is residing in a county with rural census status (as defined at § 425.20). CMS determines the county of residence for the beneficiary based on the beneficiary's mailing address.

Then, an ACO will receive a quarterly payment of $25 for each beneficiary who does not meet any of the criteria listed in paragraph (f)(2)(iii)(B)(1) of this section.

At paragraph (f)(2)(iv), we propose to specify how CMS calculates an ACO's quarterly payment amount. In new paragraph (f)(2)(iv)(A), we describe the existing process that the quarterly payment amount is the sum of the beneficiary payment amounts corresponding to each assigned beneficiary's risk factors-based score, capped at 10,000 beneficiaries, which we propose to specify would be applicable for PYs 2023 through 2027. In new paragraph (f)(2)(iv)(B), we are proposing a new methodology for PY 2028 and subsequent PYs. We propose that the ACO's quarterly payment amount will be the sum of the beneficiary payment amounts corresponding to the quarterly payments specified in paragraph (f)(2)(iii)(B) of this section. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, we will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest quarterly payment determined according to paragraph (f)(2)(iii)(B) of this section.

We are also seeking public comment on the proposed revisions to the regulation text at § 425.20:

Add new definition for the term ''Rural County Status'' to mean beneficiary residence in a mailing address with United States county status of Micropolitan (population of 10,000 to 50,000 individuals) or Noncore (population less than 10,000 individuals) per the Federal Office of Rural Health Policy (FORHP) county designation using the most recently available version of the United States Census Bureau Delineation File.

(5) Proposed Revisions to the Terminology of Allowable Uses

At § 425.630(e)(1), we state that an ACO must use an advance investment payment to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing social determinants of health. We believe that the term ''social determinants of health'' is not as precise as we would prefer, and propose to replace the term with ''upstream drivers of health.'' Specifically, while the terms are similar in describing non-medical factors that can shape beneficiaries' health, ''upstream drivers of health'' more clearly describes the focus on the upstream or root causes of health outcomes. This framing does not change the types of investments that advance investment payments can be spent on, but instead more clearly identifies these investments, which include, but are not limited to, transportation, utilities and housing-related assistance, as well as services to encourage improved fitness and nutrition and promote a healthy environment. Specifically, we propose to revise § 425.630(e)(1) to read: ''Allowable uses. An ACO must use an advance investment payment to improve the quality and efficiency of items and services furnished to beneficiaries by investing in increased staffing, health care infrastructure, and the provision of accountable care for underserved beneficiaries, which may include addressing upstream drivers of health. Expenditures of advance investment payments must comply with the beneficiary incentive provision at § 425.304, paragraph (e)(2) of this section, and all other applicable laws and regulations.'' We seek comments on this proposal.

8. Identifying ACOs Experienced With Performance-Based Risk Medicare ACO Initiatives

a. Background

In the December 31, 2018 Shared Savings Program final rule (83 FR 67816), referred to as the Pathways to Success, CMS finalized the definition of the term, ''performance-based risk Medicare ACO initiative,'' to mean an initiative implemented by CMS that requires an ACO to participate under a two-sided model during its agreement period (83 FR 67904). This includes Levels C, D and E of the BASIC track, and the ENHANCED track of the Shared Savings Program. This definition also includes other Medicare ACO initiatives involving two-sided risk, such as two-sided risk CMS Innovation Center ACO Models, as may be specified by CMS (83 FR 67904).

In the December 2018 final rule, we explained that the risk experience of ACOs and their ACO participants in Medicare ACO initiatives is considered in determining which agreement track (BASIC or ENHANCED) the ACO is eligible to enter as well as the applicability of policies that phase in over time, namely the equal weighting of benchmark year expenditures, the policy of adjusting the benchmark based on regional FFS expenditures, and the phase-in of pay-for-performance under the program's quality performance standards (83 FR 67904–67907). As a factor in determining an ACO's participation options, we established requirements for evaluating whether an ACO is inexperienced with performance-based risk Medicare ACO initiatives such that the ACO would be eligible to enter into an agreement period under the BASIC track's glide path or whether the ACO is experienced with performance-based risk Medicare ACO initiatives and therefore limited to participating under the higher-risk tracks of the Shared Savings Program (either an agreement period under the maximum level of risk and potential reward for Level E of the BASIC track or the ENHANCED track) (83 FR 67894).

We later identified a policy refinement around identifying ACOs experienced with risk based on an ACO Participant TIN's prior participation in the CY 2024 PFS final rule published on November 16, 2023, adding that ''an ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years,'' to the

definitions of ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' under § 425.20 (88 FR 79219 through 79220; 79543 through 79544). This was not a policy change, but an attempt to more clearly communicate ongoing operational policy.

Accordingly, as codified under § 425.20, we defined ''experienced with performance-based risk Medicare ACO initiatives'' to mean an ACO that CMS determines meets either of the following criteria:

(1) The ACO is the same legal entity as a current or previous ACO that is participating in, or has participated in, a performance-based risk Medicare ACO initiative as defined under this section, or that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

We defined ''inexperienced with performance-based risk Medicare ACO initiatives'' to mean an ACO that CMS determines meets both of the following criteria:

(1) The ACO is a legal entity that has not participated in any performance-based risk Medicare ACO initiative as defined under this section, and has not deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e).

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years.

The established definitions of ''experienced with performance-based risk initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives'' are intended to support both determinations of participation options and the phase-in of requirements over time by considering ACOs' prior participation in the program (83 FR 67906).

Under § 425.20, the second prong of the ''experienced with performance-based risk initiatives'' definition relies on whether 40 percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative in any of the 5 most recent performance years. For this purpose, an ACO participant is treated as having participated when the ACO participant TIN ''was or will be included in financial reconciliation'' for one or more performance years under a qualifying two-sided initiative during the 5-year lookback. This means the ''experience'' determination is sensitive to the ACO's participant composition at the TIN level. If an ACO's participant list includes a substantial number of TINs that were recently reconciled under two-sided risk (for example, under a prior ENHANCED track or another qualifying CMS initiative), those TINs count toward the 40 percent threshold. Conversely, if an ACO's participant TINs lack such recent two-sided reconciliation history, the ACO may be treated as inexperienced for purposes of participation options.

Consistent with our TIN-based approach to evaluating prior participation, these policies rely on the financial reconciliation history associated with specific billing TINs. These policies were intended to capture TINs that at least partially participated in a performance-based risk initiative, as TINs that participate in a full or partial year are generally still included in financial reconciliation. However, we have identified a category of TINs that are included in financial reconciliation for performance based-risk initiatives, but that do not have a written agreement to participate in the performance-based risk ACO initiative and thus are ineligible for the benefits of being in an ACO (such as shared savings). In ACO REACH, and other CMS Innovation Center ACO Models, a ''Legacy TIN or CCN'' means a TIN or CCN that a Participant Provider or Preferred Provider previously used for billing Medicare Parts A and B services but no longer uses to bill for those services, and includes a ''sunsetted'' Legacy TIN or CCN (a TIN or CCN that is no longer used for billing for Medicare Parts A and B services by any Medicare-enrolled provider or supplier) or an ''active'' Legacy TIN or CCN (a TIN or CCN that may be in use by a Medicare-enrolled provider or supplier that is not a Participant Provider or Preferred Provider).[332] The purpose of Legacy TINs or CCNs is to allow a provider/supplier who used to practice under an old TIN, but has begun practicing under a new TIN, to use the historical claims information to help establish an ACO's benchmark. Legacy TINs or CCNs are not considered to be ''Participant Providers'' in ACO REACH, as they do not have a written agreement to participate in the performance-based risk ACO initiative.[333] These TINs or CCNs do not receive any benefits of ACO participation, including ACO financial arrangements or use of model waivers and are not required to comply with ACO policies. Their claims history is solely used for financial reconciliation for the ACO.

However, given the current definitions of ''Experienced with performance-based risk Medicare ACO initiatives'' and ''Inexperienced with performance-based risk Medicare ACO initiatives,'' Legacy TINs or CCNs are currently included in the calculation of whether 40 percent of ACO participants have prior experience with a performance-based risk Medicare ACO initiative, as they are included in financial reconciliation for the ACO REACH model ACO. The current or prior presence of a Legacy TIN or CCN on an ACO REACH model ACO's Participant Provider List can determine whether an ACO applying to the Shared Savings Program is eligible for entry into the BASIC track glide path or is instead limited to BASIC track Level E (if low revenue) or the ENHANCED track. CMS did not anticipate the interaction between the use of Legacy TINs in CMS Innovation Center ACO models and the definitions of experienced and inexperienced with performance-based Medicare ACO initiatives when these policies were developed. We identified this interaction when it impacted a few ACOs applying to the Shared Savings Program in recent years, limiting the participation options available to the ACOs.

We believe that the inclusion of Legacy TINs and CCNs in the definitions of experienced or

[332] *ACO REACH Model Third Amended and Restated Participation Agreement.* Refer to page 12 under Article II Definitions for the definition of ''Legacy TIN or CCN''.

[333] *ACO REACH Model PY 2026 Participant and Preferred Provider Management Guide: https://www.cms.gov/files/document/aco-reach-py26-part-pref-provider-mgmt-guide.pdf.*

inexperienced with performance-based risk is overly broad and not in line with the original goals of the definition, and we propose to amend the current regulation to exclude such TINs and CCNs from the calculation.

b. Proposed Revisions

Under the existing regulations codified in the December 2018 final rule, the definition of an ACO experienced or inexperienced with performance-based risk Medicare ACO initiatives includes consideration of ACO participant TINs in determining whether an ACO has prior experience under performance-based risk. Specifically, an ACO participant TIN is considered to have such experience if it was or will be included in the financial reconciliation of a Medicare ACO for any of the 5 most recent performance years under a qualifying two-sided model (83 FR 67895). For purposes of this determination, an ACO participant is treated as having participated in a performance-based risk initiative when its TIN was or will be included in financial reconciliation for one or more performance years during the applicable 5-year lookback period (83 FR 67895; § 425.20). As a result, the determination of whether an ACO is experienced or inexperienced with performance-based risk can depend on the composition of the ACO participant list at the TIN level.

To ensure TINs that have only been used as Legacy TINs or CCNs in CMS Innovation Center models would not be considered as experienced with risk, we are proposing to exclude ACO participant TINs that did not have a written agreement to participate in a performance-based risk Medicare ACO initiative from our consideration of whether the ACO participant TIN participated in a performance-based risk Medicare ACO initiative. This consideration ultimately impacts an ACO's designation as experienced or inexperienced with performance-based risk within the Shared Savings Program. Because determining an ACO's experience with performance-based risk is based on the experience of the ACO participant TIN, we propose to modify the regulations at § 425.20 to exclude Legacy TINs or CCNs from the definition of ''experienced with performance-based risk Medicare ACO initiatives'' and ''inexperienced with performance-based risk Medicare ACO initiatives.'' As future CMS Innovation Center models may not use the term ''Legacy TIN or CCN'' to identify these TINs or CCNs, we propose to exclude these and similarly situated ACO participant TINs and CCNs by excluding those that did not have a written agreement to participate with the performance-based risk Medicare ACO.

We propose revising the definition of experienced with performance-based risk Medicare ACO initiatives under § 425.20 by adding to paragraph (2), '', unless the ACO participant TIN did not have a written agreement to participate in the performance-based risk Medicare ACO initiative.'' Similarly, we propose revising the definition of inexperienced with performance-based risk Medicare ACO initiatives under § 425.20 by adding to paragraph (2), '', unless the ACO participant TIN did not have a written agreement to participate in the performance-based risk Medicare ACO initiative.''

These proposed additions would permit CMS to exclude Legacy TINs or CCNs from this calculation.

We propose that these modifications would be effective and applicable on January 1, 2027. Considering when the CY PFS final rule will be issued, and the Shared Savings Program application cycle for the January 1, 2027 start date (occurring in CY 2026), ACO applicants would have notice of this proposed change after the deadline for submitting their applications to participate in the Shared Savings Program. Additionally, under a previously established timeline for application actions and deadlines, the application cycle would require CMS deem an applicant ACO experienced with performance-based risk in October 2026,[334] which is before the CY 2027 PFS final rule is issued.

To mitigate the potential impact on ACO applicants, following issuance of the CY 2027 PFS final rule, we would communicate to ACOs their status as an ACO experienced or inexperienced with performance-based risk if these changes are finalized. We are committed to accurately identifying ACOs' experience with performance-based risk and providing them the opportunity to select their track/level of participation should we finalize these changes to these definitions in the CY 2027 PFS final rule. We believe it would be appropriate to accommodate this modification during the application cycle for the January 1, 2027 start date (occurring in CY 2026) to apply the most accurate definition for determining experience with performance-based risk based upon the outcome of the final rule and the potential for the inclusion of a legacy TIN on an applicant ACO's ACO participant list.

We seek comment on this proposal.

9. Beneficiary Notification Requirements

a. Background

The November 2011 final rule established requirements at § 425.312 for how a Shared Savings Program ACO must notify Medicare FFS beneficiaries receiving primary care services at the point of care that the physician, hospital or other provider is participating in a Shared Savings Program ACO (76 FR 67945 through 67946). Since then, the regulations at § 425.312 have been updated through subsequent rulemaking. Presently, under § 425.312(a)(1), an ACO is required to ensure that Medicare FFS beneficiaries are notified of the following: (i) each ACO participant and its ACO providers/suppliers are participating in the Shared Savings Program; (ii) the beneficiary's opportunity to decline claims data sharing; and (iii) the ability to, and process by which, the beneficiary may identify or change identification of a primary care provider for purposes of voluntary alignment.[335]

Section 425.312(a)(2) sets forth the manners in which ACOs or ACO participants are required to notify beneficiaries of this information. ACO participants must post signs in their facilities and, in settings in which beneficiaries receive primary care services, make standardized written notices available upon request (§ 425.312(a)(2)(i) and (ii)). In addition, ACOs must furnish standardized written notices to certain beneficiaries, with the timing depending on the ACO's assignment methodology. For ACOs that have selected preliminary prospective assignment with retrospective reconciliation, the ACO or ACO participant must provide each FFS beneficiary who received at least one primary care service from certain ACO professionals in the ACO during the assignment window (or expanded window) with a standardized written notice at least once per agreement period. The ACO or ACO participant must provide this notice prior to or at the first primary care visit of the performance year (§ 425.312(a)(2)(iii)). For ACOs that have selected prospective assignment, the ACO or ACO participant must provide the standardized written notice to each prospectively assigned beneficiary at least once per agreement period, during the performance year for which the

[334] Medicare Shared Savings Program, Key Application Actions and Deadlines For Agreement Periods Beginning on January 1, 2027, available at *https://www.cms.gov/files/document/key-application-actions-deadlines.pdf.*

[335] *See generally* Shared Savings Program Guidance & Specifications, Beneficiary Information section, *https://www.cms.gov/medicare/payment/fee-for-service-providers/shared-savings-program-ssp-acos/guidance-regulations#Beneficiary_Information.*

beneficiary is prospectively assigned to the ACO (§ 425.312(a)(2)(iv)). Additionally, in the CY 2023 PFS final rule (87 FR 69404), we finalized that the ACO or ACO participant must provide a verbal or written follow-up communication to the beneficiary no later than 180 days from the date the standardized written notice was provided and maintain record of such notice (§ 425.312(a)(2)(v)).

Over the years, the Shared Savings Program has received ongoing feedback that these beneficiary communication requirements can be operationally burdensome and may confuse beneficiaries, including causing some beneficiaries to believe they are being targeted by a fraudulent actor or have been enrolled in a managed care plan,[336] which ACOs then must work to address. Interested parties have identified that the beneficiary notice requirements implemented in some CMS Innovation Center models may be less burdensome for ACOs to implement. For example, under the ACO REACH model, ACOs must distribute beneficiary information notices by CMS-specified dates, including for beneficiaries aligned to the ACO at the start of the performance year and for beneficiaries who become aligned during the performance year.[337] Specifically, ACOs that participate in the ACO REACH model are required to distribute a beneficiary information notice by May 30 for beneficiaries who start the year aligned to the ACO and remain aligned by April 1.[338] By contrast, under the Shared Savings Program, ACOs that have selected preliminary prospective assignment with retrospective reconciliation must provide the beneficiary information notice either at or before a beneficiary's first primary care visit. Additionally, while ACOs that have selected prospective assignment are required to provide the standardized written notice in the form and manner set by CMS, we have historically required them to align with the same timing of at or before the beneficiary's first primary care visit.

We believe that fixed deadlines would allow ACOs to better prepare for the distribution of the beneficiary notice, as they would have several months after the start of the year to organize their staff and resources, whereas the Shared Savings Program requirement tied to a beneficiary's first primary care visit, which could occur as early as the very beginning of the performance year, requires the ACO to be prepared to distribute the notice immediately at the start of the performance year.

b. Proposed Revisions

(1) Proposal To Revise Distribution Timing of Standardized Written Notices

We continue to believe that requiring ACOs to provide periodic beneficiary notifications affords ACOs and ACO participants an opportunity for direct engagement with beneficiaries, thereby serving to strengthen the beneficiary's relationship with the ACO and ACO participants from whom the beneficiary may receive care. The requirement to provide beneficiary notifications promotes transparency about ACO participants and their ACO providers/suppliers participating in the Shared Savings Program and educates beneficiaries on how ACO participation could improve their care experience.

At the same time, distributing these notices to beneficiaries imposes operational burden on ACOs and ACO participants. ACOs must accurately identify beneficiaries who require notification, operationalize workflows to distribute the notifications, and prepare for beneficiary questions and concerns.

We recognize that current operational timeframes can further contribute to implementation challenges. Operationally, CMS generally makes available the first beneficiary assignment list report for each PY in the month of December. We recognize this can be a very tight turnaround for ACOs to prepare beneficiary outreach processes for beneficiaries who begin receiving primary care services in the following month.

We recognize that ACOs have developed processes, workflows or materials to meet the requirement for the timing for distributing the beneficiary notice. Under this proposal, ACOs would no longer be required to maintain those processes solely for purposes of complying with this requirement, which we believe would reduce ongoing administrative burden and expense. Nothing in this proposal would prohibit an ACO from continuing similar activities that it determines are beneficial, such as other beneficiary communications and marketing efforts, provided those activities comply with all otherwise applicable program requirements. We seek to have policies that balance the benefits of beneficiary education and engagement with the burden placed on ACOs, to maximize Shared Savings Program ACO participation and therefore the broad availability of ACOs and the benefits they can offer for beneficiaries. In the interest of an overall reduction in administrative burden, we propose to modify § 425.312(a)(2)(iii) and § 425.312(a)(2)(iv) with the following changes.

First, we propose to revise the requirement at § 425.312(a)(2)(iii) that ''the standardized written notice must be furnished to all of these beneficiaries prior to or at the first primary care service visit during the first performance year in which the beneficiary receives a primary care service from an ACO participant.'' The revised language would read, ''The standardized written notice must be furnished to all of these beneficiaries by May 30, unless CMS specifies a later date during the Performance Year.'' We also propose to add a similar change to § 425.312(a)(2)(iv) to add a new final sentence to that paragraph which states, ''The standardized written notice must be furnished to all of these beneficiaries by May 30, unless CMS specifies a later date during the Performance Year.'' These deadlines align with those used in the ACO REACH model. Beneficiaries must still receive the notice, but we believe this would allow ACOs to better prepare to distribute the notices and better prepare to answer the subsequent beneficiary questions they typically receive. We also believe that better aligning with CMS Innovation Center policies in this area would reduce burden for ACOs who compare policies across programs and models to determine the best fit for their organization. We do not believe this revised timing requirement would impact beneficiary engagement with the ACO or ACO participant. Beneficiaries would still receive the notification, and the ACO participants will have posted signs displayed in their facilities designed to alert beneficiaries to their practitioner's participation in an ACO (§ 425.312(a)(2)(i)) and allow the beneficiaries the opportunity to engage with the practitioner further. We remind interested parties that, irrespective of our proposal in this proposed rule, ACOs would continue to be permitted to communicate more frequently or thoroughly with beneficiaries if they wish to do so, as long as they comply

[336] Reimagining Beneficiary Engagement in Accountable Care Models, A Resource Published by HCTTF and NAACOS. *https://hcttf.org/wp-content/uploads/2026/03/HCTTF-NAACOS-2026-Resource-1.pdf.*

[337] ACO REACH Model Third Amended and Restated Participation Agreement (2023 Starters), Section 5.05 Beneficiary Notifications, Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation, Last Modified: December 5, 2025.

[338] ACO REACH Model PY2025 Beneficiary Notification Process p. 2, Centers for Medicare & Medicaid Services, Center for Medicare and Medicaid Innovation.

with the marketing requirements detailed at § 425.310(a). This could include sharing supplemental ACO marketing materials alongside the beneficiary notification.

We propose that the change would have an effective date of January 1, 2027 and anticipate this approach would reduce the net burden to ACOs and ACO participants of providing the beneficiary notification.

We seek comments on this proposal.

(2) Proposal To Remove the Beneficiary Follow-Up Communication

In the CY 2023 PFS final rule (87 FR 70233), CMS finalized the requirement at § 425.312(a)(2)(v) that ACOs or ACO participants provide a verbal or written follow-up communication to the beneficiary no later than 180 days from the date the standardized written notice was provided. Currently, under § 425.312(a)(2)(v)(A), ''The follow-up communication must occur no later than 180 days from the date the standardized written notice was provided.'' Section 425.312(a)(2)(v)(B) requires ACOs to retain a record of the follow-up communication and that all beneficiaries receive the follow-up communication, and to make the records available to CMS upon request.

In comments summarized in the CY 2023 PFS final rule (87 FR 69961–69963), most commenters opposed the requirement to provide beneficiary follow-up communications, expressing concern that the follow-up communication would increase administrative and operational burden for ACOs without creating meaningful additional beneficiary benefit. Commenters noted that follow-up communications may require substantial resources to operationalize, including workflows to identify beneficiaries requiring outreach, conduct and document communications, respond to beneficiary questions and maintain records demonstrating compliance. Some commenters indicated that these activities could create competing demands during clinical encounters, requiring providers to devote visit time to explaining ACO participation and value-based care concepts rather than focusing on the beneficiary's immediate clinical needs. Commenters also raised concerns that repeated communications on similar materials could contribute to beneficiary confusion rather than improve understanding. Commenters suggested we explore other strategies and work with ACOs to promote beneficiary education and engagement.

While we considered the commenters' concerns when finalizing the follow-up communication requirement in the CY 2023 PFS rule, we adopted it with the expectation that it would improve beneficiary understanding of the Shared Savings Program and give beneficiaries the opportunity to ask questions. Since its implementation, however, we have not seen evidence that the follow-up communication improves beneficiaries' understanding of ACO assignment, value-based care or the benefits of being in an ACO. Although we propose to eliminate the follow-up communication requirement, we remain committed to improving beneficiary education about the Shared Savings Program. We are currently researching additional ways CMS can support beneficiary education, but we do not believe the 180-day follow-up communication requirement is helping achieve that goal. As noted earlier, we recognize that ACOs have developed processes and incurred expenses to meet these requirements. While we believe removing the requirement would relieve an ongoing burden and expense, ACOs are free to continue to utilize those processes to communicate with beneficiaries if they believe they provide a benefit, as long as such processes are consistent with any other applicable program requirements. We are interested in additional feedback on how to improve beneficiary communications and will continue to work with interested parties to strengthen communications and beneficiary understanding.

To be responsive to interested parties' feedback, prevent potential beneficiary confusion and reduce administrative burden to ACOs and ACO participants, we are proposing to remove the requirement that ACOs must provide a follow up communication as specified in § 425.312(a)(2)(v). Specifically, we propose to remove § 425.312(a)(2)(v) in its entirety.

If finalized, this proposal would be effective beginning January 1, 2027.

We seek comments on this proposal.

10. Request for Information: Specialty Care in the Shared Savings Program

a. Background

We have a goal to grow the number of health care providers and beneficiaries in accountable care relationships. As of January 2025, 53.4 percent of OM beneficiaries were in such a relationship,[339] including through ACOs that participate in the Shared Savings Program and entities participating in CMS Innovation Center ACO models such as ACO REACH.

The Shared Savings Program is central to this strategy: since it was established in 2012, the Shared Savings Program has been associated with improved quality performance, stronger care coordination, better beneficiary experience, and consistent evidence of savings. In 2026, the Shared Savings Program includes 511 ACOs, comprising more than 700,000 providers and organizations and serving over 12.6 million OM beneficiaries. At the same time, nearly 11 million OM beneficiaries are not currently in an accountable care relationship and may be potentially assignable to an ACO. This presents a significant opportunity to expand access to accountable, coordinated care and accelerate progress towards our goal of growing accountable care relationships.

Much of the Shared Savings Program's design, assignment, and accountability are centered around the delivery of primary care services. This structure has supported improvements in population-based care management, outcomes, and efficiency, with 75 percent of the 476 ACOs participating in PY 2024 demonstrating savings while meeting quality of care objectives.[340] Low revenue ACOs (which are typically physician-led ACOs or are comprised of FQHC/RHCs), have consistently outperformed high revenue ACOs in generating savings.[341] High revenue ACOs, which are typically hospital-led, tend to generate smaller savings rates. A low-revenue ACO is usually physician led, where the total Medicare Parts A and B FFS revenue of the ACO participants is less than 35 percent of the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries.[342] A high-revenue ACO is generally hospital-based, and the total Medicare Parts A and B FFS revenue of the ACO participants is 35 percent or greater of the total Medicare Parts A and B FFS expenditures for the ACO's assigned beneficiaries.[343] Low-revenue ACOs often have less ability to control total spending than high-revenue ACOs

[339] Centers for Medicare & Medicaid Services. ''CMS Moves Closer to Accountable Care Goals with 2025 ACO Initiatives.'' *CMS,* 15 Jan. 2025, *https://www.cms.gov/newsroom/fact-sheets/cms-moves-closer-accountable-care-goals-2025-aco-initiatives.*

[340] Centers for Medicare & Medicaid Services. *Medicare Shared Savings Program Performance Year 2024 Financial and Quality Results.* 29 Sept. 2025, *https://www.cms.gov/files/document/fact-sheet-ssp-py24-financial-quality-results.pdf.*

[341] Centers for Medicare & Medicaid Services. *Medicare Shared Savings Program Accountable Care Organizations: Updated Performance Year 2024 Financial and Quality Results.* 29 Sept. 2025

[342] United States, Code of Federal Regulations. ''§ 425.20 Definitions.'' *Electronic Code of Federal Regulations,* Title 42, Chapter IV, Part 425, SubPart A, 2026, *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-425/subpart-A/section-425.20.* Accessed 18 June 2026.

[343] Ibid.

do. As we pursue OM accountable care goals, we are exploring how to better support the financial performance of our high revenue ACO participants, which are more likely to have a high proportion of high-cost specialists participating in their ACO compared to low revenue participants.

Specialty care represented roughly 80 percent of Medicare Part B physician spend in 2024 (as opposed to roughly 20 percent on primary care).[344] CMS reaffirms the central role of primary care in coordinating care; however, we recognize that growth in specialty care has increased the number of specialists involved in beneficiary care. As a result, primary care teams must now coordinate with more specialists than ever before to support the delivery of longitudinal, whole-person care.[345] This also increases the potential for fragmented care delivery to patients, especially those with high-cost and high-need conditions and those receiving long-term care. Accordingly, we seek to strengthen low and high revenue ACOs in incorporating specialists and facilitating care coordination.

Relative to their efforts in primary care, ACOs have had limited direct influence on the type and frequency of specialty care furnished to beneficiaries assigned to an ACO, despite specialists constituting a significant share of participating clinicians. While this varies by ACO type and the role of the specialists, many specialists participating in ACOs remain unaware of their role in the program. They are not consistently engaged in efforts to improve cost and quality for their assigned beneficiaries and are often not held accountable to ACO-related performance targets. Furthermore, existing program data shows high rates of specialty care delivered outside ACO networks, which contributes to fragmented care and limits visibility into the quality, appropriateness, and coordination of specialty services.[346]

Existing literature on specialist engagement and performance in ACOs may inform future directions and opportunities. One study exploring specialist costs in ACOs found that a quarter of ACOs have used cost reduction measures to help determine specialist compensation, however, there was no association between these efforts and cost reduction incentives or specialist performance.[347] Another study suggests that ACOs in which specialists, specifically cardiologists, were included and actively engaged were more likely to have lower spending and utilization.[348] This indicates that there is the potential for cost and quality improvements with enhanced policies that target specialist inclusion in the Shared Savings Program.

As OM beneficiaries increasingly rely on specialty care, it is important to understand the drivers of successful specialty integration and engagement, as well as its barriers. These considerations may differ across ACO types. In low revenue ACOs and outpatient, primary care-focused organizations, primary care teams often coordinate across a broad network of unaffiliated specialists. In contrast, in health system-affiliated organizations, including high revenue ACOs, specialists are more likely to be employed or otherwise closely aligned within a single system, and integration efforts may center on aligning incentives across service lines and advancing system-wide care management approaches. Given the scope of specialty involvement in Medicare spending and the importance of integrated and accountable specialty care to beneficiary outcomes, CMS is seeking public input to inform potential future updates to the Shared Savings Program. These insights may also inform future CMS Innovation Center ACO model features. Responses will assist us in identifying policy options that may promote high quality, coordinated specialty care within the accountable care framework and advance the agency's goals of improving care, promoting efficiency, and ensuring the long-term sustainability of the Medicare program.

b. Solicitation of Public Comments

We are releasing this RFI to gather feedback on policy changes and resources that could improve clinical outcomes and reduce inappropriate Medicare spending through accountable care programs and models. We request feedback on the following:

- Meaningful engagement;
- CMS-delivered tools and support;
- Attribution or assignment modifications;
- Benchmarking;
- Specialist performance measurement;
- Waiver flexibilities; and
- ACO and provider burden.

Whenever possible, respondents are requested to draw their responses from objective, empirical, and actionable evidence and to cite this evidence within their responses. Where applicable, we encourage respondents to distinguish between experiences in low revenue and high revenue ACOs, given differences in organizational structure, incentives, and approaches to care delivery.

(1) Meaningful Engagement

For the purposes of this request, ''meaningful engagement'' refers to the extent to which specialists are aware of, aligned with, and actively contributing to an ACO's cost and quality goals. This includes participation in care coordination, adherence to evidence-based care pathways, and responsiveness to financial and non-financial incentives tied to total cost of care.

Specialists represent 65 percent of Shared Savings Program participating physicians and play an increasingly central role in patient care. Between 2000 and 2019, the proportion of beneficiaries seeing five or more physicians increased from 17.5 percent to 30.1 percent.[349] Specialists have become integral to many beneficiaries' care, and their engagement is needed to help meaningfully improve care coordination, reduce unnecessary utilization, and influence high-cost clinical decisions. Despite these opportunities, specialist engagement in ACOs remains limited, and there has been no consistent approach to date that explicitly aligns ACO incentives with specialist behavior.

Analyses across the Shared Savings Program and ACO REACH reinforce these findings. Among 101 respondents

[344] Centers for Medicare & Medicaid Services. ''Medicare Fee-for-Service Part B Utilization and Expenditures.'' *CMS, https://www.cms.gov/data-research/statistics-trends-reports/medicare-fee-service-parts-b-utilization-reports/medicare-utilization-part-b/expenditures-services-specialty-reports.*

[345] Timmins L, Urato C, Kern LM, Ghosh A, Rich E. Primary Care Redesign and Care Fragmentation Among Medicare Beneficiaries. The American Journal of Managed Care, March 2022, Volume 28, Issue 3.

[346] McWilliams, J. Michael, et al. ''Outpatient Care Patterns and Organizational Accountability in Medicare.'' *JAMA Internal Medicine,* vol. 174, no. 6, 2014, pp. 938–945. *JAMA Network, https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1861039.*

[347] Ganguli, Ishani, et al. ''Association between Specialist Compensation and Accountable Care Organization Performance.'' *Health Services Research,* vol. 55, no. 5, Oct. 2020, pp. 722–728. PubMed, *https://pubmed.ncbi.nlm.nih.gov/32715464/.*

[348] Cohen, Andrew J., et al. ''Perspectives From Authors and Editors in the Biomedical Disciplines on Predatory Journals: Survey Study.'' *Journal of Medical internet Research,* vol. 21, no. 8, 2019, e13769. PubMed Central, *https://pmc.ncbi.nlm.nih.gov/articles/PMC6750277/.*

[349] Barnett Michael L et al. ''Trends in Outpatient Care for Medicare Beneficiaries and Implications for Primary Care, 2000 to 2019.'' *Annals of Internal Medicine,* vol. 174, no. 12, 2021, pp. 1658–1665, *https://doi.org/10.7326/M21-1523.*

representing 174 ACOs in the Shared Savings Program and ACO REACH, only 11 percent reported that employed specialists were highly aligned with ACO costs and quality objectives and just 7 percent reported high alignment among contracted specialists.[350] These results indicate areas of opportunity to further integrate specialists into accountable care frameworks. Data from a survey of participating providers in a Michigan ACO support this. Compared to primary care providers (PCPs), specialists reported significantly lower levels of awareness and alignment: 57 percent of specialists do not know they are participating in an ACO (versus 37 percent PCP), 71 percent are not aware of accountability for spending and costs (versus 53 percent PCP), and 75 percent report that the financial bonuses are not large enough to influence their behavior (similar to PCP).[351] These findings demonstrate the potential of expanding education efforts, offering direct incentives, and improving accountability for specialists to advance engagement with ACOs.

Recent trends in physician employment and consolidation have shifted a growing share of specialists into health system-affiliated or other integrated organizational arrangements, rather than independent practice.[352] As a result, approaches to specialty care engagement may vary depending on whether specialists are independent or operating within a health system context. In particular, non-health system ACOs may rely more heavily on contractual or payment-based mechanisms to align incentives and support collaboration with unaffiliated specialists.

To engage specialists, some non-health system organizations may implement sub-capitation (''sub-cap'') arrangements, in which ACOs distribute prospective or risk-based payments to specialists tied to defined populations or services. For example, in the forthcoming Long-term Enhanced ACO model (LEAD), the Innovation Center anticipates including an optional component called CMS Administered Risk Arrangements (CARA), which would enable downstream episode-based risk arrangements between ACOs and specialists. Additionally, under the Advanced Payment Option (APO) in ACO REACH, LEAD's predecessor, ACOs can receive and distribute prospective monthly payments for non-primary care services to specialists as defined by their downstream sub-cap arrangement(s). Other Innovation Center models have also sought to improve meaningful specialist engagement by requiring structured arrangements or incentivizing activities through enhanced payment. The Making Care Primary (MCP) model sought to require certain primary care participants to enter Collaborative Care Arrangements (CCAs) with specialists.[353] CCAs help to formalize expectations around collaboration and communication between PCPs and specialists. MCP also created a new Healthcare Common Procedure Coding System (HCPCS) code, the MCP E-consult Code (MEC), which sought to incentivize more frequent and enhanced electronic consults between primary care participants and specialists. Relatedly, the Innovation Center's Ambulatory Specialty Model (ASM) requires that specialist participants enter at least one CCA with a primary care practice, and that the CCA should include elements such as information sharing, referrals, co-management, and transitions in care. These approaches may be particularly relevant in settings where primary care clinicians and specialists are not part of the same organization, as they help to formalize collaboration and accountability across unaffiliated clinicians. Finally, the Advancing Chronic Care with Effective, Scalable Solutions (ACCESS) Model offers limited co-management payments to support collaboration with PCPs and other referring clinicians in activities like documenting care-coordination actions, such as medication adjustments or problem-list updates.[354] These activities aim to meaningfully engage specialists and PCPs in care coordination for beneficiaries.

We are seeking feedback on how we could better support meaningful specialist engagement and accountability within the Shared Savings Program.

- Which aspects of the Shared Savings Program's design most influence specialists' ability and willingness to meaningfully participate in accountable care arrangements (for example, data access, attribution/assignment, financial incentives, clinical autonomy)?
- How could the Shared Savings Program better support adoption of care delivery interventions (for example, e-consults, co-management models) to improve primary and specialty care integration? Are there other interventions that should be considered?
- Which incentives (financial, quality-based, or operational) most effectively drive adoption of value-based care interventions? Examples include the use of care coordination codes billed by specialists (for example, MCP), MIPS submission exemption for Qualifying Providers (QPs), and the sub-capitation arrangements between ACOs and specialists (for example, the recently announced CARA in LEAD).[355]
- How does specialist engagement differ across high revenue and low revenue ACOs, including differences in the roles of employed and contracted specialists? What types of specialists are most critical to achieving care coordination and cost and quality goals in each setting, and what strategies have been effective in engaging them?
- How should engagement strategies be tailored to reflect differences across specialties (for example, procedural specialists versus chronic disease co-managers)?[356]
- Are there specific specialist engagement approaches that are particularly effective for high-need, high-cost populations or beneficiaries receiving long-term care services and supports?
- How can we engage specialists in ways that support physician autonomy while advancing accountability for cost and quality?

(2) CMS-Delivered Tools and Support

ACOs often report that access to actionable data and tools is critical to improving care coordination and

[350] Mechanic, Robert E., et al. ''Accountable Care Organization Initiatives to Improve the Cost and Outcomes of Specialty Care.'' *The American Journal of Managed Care,* vol. 30, no. 5, May 2024, pp. 237–240, *https://www.ajmc.com/view/accountable-care-organization-initiatives-to-improve-the-cost-and-outcomes-of-specialty-care*.

[351] Markovitz, Adam A., et al. ''ACO Awareness and Perceptions Among Specialists Versus Primary Care Physicians: A Survey of a Large Medicare Shared Savings Program.'' *Journal of General Internal Medicine,* vol. 37, no. 2, 2022, pp. 492–494. *https://doi.org/10.1007/s11606-020-06556-w*.

[352] U.S. Government Accountability Office. *Health Care Consolidation: Published Estimates of the Extent and Effects of Physician Consolidation.* GAO–25–107450, Sept. 2025. *GAO, https://www.gao.gov/products/gao-25-107450*.

[353] MCP wrapped up early on June 30, 2025. See CMS website for more information: *https://www.cms.gov/priorities/innovation/innovation-models/making-care-primary*.

[354] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. ''*ACCESS Technical Frequently Asked Questions*.'' *CMS.gov,* 2026, *https://www.cms.gov/priorities/innovation/access-technical-frequently-asked-questions#ovw*''.

[355] ''LEAD'' *Centers for Medicare & Medicaid Services,* U.S. Department of Health and Human Services, *https://www.cms.gov/priorities/innovation/innovation-models/lead*.

[356] Forrest, Christopher B. ''A typology of specialists' clinical roles.'' *Archives of internal medicine* vol. 169,11 (2009): 1062–8. *https://doi.org/10.1001/archinternmed.2009.114*.

driving value-based care.[357] However, gaps remain in both the availability and accessibility of these resources, particularly for driving specialty care accountability and enabling specialist engagement.

One example that was developed in response to ACO feedback is the provision of ''shadow bundles'' data, which CMS began providing in February 2024 to ACOs participating in the Shared Savings Program and the ACO REACH Model.[358] ''Shadow bundles'' aggregate claims data for services, supplies, and associated payments into standardized, condition or procedure-specific episodes of care. These episodes are constructed using consistent rules for attributed beneficiaries and include benchmark pricing to support performance comparison and potential shared savings arrangements between a health care provider and an ACO. This CMS-generated dataset offers ACOs actionable insights into specialist care patterns, potentially enabling more informed engagement with specialists. By identifying variations in cost across episodes, ACOs can better understand referral patterns, support high-value care, and design their own episode-based payment initiatives.[359] High-value care in this instance is defined as the appropriate standard of care for a patient with no unnecessary care, complications, or other unnecessary spending. Standardized episode definitions also enhance transparency and allow for more consistent comparisons over time. Ultimately, these insights can help PCPs refer patients to specialists who deliver the highest quality, most cost-effective care. Despite this potential, a 2025 ACO REACH participant survey indicates that 22 percent of ACOs participating in that model use shadow bundle data, highlighting an opportunity to expand uptake and better understand barriers to use, particularly for specialist engagement. Shared Savings Program shadow bundle downloads also declined by 57 percent over the same period, falling from 54 percent in February 2025 and continuing downward in subsequent months.[360]

Effective data use requires adequate infrastructure and analytic capacity, yet many ACOs face significant challenges in collecting, integrating, and analyzing clinical data. Fragmentation across health IT systems further compounds these issues, making it difficult to consolidate and report data consistently. For example, 77 percent of ACOs report that their ACO participants use six or more different electronic health record (EHR) systems, creating substantial interoperability and workflow barriers. These barriers can limit an ACO's ability to invest in and prioritize advanced analytics or data tools needed to support initiatives such as specialist engagement.[361]

Beyond data, ACOs also rely on toolkits and educational resources, some produced by us, that focus on specific topics such as care coordination and care transformation.[362] However, existing resources tend to emphasize primary care transformation and may be less applicable to specialists within ACO models, particularly in low revenue ACOs and outpatient settings. We are interested in understanding how the need and applicability of such resources may differ across low revenue and high revenue ACOs, including those with more integrated health system structures.

We seek feedback on how CMS-delivered tools and data could better support specialist engagement and accountability within the Shared Savings Program.

- How is your organization using shadow bundle data or other specialty-specific data?
- If you have had the opportunity to use shadow bundle data and elected not to use it, why not?
- Which data or tools would help ACOs provide meaningful feedback to specialists?
- How could CMS improve specialty care data to better support referrals to specialists based on proven outcomes, low complications, and efficient use of resources?
- How would the CMS-delivered tools and data need to vary to support the needs of low revenue ACOs versus high revenue ACOs?
- What other tools and resources could CMS provide to support specialty integration?

(3) Attribution/Assignment Modifications

In performing claims-based assignment, we determine whether allowed charges for a beneficiary's primary care services (as identified for ACO professionals, including at Electing Teaching Amendment (ETA) hospitals and Method II Critical Access Hospitals (CAHs), and services furnished at an FQHC or RHC) in an ACO are greater than allowed charges for the beneficiary's primary care services in any other ACO, or other individual practitioners, or groups of practitioners identified by Medicare-enrolled billing TINs or CCNs [363] that are not participating in the Shared Savings Program.[364] While this approach appropriately centers around primary care, it can limit opportunities for specialists to be accountable for populations they meaningfully manage, particularly when they often influence total cost of care. We employ the step-wise assignment methodology described in § 425.402 and § 425.404 and a Medicare beneficiary is assigned to an ACO if (1) the beneficiary meets the eligibility criteria under § 425.401(a); and (2) the beneficiary's utilization of primary care services meets the criteria established under the assignment methodology described in § 425.402 and § 425.404.

We have tested specialty models such as the Enhancing Oncology Model (EOM) and Kidney Care Choices (KCC), where beneficiaries are attributed to specialists for specific conditions. EOM attributes condition episodes for beneficiaries with high-risk breast cancer, chronic leukemia, lymphoma, lung cancer, colorectal/small intestine cancer, multiple myeloma, and high-risk prostate cancer to oncologists. KCC attributes beneficiaries with chronic kidney disease stages 4 and 5, end-stage renal disease, and post-kidney transplant patients to nephrologists. The heterogeneous nature of a specialist's role in beneficiary care, which can range from cognitive or procedural consult to co-manager (with primary care) or principal care manager, can make it difficult for specialists to sustain attributed/assigned populations under current rules, even when they can play a central role in managing care.[365] The use of condition-specific HCPCS codes in specialties such as cardiology and

[357] National Association of ACOs. *ACO Drivers for Success.* 2024, *https://www.naacos.com/aco-drivers-for-success/.*

[358] Fowler, Elizabeth, et al. ''The CMS Innovation Center's Strategy to Support Person-Centered, Value-Based Specialty Care: 2024 Update.'' *Health Affairs Forefront,* 2 Apr. 2024.

[359] Congressional Budget Office. *Medicare Accountable Care Organizations: Past Performance and Future Directions.* 2024, *www.cbo.gov/publication/59879.*

[360] NORC at the University of Chicago. *2025 ACO REACH Pulse Check Survey.* 2025. Internal report.

[361] ''Use of Electronic Health Record Systems in Accountable Care Organizations.'' *The American Journal of Managed Care, www.ajmc.com/view/use-of-electronic-health-record-systems-in-accountable-care-organizations.*

[362] Centers for Medicare & Medicaid Services. *ACO Care Coordination Toolkit.* Mar. 2019. Centers for Medicare & Medicaid Services. *ACO Care Transformation Toolkit.* Jan. 2021.

[363] FQHCs, RHCs, ETA hospitals, and Method II CAHs will be identified on claims by their CCNs.

[364] Refer to § 425.402(b)(3) and (b)(4); § 425.404(b).

[365] Forrest, Christopher B. ''A typology of specialists' clinical roles.'' *Archives of internal medicine* vol. 169,11 (2009): 1062–8. *https://doi.org/10.1001/archinternmed.2009.114.*

ophthalmology could also potentially identify beneficiaries for specialty attribution.

We seek feedback on how specialty-specific attribution methodologies could better support specialist engagement and accountability within the Shared Savings Program.

- How should CMS consider incorporating specialists into beneficiary assignment methodologies, if at all, while ensuring CMS maintains strong primary care relationships?
- Across ACO types, such as low revenue and high revenue ACOs, how can CMS account for care delivered by nurse practitioners (NP) and physician assistants (PA) in assignment methodologies, and what role does NP/PA-led care play in supporting beneficiary attribution, recognizing that section 1899(c)(1) of the Social Security Act requires CMS to assign beneficiaries to a Shared Savings Program ACO based on their utilization of primary care services furnished by physicians and, for applicable performance years, primary care services furnished by Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs).
- How could the Shared Savings Program assignment methodology better recognize situations where specialists serve as a beneficiary's principal longitudinal care provider?
- How could the Shared Savings Program ACOs enable specialists to share accountability for total cost and quality of care without serving as the primary clinician?
- What design features could support shared accountability between PCPs and specialists for specific conditions and episodes within the Shared Savings Program?

(4) Benchmarking

Another critical element to designing the Shared Savings Program to more appropriately incorporate specialists is the use of benchmarking methodologies tailored to specialty care. Within the Shared Savings Program and Innovation Center ACO models, benchmarks have traditionally been defined as the risk-adjusted, projected total cost of care targets for an ACO's assigned population. These benchmarks serve as the basis for assessing financial performance and determining shared savings or losses. While this population-based approach supports accountability for overall cost and care coordination, it may not fully capture variation in performance at the specialty or condition-specific levels, where significant opportunities for improving efficiency and quality exist.

Expanding benchmarking to more targeted sub-populations or specialty-specific services could provide ACOs with more actionable insights into, and drive improvements in, specialty care delivery. Benchmarking for specialty conditions can be challenging due to the high-cost variability for many conditions overseen by a specialist, for example multiple myeloma, Chronic Obstructive Pulmonary Disease (COPD), and heart failure. However, as clinical scope becomes more narrowly defined, statistical reliability may decrease due to smaller sample sizes, particularly for low-volume, high-cost services. Addressing these methodological challenges would be critical to ensuring that specialty-specific benchmarks are accurate.

We have experience with alternative benchmarking approaches that may inform this work. For example, the Quality Payment Program (QPP), including the Merit-based Incentive Payment System (MIPS), and the Ambulatory Specialty Model incorporate Episode-Based Cost Measures (EBCMs) to assess cost performance at the clinician or group level. EBCMs estimate the total cost of care for a defined clinical episode or condition, rather than for a patient over an entire year. Using Medicare claims data, CMS attributes services to episodes, applies risk adjustment to account for patient complexity, and calculates standardized costs that can be compared across providers and organizations. These episode-based approaches offer a methodologically robust framework for evaluating efficiency in discrete areas of care and may be adaptable for use within ACO models to support specialty engagement. By focusing on specific procedures or conditions, EBCMs can help identify variation in practice patterns, highlight opportunities for improvement, and support more targeted accountability.

In addition to episode-based approaches, certain clinical conditions with more predictable care trajectories may be particularly well-suited for specialty-specific benchmarking. For example, End Stage Renal Disease and cardiology may have sufficient volume and more defined clinical pathways (when appropriately risk adjusted) that could support more stable and reliable cost and quality comparisons at the ACO level. Targeting these types of clinical areas could mitigate some of the challenges associated with low volume and high variability.

We seek feedback on how benchmarking approaches could better support meaningful specialist engagement and accountability.

- What approaches should CMS consider for developing specialty-specific cost benchmarks within the Shared Savings Program? How can CMS mitigate challenges associated with conditions that may have low volumes and/or high-cost variability?
- How could CMS define sub-populations for specialty benchmarking (for example, by chronic condition, procedure type, or specialty service category)? Are there specific sub-populations that lend themselves to specialty benchmarking?
- What risk adjustment factors could CMS incorporate into specialty-specific benchmarks to ensure they reflect patient complexity?
- How could specialty-specific benchmarks interact with existing total cost of care benchmarks in the Shared Savings Program?

(5) Specialty Performance Measures

Quality measurement is central to assessing ACO performance and advancing CMS's goals of improving patient outcomes and promoting high-value care. Quality measures provide critical insight to both CMS and ACOs on how effectively care is being delivered and where opportunities may exist to improve clinical outcomes, patient experience, and safety.

Within the Shared Savings Program, the current quality measurement framework emphasizes the foundational role of primary care in population health management, which aligns with the primary-care based assignment methodology discussed above. As a result, the current Shared Savings Program quality measure set (the Alternative Payment Model (APM) Performance Pathway (APP) Plus measure set under MIPS) focuses on preventive care, chronic disease management, and care coordination activities typically driven by PCPs.

The current primary-care-focused measurement approach may create a gap in assessing the contribution of specialists to beneficiaries' care and ACO performance. This gap may manifest differently across ACO types. In low revenue ACOs, which are more often primary care and physician-led, the existing measure set may more closely align with organizational structure and care delivery models, though it may still underrepresent specialist contributions. In contrast, in high revenue ACOs, where specialists often play a larger role in care delivery and cost drivers, the limited inclusion of specialist-focused quality measures may result in a more pronounced gap in

assessing performance across the full continuum of care and may reduce incentives for specialty engagement in quality improvement efforts. Specialty care plays a critical role in the management of acute and chronic conditions and procedural interventions, which can significantly influence both quality outcomes and total cost of care. Without meaningful inclusion of specialist-focused quality measures, ACOs and CMS may have an incomplete view of performance across the full continuum of care.

This challenge is not unique to the Shared Savings Program. In other CMS programs, such as MIPS, participants have historically had to report on metrics that are more readily reportable or broadly applicable, which tend to be primary care-oriented (for example, screening, preventive services, and management of high-volume chronic conditions such as hypertension and diabetes). To address this, we have established the option to report MIPS Value Pathways (MVPs), which allow providers to report a set of measures more relevant to their specialty. In response to a request for information on MVP reporting for specialists in Shared Savings Program ACOs in the CY 2024 Physician Fee Schedule proposed rule (88 FR 52437), we received feedback in support of the aim to increase specialist participation in ACOs, with some commenters encouraging incentives and flexibility, while others expressed concern that MVPs may increase burden on specialists in ACOs.

Interested parties' feedback has further indicated that specialists may have limited visibility into how their clinical decisions, care patterns, and outcomes contribute to overall ACO performance, particularly when quality measurement and reporting do not reflect their areas of practice. This lack of visibility may reduce opportunities for engagement, alignment, and accountability among specialists participating in ACOs.

We seek feedback on how specialty performance measures could better support meaningful specialist engagement and accountability in the Shared Savings Program, keeping in mind that they may differ between low and high revenue ACOs.

- What considerations should inform how specialist performance is assessed within ACOs and should it differ from how ACOs are currently assessed?
- What specialty-specific performance profiles or feedback mechanisms would drive improvement?
- How could performance measurement approaches support prevention and upstream management by specialists?
- What specialist quality performance information would be of use to ACOs in maximizing care coordination, outcomes, and cost management in their programs? How could CMS incentivize specialists or their ACOs to report on specialist quality performance?
- How can ACOs align financial and non-financial incentives to better reflect specialists' contributions to cost and quality outcomes?
- What are the barriers and burden associated with collecting data from specialists and how can these issues be mitigated?
- Is there an opportunity to tie ACO performance to system-level metrics? Would this remove or increase burden on PCPs and specialists? What potential issues could arise from system-level metrics?
- How could MVPs be leveraged to better support meaningful specialist engagement and accountability in the Shared Savings Program, and in which areas are there opportunities to improve how MVPs could be leveraged? In which contexts, such as low revenue versus high revenue ACOs or different specialty types, have MVPs been most and least effective?

(6) Waiver Flexibilities

Under Section 1899 of the Act, we have the authority to waive certain sections of the Act, as necessary to implement the Shared Savings Program. This waiver authority authorizes us to use trust fund dollars to reduce barriers to care delivery within ACOs, such as to pay participating ACOs for items and services that are not typically covered under Medicare (to include items and services that fall within a Medicare benefit category solely by virtue of waivers of certain requirements issued for purposes of testing the model). These tools may create opportunities for specialists to participate more meaningfully in accountable care by expanding access; reducing burden; and allowing more flexible care delivery, referral, and payment.

One example is the Skilled Nursing Facility (SNF) 3-day rule waiver, which eliminates the requirement for a 3-day inpatient stay prior to a SNF admission. This waiver is highly utilized in many ACOs, with 36 percent of Shared Savings Program ACOs approved for the waiver in 2026.[366] Sixty percent of ACO REACH participants report this waiver is operational as of 2025.[367] Data suggests that when used, it can reduce avoidable inpatient and ED utilization without increasing overall SNF spending.[368] Another example is the diabetic shoe waiver, which in the Primary Care First (PCF) model, allowed NPs/PAs to certify a diabetic shoe prescription. There is no statistical data on waiver uptake, but anecdotal evidence suggests uptake was large and this continues to be a highly requested waiver.

Telehealth flexibilities introduced during the COVID–19 public health emergency are an example of regulatory flexibilities. These policies expanded access to care by allowing beneficiaries to receive telehealth anywhere in the US, permitting all Medicare providers to furnish telehealth services, and paying for audio-only visits when necessary and appropriate. The Shared Savings Program also allows for telehealth flexibilities, which similarly allow certain ACOs in two-sided risk tracks to provide and bill for telehealth services to assigned beneficiaries anywhere in the U.S. Telehealth flexibilities have been widely adopted by many specialists, particularly for consultations and follow-up visits. Data suggests that virtual consultations in a commercial population can reduce expenditures by $195 per person, primarily driven by lower cost of specialist care.[369]

We are seeking feedback on how waivers and regulatory flexibilities can better support specialist engagement and participation in the Shared Savings Program.

- Which current Shared Savings Program waivers (for example, SNF 3-day rule, telehealth flexibilities) have been most effective in supporting specialty integration? What barriers limit their adoption and how could CMS address them?
- How could CMS modify or expand existing waiver flexibilities to better support specialist-driven care pathways while maintaining beneficiary safety and appropriate utilization?
- What additional waivers should CMS consider to enable specialists to participate in ACOs?

[366] Shared Savings Program Fast Facts, *https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf.* January 1, 2026.

[367] NORC at the University of Chicago. *2025 ACO REACH Pulse Check Survey.* 2025. Internal report.

[368] Newman JS, Johnson KS, Meyer TJ, et al. *Implementing the 3-Day Skilled Nursing Facility Waiver: Key Insights.* J Prim Care Community Health. 2026;17. *https://doi.org/10.1177/21501319261456960.*

[369] ''eConsults NORC 2025 ACO REACH Pulse Check Survey Can Lower Costs and Improve Access to Specialty Care.'' *Mathematica, https://www.mathematica.org/news/econsults-can-lower-costs-and-improve-access-to-specialty-care.* Accessed 23 Mar. 2026.

• How should waivers differ by low revenue and high revenue participants?

(7) Burden

Central to CMS's strategic goals is protecting the taxpayer by improving program efficiency and integrity and reducing administrative burden.[370] Burden reduction efforts focus on simplifying program requirements, streamlining oversight, and leveraging automation and data integration so that providers can devote more time to patient care. This includes reducing duplicative or unnecessary data submissions, improving alignment across reporting systems, and enhancing the efficiency of compliance processes. At the same time, we seek to ensure that programs continue to meet their goals to drive improvements in care quality, outcomes, and value.

Our programs, including the Shared Savings Program, rely on robust data reporting, analytics, and administrative infrastructure to support these goals. Participation in these models often requires investments in care coordination, health IT systems, performance measurement, and ongoing operational optimization. While these activities are essential to advancing accountable care, they may also introduce administrative and operational burden for participating organizations.

Efforts to strengthen specialty integration within ACOs, a key opportunity for improving care coordination and reducing total cost of care, may involve additional activities that require time, resources, and technical capacity.

We are seeking feedback on how to minimize burden when improving specialist engagement and accountability within the Shared Savings Program.

• How can CMS reduce burden associated with specialty-specific quality reporting (for example, aligning measures across programs, leveraging claims-based measures) while maintaining meaningful accountability for specialty care?

• What policy changes could reduce the burden ACOs and specialists face in meeting data-sharing requirements (for example, interoperability)?

• What operational or compliance requirements disproportionately affect smaller or rural specialty practices?

• What flexibilities could CMS introduce to encourage specialist participation or engagement with the Shared Savings Program?

• What flexibilities could CMS introduce to reduce burden with the structure of ACO participation over the current FFS requirements?

H. Changes to the Regulations Associated With the Ambulance Fee Schedule

1. Ambulance Fee Schedule Background

Section 1861(s)(7) of the Act establishes an ambulance service as a Medicare Part B service where the use of other methods of transportation is contraindicated by the individual's condition, but only to the extent provided in regulations. Our regulations relating to coverage for ambulance services are set forth at 42 CFR part 410, subpart B. Since April 1, 2002, payment for ambulance services has been made under the ambulance fee schedule (AFS), which the Secretary established, as required by section 1834(l) of the Act, in 42 CFR part 414, subpart H. Payment for an ambulance service is made at the lesser of the actual billed amount or the AFS amount, which consists of a base rate for the level of service, a separate payment for mileage to the nearest appropriate facility, a geographic adjustment factor (GAF), and other applicable adjustment factors as set forth at section 1834(l) of the Act and § 414.610.

In accordance with section 1834(l)(3) of the Act and § 414.610(f), the AFS rates are adjusted annually based on an inflation factor. (For a discussion about the ambulance inflation factor (AIF), please see CY 2011 PFS final rule (75 FR 73397)). We stated in the CY 2011 PFS final rule that the AIF will be announced by instruction and on the CMS website. AIF transmittals are available on CMS' website: *https://www.cms.gov/medicare/payment/fee-schedules/ambulance/afs-regulations-and-notices* and in the Medicare Claims Processing Manual, Chapter 15, section 20.4). The AFS also incorporates two permanent add-on payments at § 414.610(c)(5)(i) and three temporary add-on payments at § 414.610(c)(1)(ii) and (c)(5)(ii) to the base rate and/or mileage rate.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110–275, enacted July 15, 2008), amended section 1834(l)(13) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008, and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

• For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.

• For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13) of the Act have been extended several times. Most recently, section 6203 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75, February 3, 2026) amended section 1834(l)(13) of the Act to extend the payment add-ons through December 31, 2027. Thus, these payment add-ons apply to covered ground ambulance transports furnished before January 1, 2028. We are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439), the CY 2015 PFS final rule with comment period (79 FR 67743), the CY 2016 PFS final rule with comment period (80 FR 71071 through 71072), the CY 2019 PFS final rule with comment period (83 FR 59681 through 59682), the CY 2024 PFS final rule with comment period (88 FR 79292 through 79293), and the CY 2026 PFS final rule with comment period (90 FR 49837)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA) (Pub. L. 108–173, December 8, 2003) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of

[370] Centers for Medicare & Medicaid Services. ''Making America Healthy Again: Innovation for Healthier Lives.'' *CMS, https://www.cms.gov/newsroom/blog/making-america-healthy-again-innovation-healthier-lives.*

the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations.

Using the methodology specified in the July 1, 2004, interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area,'' that is, to transports that originated in a rural area comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Most recently, section 6203 of the Consolidated Appropriations Act, 2026 (Pub. L. 119–75, February 3, 2026) amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2027. Therefore, we are continuing to apply the 22.6 percent rural bonus described in this section (in the same manner as in previous years) to ground ambulance services with dates of service before January 1, 2028, where transportation originates in a qualified rural area.

Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74439 through 74440), CY 2015 PFS final rule with comment period (79 FR 67743 through 67744), the CY 2016 PFS final rule with comment period (80 FR 71072), the CY 2019 PFS final rule with comment period (83 FR 59682), the CY 2024 PFS final rule with comment period (88 FR 79293), and the CY 2026 PFS final rule with comment period (90 FR 49837 through 49838)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through December 31, 2027, and does not require any substantive exercise of discretion on the part of the Secretary.

3. Ongoing Data Collection Requirements for the Medicare Ground Ambulance Data Collection System

We expect to address the ongoing data collection requirements for the Medicare Ground Ambulance Data Collection System in the CY 2028 PFS rulemaking to include the Medicare Payment Advisory Commission (MedPAC)'s June 15, 2026, Report to the Congress's findings: *https://www.medpac.gov/document/june-2026-report-to-the-congress-medicare-and-the-health-care-delivery-system/*.

4. Proposed Changes in Geographic Delineations for Ambulance Payment

Under section 1834(l)(2)(C) of the Act, the Secretary is required to consider appropriate regional and operational differences in establishing the AFS. Historically, the AFS has used the same geographic area designations as the acute care hospital inpatient prospective payment system (IPPS) and other Medicare payment systems to account for appropriate regional (urban and rural differences). The use of consistent geographic standards for Medicare payment provides for consistency across the Medicare program.

The current geographic areas used under the AFS effective CY 2015 are based on OMB standards published on June 28, 2010 (75 FR 37246 through 37252) and Census 2010 Bureau data (OMB Bulletin No. 13–01). For a discussion of OMB's delineation of Core-Based Statistical Areas (CBSAs) and our implementation of the CBSA definitions under the AFS, we refer readers to the preamble of the CY 2007 AFS proposed rule (71 FR 30358 through 30361), the CY 2007 PFS final rule with comment period (71 FR 69712 through 69716), CY 2015 PFS proposed rule (79 FR 40372 through 40376), CY 2015 PFS final rule with comment period (79 FR 67744 through 67750), CY 2015 PFS final rule correction notice (79 FR 78716 through 78719), CY 2016 PFS proposed rule (80 FR 41788 through 41792), and the CY 2016 PFS final rule with comment period (80 FR 71072 through 71078).

In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Commuting Survey (ACS). In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. A copy of OMB Bulletin No. 23–01 may be obtained at: *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*. According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data).

OMB's 2020 Standards for Delineating Core Based Statistical Areas (86 FR 37778) defines a CBSA as a geographic entity with at least one core of at least 10,000 population, where there are two types of CBSAs. A metropolitan statistical area (MSA) is one type, with populations greater than 50,000 and a micropolitan statistical area (referred to in this discussion as a Micropolitan Area) is the other type as a CBSA associated with at least one core that has a population of at least 10,000 but less than 50,000. Counties that do not qualify for inclusion in a CBSA are deemed ''outside of a CBSA.''

The July 21, 2023 OMB Bulletin No. 23–01 contains a number of significant changes to the statistical areas in the United States and Puerto Rico. For example, our analysis shows that a total of 53 counties that were once considered part of a CBSA would be considered to be located outside of a CBSA whereas a total of 54 counties that were located outside of a CBSA would be located in a CBSA under the revised OMB delineations. We believe it is important for the ambulance fee schedule to use the latest labor market area delineations available as soon as reasonably possible in order to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts.

Additionally, in the FY 2025 IPPS final rule with comment period (89 FR 69253), we finalized our proposal to adopt OMB's revised delineations based on OMB bulletin No. 23–01 to delineate areas for purposes of applying the IPPS wage index. Given that ambulance services is a transport benefit where payment is based on the ZIP code of the ambulance point of pickup and in response to industry requests to update the geographic delineations and the statutory requirement at sections 1834(l)(9), (l)(12)(B)(iv), (l)(13)(A)(i), and (l)(14)(C) of the Act that require that we use the most recent version of the Goldsmith Modification to determine rural census tracts within MSAs, we are proposing to update the geographic delineations, consistent with historical practice, rather than proposing to continue to use the current geographic delineations.

We believe it would be appropriate to adopt the same geographic area delineations for use under the AFS as are used under the IPPS and other Medicare payment systems. Thus, we are proposing to make use of the new OMB delineations as described in the July 21, 2023, OMB Bulletin No. 23–01 beginning in CY 2027, along with the geographic areas based on the most version of the Goldsmith Modification, to more accurately identify urban and rural areas for AFS payment purposes. We believe that combining the updated OMB delineations with the Goldsmith Modification's Rural-Urban Commuting Area (RUCA) codes more realistically reflect rural and urban populations, and that the use of such delineations and codes under the AFS would result in more accurate payment. Under the AFS, consistent with our current definitions of urban and rural areas (42 CFR 414.605), MSAs would continue to be recognized as urban areas, while Micropolitan Areas and other areas outside MSAs, and rural census tracts within MSAs (as discussed later in this section), would be recognized as rural areas.

In addition to the OMB's statistical area delineations, the current geographic areas used in the AFS are, as just stated, based on the most recent version of the Goldsmith Modification. Sections 1834(l)(9), (l)(12)(B)(iv), (l)(13)(A)(i), and (l)(14)(C) of the Act require that we use the most recent version of the Goldsmith Modification to determine rural census tracts within MSAs. These rural census tracts are considered rural areas under the AFS (see § 414.605). In the CY 2015 PFS final rule with comment period (79 FR 67744 through 67750), we adopted the most recent (at that time) version of the Goldsmith Modification, designated as RUCA codes. RUCA codes use urbanization, population density, and daily commuting data to categorize every census tract in the country. For a discussion about RUCA codes, we refer the reader to the CY 2007 PFS final rule with comment period (71 FR 69714 through 69716), the CY 2015 PFS final rule with comment period (79 FR 67745 and 67746), CY 2015 PFS final rule correction notice (79 FR 78716 through 78719), and the CY 2016 PFS final rule with comment period (80 FR 71073 through 71074).

As stated previously, on July 21, 2023, OMB issued OMB Bulletin No. 23–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. Several modifications of the RUCA codes were necessary to take into account updated commuting data and the revised OMB delineations. We refer readers to the U.S. Department of Agriculture's Economic Research Service website for a detailed listing of updated RUCA codes found at: *https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx*.

The updated RUCA code definitions were introduced on July 31, 2025, and are based on data from the U.S. Bureau of the Census, Department of Commerce, 2020 Census of Population and Housing and the 2017–21 Census Transportation Planning Package (CTPP) special tabulation for the Department of Transportation and the American Association of State Highway and Transportation Officials. We are proposing to adopt the most recent modifications of the RUCA codes beginning in CY 2027, to recognize levels of rurality in census tracts located in every county across the nation, for purposes of payment under the AFS. If we adopt the most recent RUCA codes, many counties that are designated as urban at the county level based on population would have rural census tracts within them that would be recognized as rural areas through our use of RUCA codes.

The 2020 Primary RUCA codes are as follows:

(1) Metropolitan core: primary commuting flow is within an urban area (UA) of 50,000 or more people (metro UA).

(2) Metropolitan high commuting: primary commuting flow is 30 percent or more to a metro UA.

(3) Metropolitan low commuting: primary commuting flow is 10 percent to 30 percent to a metro UA.

(4) Micropolitan core: primary flow is within an urban area of 10,000 to 49,999 people (micro UA).

(5) Micropolitan high commuting: primary commuting flow is 30 percent or more to a micro UA.

(6) Micropolitan low commuting: primary commuting flow is 10 percent to 30 percent to a micro UA.

(7) Small town core: primary commuting flow is within an urban area of 9,999 or fewer people (small town UA).

(8) Small town high commuting: primary commuting flow is 30 percent or more to a small town UA.

(9) Small town low commuting: primary commuting flow is 10 percent to 30 percent to a small town UA.

(10) Rural areas: primary commuting flow is to a tract outside an UA.

Based on this classification, and consistent with our current policy as set forth in the CY 2015 PFS final rule with comment period (79 FR 67745), we are proposing to designate any census tracts falling at or above RUCA level 4.0 as rural areas for purposes of payment for ambulance services under the AFS. As discussed in the CY 2015 PFS final rule with comment period (79 FR 67745), the Federal Office of Rural Health Policy (formerly the Office of Rural Health Policy) within the Health Resources and Services Administration (HRSA) determines eligibility for its rural grant programs through the use of the RUCA code methodology. Under this methodology, HRSA designates any census tract that falls at RUCA level 4.0 or higher as a rural census tract. In addition to designating any census tracts falling at or above RUCA level 4.0 as rural areas, under the updated RUCA code definitions, HRSA has also designated as rural census tracts those census tracts with RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We refer readers to HRSA's website at: *https://www.hrsa.gov/rural-health/about-us/what-is-rural* for additional information. Consistent with the HRSA guidelines discussed previously and the policy we adopted in the CY 2015 PFS final rule with comment period (79 FR 67750), we are proposing for CY 2027 to designate as rural areas those census tracts that fall at or above RUCA level 4.0. We continue to believe that this HRSA guideline accurately identifies rural census tracts throughout the country, and thus would be appropriate to apply for AFS payment purposes.

Also, consistent with the policy we finalized in the CY 2015 PFS final rule with comment period (79 FR 67749), we would not designate as rural areas those census tracts that fall at RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We have determined that it is not feasible to implement this guideline due to the complexities of identifying these areas at the ZIP code level. We do not have sufficient information available to identify the ZIP codes that fall in these specific census tracts. Also, payment under the AFS is based on the ZIP codes; therefore, if the ZIP code is predominantly metropolitan but has some rural census tracts, we do not split the ZIP code areas to distinguish further granularity to provide different payments within the same ZIP code. We believe that payment for all ambulance transportation services at the ZIP code level provides for a more consistent and administratively feasible payment

system. For example, if we were to pay based on ZIP codes for some areas and counties or census tracts for other areas, there are circumstances where ZIP codes cross county or census tract borders and where counties or census tracts cross ZIP code borders. Such overlaps in geographic designations would complicate our ability to appropriately assign ambulance transportation services to geographic areas for payment under the AFS. Therefore, under the AFS, we would not designate as rural areas those census tracts that fall at RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We invite comments on this proposal.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67746), the adoption of the most current OMB delineations and the updated RUCA codes would affect whether certain areas are recognized as rural or urban. The distinction between urban and rural is important for ambulance payment purposes because urban and rural transports are paid differently. The determination of whether a transport is urban or rural is based on the point of pick-up for the transport, and thus a transport is paid differently depending on whether the point of pick-up is in an urban or a rural area. During claims processing, geographic designation of urban, rural, or super rural is assigned to each claim for an ambulance transport based on the point of pick-up ZIP code that is indicated on the claim.

Currently, section 1834(l)(12) of the Act (as amended by section 6203 of the Consolidated Appropriations Act, 2026) specifies that, for services furnished during the period July 1, 2004 through December 31, 2027, the payment amount for the ground ambulance base rate is increased by a ''percent increase'' (Super Rural Bonus) where the ambulance transport originates in a ''qualified rural area,'' which is a rural area that we determine to be in the lowest 25th percentile of all rural populations arrayed by population density (also known as a ''super rural area''). We implement this Super Rural Bonus in § 414.610(c)(5)(ii). Adoption of the revised OMB delineations and the updated RUCA codes would have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the revised OMB delineations and the updated RUCA codes.

The adoption of the new OMB delineations and the updated RUCA codes would affect whether transports are eligible for other rural adjustments under the AFS statute and regulations. For ground ambulance transports where the point of pick-up is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles (§ 414.610(c)(5)(i)). For air ambulance services where the point of pick-up is in a rural area, the total payment (base rate and mileage rate) is increased by 50 percent (§ 414.610(c)(5)(i)). Furthermore, under section 1834(l)(13) of the Act (as amended by section 6203 of the Consolidated Appropriations Act, 2026) for ground ambulance transports furnished through December 31, 2027, transports originating in rural areas are paid based on a rate (both base rate and mileage rate) that is 3 percent higher than otherwise is applicable. (See also § 414.610(c)(1)(ii)).

If we adopt OMB's revised delineations and the updated RUCA codes, ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be Micropolitan or otherwise outside of MSAs based on OMB's revised delineations or in a rural census tract of an MSA based on the updated RUCA codes (but are currently within urban areas) may experience increases in payment for such transports because they may become eligible for the rural adjustment factors discussed previously, while those ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be urban based on OMB's revised delineations and the updated RUCA codes (but are currently in Micropolitan Areas or otherwise outside of MSAs, or in a rural census tract of an MSA) may experience decreases in payment for such transports because they would no longer be eligible for the rural adjustment factors discussed previously.

The use of the revised OMB delineations and the updated RUCA codes would mean the recognition of new urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2010 and 2020. As discussed previously in this section, we are proposing to use the updated 2020 RUCA codes to identify rural census tracts within MSAs, such that the census tracts falling at or above RUCA level 4.0 would continue to be designated as rural areas. To determine which ZIP codes are included in each such rural census tract, we are proposing to use the ZIP code approximation file developed by HRSA. This file includes the 2020 RUCA code designation for each ZIP code and can be found at: *https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes* If ZIP codes are added over time to the USPS ZIP code file (and thus are not included in the 2020 ZIP code approximation file provided to us by HRSA) or if ZIP codes are revised over time, we would determine the appropriate urban/rural designation for such ZIP code based on any updates provided on the HRSA and OMB websites located at: *https://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx* and *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*.

Based on the April 2026 United States Postal Service (USPS) ZIP code file that we are using in this proposed rule to assess the impacts of the revised geographic designations; there are a total of 42,956 ZIP codes in the U.S. Table B–H1 sets forth an analysis of the number of ZIP codes that changed urban/rural status in each U.S. State and territory using the April 2026 USPS ZIP code file, the revised OMB delineations (OMB Bulletin No. 23–01), and the updated 2020 RUCA codes. Based on this data, the geographic designations for approximately 95.87 percent of ZIP codes would be unchanged by OMB's revised delineations and the updated RUCA codes. As reflected in Table B–H1, more ZIP codes would change from urban to rural (1,172, or 2.73 percent) than rural to urban (602, or 1.40 percent). In general, it is expected that ambulance providers and suppliers in 1,172 ZIP codes within 47 States and Puerto Rico may experience payment increases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from urban to rural. The State of Maryland would have the most ZIP codes changing from urban to rural with a total of 49, or 7.78 percent. Ambulance providers and suppliers in 602 ZIP codes within 43 States may experience payment decreases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from rural to urban. The State of South Carolina would have the most ZIP codes changing from rural to urban (20, or 3.68 percent). Our findings are illustrated in Table B–H1.

TABLE B-H1: ZIP CODES ANALYSIS BASED ON OMB'S REVISED DELINEATIONS AND UPDATED RUCA CODES

State/ Territory*	Total ZIP Codes	Total ZIP Codes Changed Rural to Urban	Percentage of Total ZIP Codes	Total ZIP Codes Changed Urban to Rural	Percentage of Total ZIP Codes	Total ZIP Codes Not Changed	Percentage of Total ZIP Codes Not Changed
AK	276	0	0.00%	0	0.00%	276	100.00%
AL	854	20	2.34%	11	1.29%	823	96.37%
AR	727	4	0.55%	18	2.48%	705	96.97%
AS	1	0	0.00%	0	0.00%	1	100.00%
AZ	571	2	0.35%	8	1.40%	561	98.25%
CA	2730	35	1.28%	93	3.41%	2602	95.31%
CO	677	3	0.44%	22	3.25%	652	96.31%
CT	421	1	0.24%	15	3.56%	405	96.20%
DC	319	1	0.31%	0	0.00%	318	99.69%
DE	99	0	0.00%	6	6.06%	93	93.94%
EK	63	0	0.00%	0	0.00%	63	100.00%
EM	858	10	1.17%	14	1.63%	834	97.20%
FL	1516	23	1.52%	27	1.78%	1466	96.70%
FM	4	0	0.00%	0	0.00%	4	100.00%
GA	1032	5	0.48%	22	2.13%	1005	97.38%
GU	21	0	0.00%	0	0.00%	21	100.00%
HI	143	2	1.40%	0	0.00%	141	98.60%
IA	1080	7	0.65%	11	1.02%	1062	98.33%
ID	335	6	1.79%	10	2.99%	319	95.22%
IL	1630	10	0.61%	86	5.28%	1534	94.11%
IN	1002	16	1.60%	23	2.30%	963	96.11%
KY	1030	25	2.43%	23	2.23%	982	95.34%
LA	739	26	3.52%	23	3.11%	690	93.37%
MA	752	2	0.27%	27	3.59%	723	96.14%
MD	630	0	0.00%	49	7.78%	581	92.22%
ME	505	15	2.97%	14	2.77%	476	94.26%
MH	2	0	0.00%	0	0.00%	2	100.00%
MI	1186	34	2.87%	18	1.52%	1134	95.62%
MN	1044	11	1.05%	10	0.96%	1023	97.99%
MP	3	0	0.00%	0	0.00%	3	100.00%
MS	541	6	1.11%	8	1.48%	527	97.41%
MT	411	1	0.24%	0	0.00%	410	99.76%
NC	1102	25	2.27%	55	4.99%	1022	92.74%
ND	419	12	2.86%	1	0.24%	406	96.90%
NE	632	0	0.00%	4	0.63%	628	99.37%
NH	292	0	0.00%	12	4.11%	280	95.89%
NJ	748	8	1.07%	5	0.67%	735	98.26%
NM	439	0	0.00%	3	0.68%	436	99.32%
NV	258	0	0.00%	3	1.16%	255	98.84%

State/ Territory*	Total ZIP Codes	Total ZIP Codes Changed Rural to Urban	Percentage of Total ZIP Codes	Total ZIP Codes Changed Urban to Rural	Percentage of Total ZIP Codes	Total ZIP Codes Not Changed	Percentage of Total ZIP Codes Not Changed
NY	2247	33	1.47%	73	3.25%	2141	95.28%
OH	1489	42	2.82%	31	2.08%	1416	95.10%
OK	792	24	3.03%	6	0.76%	762	96.21%
OR	500	12	2.40%	15	3.00%	473	94.60%
PA	2245	19	0.85%	157	6.99%	2069	92.16%
PR	178	2	1.12%	12	6.74%	164	92.13%
PW	2	0	0.00%	0	0.00%	2	100.00%
RI	91	0	0.00%	2	2.20%	89	97.80%
SC	544	20	3.68%	21	3.86%	503	92.46%
SD	418	1	0.24%	3	0.72%	414	99.04%
TN	814	19	2.33%	20	2.46%	775	95.21%
TX	2730	60	2.20%	55	2.01%	2615	95.79%
UT	361	3	0.83%	7	1.94%	351	97.23%
VA	1277	16	1.25%	41	3.21%	1220	95.54%
VI	16	0	0.00%	0	0.00%	16	100.00%
VT	309	2	0.65%	0	0.00%	307	99.35%
WA	744	8	1.08%	7	0.94%	729	97.98%
WI	919	12	1.31%	27	2.94%	880	95.76%
WK	712	12	1.69%	5	0.70%	695	97.61%
WM	342	0	0.00%	3	0.88%	339	99.12%
WV	936	7	0.75%	66	7.05%	863	92.20%
WY	198	0	0.00%	0	0.00%	198	100.00%
Totals	**42,956**	**602**	**1.40%**	**1,172**	**2.73%**	**41,182**	**95.87%**

*ZIP code analysis includes U.S. States and Territories (FM—Federated States of Micronesia, GU—Guam, MH—Marshall Islands, MP—Northern Mariana Islands, PW—Palau, AS—American Samoa; VI—Virgin Islands; PR—Puerto Rico). Missouri is divided into east and west regions due to work distribution of the Medicare Administrative Contractors (MACs): EM—East Missouri, WM—West Missouri. Johnson and Wyandotte counties in Kansas were changed as of January 2010 to East Kansas (EK), and the rest of the state is West Kansas (WK).

For more detail on the impact of our proposals, in addition to Table B–H1, the following files are available through the internet on the Ambulances Services Center website at: *https://www.cms.gov/medicare/coverage/ambulances-services-center*; ZIP Codes By State Changed From Urban To Rural: ZIP Codes By State Changed From Rural To Urban: List of ZIP Codes With RUCA Code Designations: and Complete List of ZIP Codes.

We invite public comments on our proposals to make use of the revised OMB delineations as set forth in OMB's July 21, 2023 bulletin (No. 23–01) and the most recent modifications of the RUCA codes as discussed previously for CY 2027 for purposes of payment under the AFS.

X. Request for Information (RFI) on Duplicate Laboratory Testing, Imaging, and Result Sharing and Interoperability

1. Overview

Diagnostic imaging and laboratory testing are critical to determining a patient's course of treatment. Imaging data and test results are often siloed within the acquiring systems' electronic health record and inaccessible outside of those systems. Treating health care providers often do not even know of the existence of these siloed results. The inaccessibility of laboratory and imaging data due to siloing results in incomplete or delayed care management and duplicative testing, with concomitant increased costs (and in the case of duplicative diagnostic imaging, unnecessary radiation exposure).

2. Purpose of the RFI

We are issuing this RFI to gather input from interested parties—including clinicians, laboratories, imaging health care providers, health systems, payers, health IT developers, and other interested parties—to inform potential actions aimed at addressing the interoperability and duplicate testing concerns described earlier in this section.

3. Potential Mechanisms for Addressing Duplicative Payment

Given the concerns discussed previously in this section resulting from duplicate diagnostic laboratory and image testing, we are exploring various mechanisms for addressing duplicative payment:

- Clarifications to billing instructions to laboratories and imaging centers on

parameters of duplicate laboratory or imaging tests;

- Local Medicare Administrative Contractor (MAC) edits that would result in non-payment or reductions in payment as applicable for duplicate laboratory or imaging tests;
- Use of payment integrity levers to recoup payments from health care providers and suppliers who performed duplicate laboratory or imaging tests; and
- Application of frequency limitations to certain tests where clinically appropriate.

We note that frequency limitations are already in use in certain contexts. For example, a Local Coverage Decision (LCD) from a MAC limits testing for Vitamin D levels (L33996—Vitamin D Assay Testing), providing that once a beneficiary has been shown to be Vitamin D deficient, further testing is medically necessary only to ensure adequate replacement has been accomplished, with annual testing thereafter being appropriate depending on the indication and other mitigating factors. We believe there are likely other diagnostic laboratory tests that should similarly be subject to frequency limitations.

We also recognize that in some cases more frequent testing is clinically justified and we are therefore seeking input not only on which laboratory and imaging tests should be subject to frequency limitations, but also on what exceptions should be permitted to ensure beneficiary access is not inappropriately restricted.

We seek input on how such enforcement actions can be implemented without restricting beneficiary access to necessary care, and specifically how practitioners can communicate clinical justification for repeat testing in specific circumstances—for example, in cases of trauma, stroke, or evolving emergencies where repeat imaging may be clinically appropriate.

- Should CMS consider possible changes to payment policies when diagnostic tests are billed duplicatively; that is, additional imaging or diagnostic laboratory tests for the same condition? For example, is there a time period which an image or laboratory test should automatically be considered ''duplicate'' and therefore subject to payment consequences? To which kinds of tests or subsets of tests should such policies apply? We welcome responses from both the clinical community as well as payors who have likely addressed or considered these or similar issues related to the payments they make.

4. Laboratory and Imaging Interoperability

Several agencies within HHS have indicated an interest in gaining public input on interoperability for various health programs. Section 4003 of the 21st Century Cures Act (Pub. L. 114–255) amended section 3000 of the PHSA to add a new paragraph (10) to include a statutory definition of ''interoperability.'' Interoperability is defined to mean, with respect to health information technology, such health information technology that— (A) enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without special effort on the part of the user; (B) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable State or Federal law; and (C) does not constitute information blocking as defined in section 3022(a) of the Public Health Service Act.

We view duplicate imaging and laboratory testing as one of several use cases in which the lack of clinical interoperability causes non-trivial beneficiary harm and program integrity concerns. In recognition of that perspective, the broader department, and the Office of the National Coordinator for Health Information Technology (ONC) in particular, adopts standards that facilitate easier exchange of diagnostic clinical information and includes criteria in the ONC Health IT Certification Program that address the certification of health IT to exchange this information. In the January 30, 2026 **Federal Register** (91 FR 4054), ONC published an RFI titled, ''Request for Information: Diagnostic Imaging Interoperability Standards and Certification''.

The regulatory background section of the January 2026 RFI (91 FR 4055) outlined the following prior efforts:

- Federal efforts to incorporate diagnostic imaging requirements into certification criteria for electronic health record (EHRs) and other health IT systems span more than a decade, marked by a recurring cycle of proposals, reversals, and unresolved interoperability challenges.
- In 2012, the Secretary published the proposed rule titled, ''Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' (77 FR 13832) (hereinafter '' 2014 Edition Proposed Rule''), which proposed an imaging certification criterion (§ 170.314(a)(12)) without requiring the Digital Imaging and Communications in Medicine (DICOM) standard, while simultaneously requesting public comments on its use (77 FR 13838). The proposed rule also proposed to require EHR technology certified under the View, Download, and Transmit (VDT) certification criterion (§ 170.314(e)(1)) to be capable of enabling images formatted according to the DICOM-formatted images (77 FR 13839 and 13840). However, when the 2014 Edition Final Rule was published later that year (77 FR 54163), the DICOM standard was not adopted, and the image download and transmission requirement was removed from the VDT certification criterion—largely due to complexity and implementation burden raised by commenters (77 FR 54183). Instead, the 2014 Edition Final Rule adopted an ''image results'' certification criterion that required Health IT Modules certified to that criterion to indicate the availability of patient images and narrative interpretations, accessible either through a direct link within the EHR or a context-sensitive link to an external application (77 FR 54172 and 54173).

Between 2014 and 2024, ONC continued efforts to modernize the VDT imaging related criteria. Public feedback consistently underscored challenges related to standards maturity, uneven implementation across settings, and fragmentation in available technologies. Imaging exchange remains uniquely complex: in addition to narrative reports, large image files, associated metadata, and viewing capabilities must be exchanged in a manner that is performant, secure, and consistent across systems. Information blocking, economic and workflow burdens, and inconsistent conformance to existing standards all continue to affect access to diagnostic imaging across organizational boundaries.

- Responses to other recent RFIs (for example, ''Request for Information; Health Technology Ecosystem'' which appeared in the May 16, 2025 **Federal Register** (90 FR 21034) (hereinafter ''Health Technology Ecosystem RFI'') indicate that the imaging exchange environment remains fragmented and unreliable, with ongoing dependence on CDs and DVDs and limited availability of modern, API-enabled tools that would allow patients and health care providers to access and share images seamlessly. Interested parties have also highlighted privacy and security considerations that must be accounted

for as exchange capabilities evolve. Public feedback highlights support for building on existing standards rather than creating entirely new exchange paradigms.

- Similar patterns are evident in laboratory interoperability, where challenges frequently stem from differing ordering workflows, variations in result reporting practices, local coding conventions, and inconsistent implementation of standards. These issues mirror broader interoperability challenges and reinforce the need for coordinated, standards-based approaches across diagnostic domains.

Other key information received in response to the Health Technology Ecosystem RFI:

- The current system of fragmented patient portals is unworkable.
- A unified, ''one-stop shop'' for health records is the universal goal.
- API access must go beyond the USCDI data set to the full electronic health information (EHI).
- Existing data access tools are insufficient.

Given what we discussed earlier in this section, we believe there are opportunities to establish or improve interoperability between laboratories and physicians, hospitals, and other care delivery organizations. Specifically, participation in a national interoperability network for exchanging diagnostic imaging and laboratory results in a standardized format remains top of mind for the Department. Such participation would allow physicians, hospitals, laboratories, and other care delivery organizations to more easily access relevant clinical data to prevent the duplicate imaging and testing discussed previously in this section. We are aware that such participation is insufficient. The networks must resolve fundamental technical issues like authentication (for example, are you who you say you are?); authorization (for example, are you allowed to access the data?); and patient matching (for example, what records are associated with the individual in question?). Without a reliable way to match records across systems, even well-connected networks would return incomplete or incorrect results.

We have also considered building on the existing Electronic Notifications Condition of Participation (CoP) at 42 CFR 482.4(d) to require hospitals to participate in a national interoperability network. We believe that the relationship to patient health and safety is clear: timely and accurate information leads to coordinated, safer care and treatment decisions for patients. While we believe a CoP, for Medicare and Medicaid participating hospitals, would be an appropriate mechanism to drive interoperability, we also recognize that unlike other provider types the only statutorily available penalty for noncompliance with the hospital CoPs is termination from the Medicare program, as provided under section 1866(b)(2)(A) and (B) of the Act. We believe this would be overly burdensome. However, we will continue to monitor hospital advances in interoperability and may consider future rulemaking or look to other programs like the Medicare Promoting Interoperability Program or the Hospital Inpatient Quality Reporting program (IQR) or both.

Building upon the RFIs noted previously, we would like to further explore opportunities related to interoperability, specifically for diagnostic laboratory tests and imaging services. The following are questions for which we seek input.

- Because image exchange can involve substantial technical and operational costs, should HHS or CMS consider incentives to support adoption and implementation, and if so, what form should those incentives take?
- Given variability in conformance to existing laboratory and imaging exchange standards, would interested parties find value in expanded conformance testing tools, certification approaches, or implementation guidance?
- How should CMS account for cases in which repeat imaging occurs because prior imaging results were not available for timely, standards-based reuse? Should CMS consider payment, quality, or participation policies that create accountability for the initial imaging provider, furnishing entity, or facility when failure to make results reusable contributes to avoidable repeat imaging? Are there penalties or disincentives for non-compliance we should consider?
- For laboratory interoperability specifically, what barriers continue to impede exchange despite the availability of established standards, and what policy levers could help address those barriers? Should we consider incentives to support laboratory adoption and implementation of health data standards?

Should CMS establish a minimum data standard for result shareability, for example, a United States Core Data for Interoperability (USCDI+) supplement for imaging and laboratory results, requiring all participating entities to deliver both a structured Fast Healthcare Interoperability Resources (FHIR) R4 Diagnostic Report resource and a human-readable Portable Document Format/Archive (PDF/A) rendition to the ordering health care provider's designated endpoint as a condition of Medicare payment? How should CMS address health care providers who have not yet implemented FHIR-native workflows, especially in rural areas?

IV. Updates to the Quality Payment Program

A. CY 2027 Modifications to the Quality Payment Program Reporting and Data Submission

1. Executive Summary

a. Overview

This section of this proposed rule outlines changes to the Quality Payment Program starting January 1, 2027, except as otherwise noted for specific provisions. We continue to move the Quality Payment Program forward, including focusing more on alignment between the Merit-based Incentive Payment System (MIPS) and Advanced Alternative Payment Models (APM) tracks of participation, alignment with broader CMS initiatives, and new options for clinicians to participate in more meaningful ways. We aim to achieve continuous improvement in the quality of health care services provided to Medicare beneficiaries and other patients through MIPS and Advanced APMs for the CY 2027 performance period/2029 payment year.

Authorized by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015), the Quality Payment Program is a value-based payment program, by which clinicians are rewarded for providing high-value, high-quality care to their patients in a cost-efficient manner. There are two ways for clinicians who provide services under the Medicare program to participate in the Quality Payment Program: MIPS and Advanced APMs. The statutory requirements for the Quality Payment Program are set forth in section 1848(q) and (r) of the Act for MIPS and section 1833(z) of the Act for Advanced APMs.

For the MIPS participation track, MIPS eligible clinicians (defined at § 414.1305) [371] are subject to a MIPS payment adjustment (positive, neutral, or negative) based on their performance in four performance categories: cost, quality, improvement activities, and Promoting Interoperability. We assess

[371] We note that the term MIPS eligible clinician is defined at § 414.1305 as including a group of at least one MIPS eligible clinician billing under a single tax identification number. We refer readers to our policies governing group reporting and scoring under MIPS as set forth at § 414.1310(e).

each MIPS eligible clinician's total performance according to established performance standards for the applicable measures and activities specified in each of these four performance categories during a performance period to compute a final composite performance score (a ''final score'' as defined at § 414.1305). In calculating the final score, we must apply different weights for the four performance categories, subject to certain exceptions, as set forth in section 1848(q)(5) of the Act and at § 414.1380. Unless we assign a different scoring weight under these exceptions, for the CY 2027 performance period/2029 MIPS payment year, the scoring weights are as follows: 30 percent for the quality performance category; 30 percent for the cost performance category; 25 percent for the Promoting Interoperability performance category; and 15 percent for the improvement activities performance category.

Once calculated, each MIPS eligible clinician's final score is compared to the performance threshold established in prior rulemaking for that performance period to calculate the MIPS payment adjustment factor as specified in section 1848(q)(6) of the Act, such that the MIPS eligible clinician will receive in the applicable MIPS payment year: (1) a positive adjustment, if their final score exceeds the performance threshold; (2) a neutral adjustment, if their final score meets the performance threshold; or (3) a negative adjustment, if their final score is below the performance threshold. In calculating the MIPS payment adjustment factor for a MIPS eligible clinician, we account for scaling factor and budget neutrality requirements, as further specified in section 1848(q)(6) of the Act. We then apply the MIPS payment adjustment factor to amounts otherwise paid under Medicare Part B for covered professional services for the MIPS eligible clinician for the applicable MIPS payment year and payments for covered professional services are increased, decreased, or not adjusted based on the MIPS eligible clinician's final score relative to the performance threshold.

Section 1848(q) of the Act sets forth other requirements applicable to MIPS, including opportunities for feedback and targeted review and public reporting of MIPS eligible clinicians' performance. Section 1848(r) of the Act sets forth more specific requirements for development of measures for the cost performance category under MIPS.

For the Advanced APM track, if an eligible clinician participates in an Advanced APM and achieves Qualifying APM Participant (QP) or Partial QP status, they are excluded from the MIPS reporting requirements and payment adjustment (though eligible clinicians who are Partial QPs may elect to participate in MIPS and be subject to the MIPS reporting requirements and payment adjustment). In alignment with the application of QPP eligibility determinations, we are proposing to apply QP and Partial QP status to the TIN/NPI under which a clinician achieves QP or Partial QP status. Under current law, eligible clinicians who are QPs for the 2024 performance year/2026 payment year and beyond will receive an increased physician fee schedule update of 0.75 percent qualifying APM conversion factor. We note that, historically, QPs received a lump sum APM Incentive Payment in the corresponding payment year, calculated as a specified percentage of the QP's paid claims for covered professional services from the base year. Only legislation enacted by Congress can make changes to either the enhanced QP conversion factor updates or the APM Incentive Payment.

We plan to continue developing policies for the Quality Payment Program that more effectively reward high-quality of care for patients and increase opportunities for Advanced APM participation. We continue to implement MIPS Value Pathways (MVPs) to allow for a more cohesive participation experience by connecting activities and measures from the four MIPS performance categories that are relevant to a specialty, medical condition, or a particular population.

As we move into the 10th year of the Quality Payment Program, we will be implementing the updates set forth in this section of this proposed rule, encouraging continued improvement in clinicians' performance with each performance year and driving improved quality of health care through payment policy.

b. Summary of Major Proposals

(1) Transforming the Quality Payment Program

The Making America Healthy Again (MAHA) initiative (*https://www.hhs.gov/maha/index.html*) represents a shift from the focus on chronic disease management and moves toward prevention and restoring foundational wellness. This initiative aims to address the root causes of poor health outcomes by reducing chronic disease rates, improving nutrition, promoting preventative care, and increasing transparency in health systems. This vision is supported by aligning policies in MIPS and APMs within the Quality Payment Program with the foundational pillars of MAHA. We are expanding the MVP portfolio to include Diabetic Disease and Hypertension MVPs that address the prevention of chronic illnesses and aim to reduce the incidence and impact of long-term conditions. In alignment with the goal of promoting preventive care and fostering a more proactive and holistic approach to health management, we are proposing new improvement activities under the ''Advancing Health and Wellness'' subcategory within the improvement activities performance category. The proposed improvement activities integrate concepts that address nutrition, implement lifestyle approaches to disease management, and support patient wellness to ensure a healthier future.

Through the policies described in this proposed rule, we intend to transform and simplify MIPS, promote the use of connected measures and activities, continue rewarding clinicians for providing high value care, and use data-driven information to help all clinicians improve care and engage patients. In accordance with the stated intent, we are proposing the traditional MIPS reporting option would be sunset and that MVPs will be the only reporting option for MIPS beginning with the CY 2029 performance period/2031 MIPS payment year. Traditional MIPS would continue to be an available reporting option until the CY 2029 performance period/2031 MIPS payment year, when sunsetting occurs.

(a) Transforming MIPS: MVP Strategy

MVPs will improve value, reduce burden, and inform patient choice in selecting clinicians. To support our goal of phasing out traditional MIPS and transitioning eligible clinicians to MVP reporting, we are proposing policies supporting MVP only reporting for MIPS. The MVP reporting option offers aligned measures and activities across quality, cost, improvement activities, and Promoting Interoperability performance categories, focusing on specific specialties, conditions, or patient populations to make reporting more meaningful. Specifically, we propose that beginning in the CY 2029 performance period/2031 MIPS payment year, eligible clinicians participating in MIPS, and not reporting the APM Performance Pathway (APP), would be required to report the measures and activities in a selected MVP for MIPS. We also propose including virtual groups in MVP reporting to ensure all eligible clinicians can report MVPs.

(b) MIPS Value Pathways Development and Maintenance

To continue moving the healthcare community toward value-based, high-quality, safe, and cost-efficient care, we are proposing three new MVPs around the following topics: Diabetic Disease, Hypertension, and Hospitalist.

We are also proposing MVP maintenance updates to our MVP inventory that are aligned with the MVP development criteria and take into consideration feedback from interested parties we have received through the maintenance process. Additionally, we updated all the MVPs to include MIPS core measures. Finally, we are renaming the Rehabilitative Support for Musculoskeletal Care MVP to Rehabilitative Support MVP to better represent the measures and activities included in the MVP.

(c) APM Performance Pathway

We are proposing to align quality measures in the APM Performance Pathway (APP), original quality measure set and the APP Plus quality measure set to reflect our proposed changes to measures specified for the quality performance category as discussed in section IV.A.4.b.2 of this proposed rule.

(d) Fast Healthcare Interoperability Resources (FHIR) Request for Information

We are advancing quality measurement by transitioning existing quality measures and reporting processes to Fast Healthcare Interoperability Resources® (FHIR®)-based digital reporting options. In this proposed rule, we seek input on the anticipated transition timeline, key milestones, and implementation considerations for FHIR-based quality reporting in the Quality Payment Program and other CMS quality reporting programs.

(e) MIPS Quality Performance Category

For the CY 2027 performance period/2029 MIPS payment year, we are proposing to establish a measure set inventory of 180 MIPS quality measures, of which 177 are available in traditional MIPS and three are available only for utilization in MVPs. Proposed changes to the measure set inventory include 20 measure removals, 10 measure additions for CY 2027, one measure addition for CY 2028, and 43 substantive changes to existing measures.

The proposed measure removals focus on low bar process measures, measures reaching extremely topped-out status or the end of the topped-out measure lifecycle, measures that are duplicative of new or current measures, measures with limited adoption and therefore no benchmark, measures lacking robustness, and measures the steward would no longer maintain. The proposed measure additions focus on measuring patient-reported outcomes and chronic disease management. Proposed substantive changes to existing measures would ensure the measures included in MIPS continue to be meaningful and drive improvements in quality of care.

Beginning with the CY 2027 performance period/2029 MIPS payment year, we are proposing to implement the MIPS core measure designation in traditional MIPS and MVPs. We are also proposing to remove the high priority designation from MIPS quality measures and the MVP inventory. Additionally, we are proposing to no longer use the high priority designation as one of the retention criteria for MIPS quality measures and the MVP inventory.

Furthermore, beginning with the CY 2027 performance period/2029 MIPS payment year, we propose removing the current quality measure data submission requirement of one outcome (or one high priority measure if an outcome measure is not available) for traditional MIPS and MVP reporting and replacing it with the requirement that eligible clinicians must report at least one MIPS core measure (or, if an applicable MIPS core measure is not available, report one other MIPS non-core measure). We are also proposing that if a MIPS eligible clinician does not have an available and applicable MIPS core measure, they must attest during the data submission period that a MIPS core measure is not available and applicable for them to report. The clinician would then be required to choose another measure to report instead of the MIPS core measure.

Also, we are proposing that clinicians in small practices would be exempt from the proposed MIPS core measure requirement and would not need to submit an attestation if a MIPS core measure is not available and applicable to them.

Lastly, we are proposing to expand the definition of the collection type to include Medicare Electronic Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs); establish the data submission criteria for Medicare eCQMs; and establish the data completeness criteria for Medicare eCQMs.

(f) MIPS Cost Performance Category

We are proposing to update the operational list of care episodes and patient condition groups and codes to reflect coding changes identified through our annual maintenance process for MIPS cost measures.

(g) MIPS Improvement Activities Performance Category

We are proposing the following updates to the MIPS Improvement Activity Inventory beginning with the CY 2027 performance period/2029 MIPS payment year. First, we are proposing to add six new improvement activities into two subcategories: (1) Care Coordination and (2) Advancing Health and Wellness, our newest subcategory. Second, we propose modifying five existing improvement activities currently specified for the performance category. Third, we propose to remove eleven improvement activities currently specified for the performance category.

(h) MIPS Promoting Interoperability Performance Category

We are proposing the following policies:

- Starting with the CY 2026 performance period/2028 MIPS payment year, we are proposing to remove the ONC Direct Review attestation and the ONC-Authorized Certification Bodies (ACB) Surveillance attestation.
- Starting with the CY 2027 performance period/2029 MIPS payment year, we are proposing to:

++ Modify the definition of Certified Electronic Health Record Technology (CEHRT) to align with the applicable Office of the National Coordinator for Health Information Technology's (ONC) proposals to remove certain certification criteria from the ONC Health IT Certification Program as outlined in the Health Data, Technology, and Interoperability: Office of the Assistant Secretary for Technology Policy (ASTP)/ONC Deregulatory Actions to Unleash Prosperity (HTI–5) proposed rule;

++ Modify the Electronic Prior Authorization measure by updating the measure description, and for the CY 2027 performance period, changing the measure from being a required measure to being an optional measure; and

++ Remove the Security Risk Analysis measure.

- Starting with the CY 2028 performance period/2030 MIPS payment year, we are proposing to:

++ Modify the Electronic Prior Authorization measure by updating the measure description to account for additional requirements pertaining to the measure, and changing the measure to being a required measure; and

++ Add a new measure, Electronic Prior Authorization for Prescription

Drugs, as a required measure under the Health Information Exchange objective.

(i) MIPS Scoring

We are proposing scoring policies consistent with the proposed MIPS core measure requirement for MIPS eligible clinicians beginning in the CY 2027 performance period/2029 MIPS payment year. Specifically, we propose to assign zero measure achievement points for one quality measure for clinicians reporting data under traditional MIPS and MVP reporting, if they do not submit a MIPS core measure and do not attest during data submission that they do not have an available and applicable MIPS core measure.

We are seeking feedback on the proposed list of topped out measures impacted by limited measure choice in specialty measure sets and MVPs to be subject to the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year. We propose to modify the publishing location of topped out measures impacted by limited measure choice and scored according to the defined topped out benchmark. We also propose to apply the defined topped out benchmark for MIPS core measures that are topped out for 2 or more consecutive years. Additionally, we seek feedback in a request for information (RFI) on the future direction of MVP scoring policies.

Lastly, we are proposing the following modifications: The benchmarking methodology for the Medicare CQMs collection type by extending the use of flat benchmarks; establishment of a flat benchmarking methodology for the proposed Medicare eCQMs collection type; and modification of the Electronic Prior Authorization measure from a required measure to an optional measure worth 10 bonus points under the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year.

(j) Third Party Intermediaries

In this proposed rule, we seek to update our requirements for third-party intermediaries related to the conditions for approval of Qualified Clinical Data Registries (QCDRs) and qualified registries, remove the additional requirements for health IT vendors, and revise our remedial action and termination policies. At a high level, we are proposing the following:

- Clarify that the additional requirements for health IT vendors no longer apply beginning with the CY 2025 performance period/2027 MIPS payment year, as health IT vendors are no longer permitted to submit MIPS data as a third-party intermediary starting in that year;
- Make minor revisions to the audit requirements;
- Modify our policy so that third-party intermediaries that do not submit data for 1 year would be terminated;
- Revise existing policies to specify a QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one MIPS core measure to align with the proposed removal of high priority designation from MIPS quality measures and the MIPS core measure reporting requirements in section IV.A.4.d.(1)(c) of this proposed rule; and

(k) Calculating MIPS Final Score

In this proposed rule, we propose that beginning with the CY 2027 performance period/2029 MIPS payment year we will use whatever data is most current and reliable to determine if an individual MIPS eligible clinician is located in an area that has been identified as being affected by an extreme and uncontrollable circumstance (EUC). We also propose to adjust the deadline by which clinicians would be able to submit reweighting requests for the quality, improvement activities, and Promoting Interoperability performance categories due to scenarios where a third-party intermediary did not submit data on their behalf in accordance with the applicable data submission deadlines. Specifically, we propose that beginning with the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians would be able to submit reweighting requests on or before December 31st of the year preceding the relevant MIPS payment year.

(l) Public Reporting

The public reporting section of this proposed rule contains a policy proposal and RFI for improvements to the CMS Compare Tools hosted by the U.S. Department of Health and Human Services (HHS) available on clinician profile pages at *https://www.medicare.gov/care-compare/* and in the Medicare Provider Data Catalog available at *https://data.cms.gov/provider-data/topics/doctors-clinicians*.

We propose to remove the requirement preventing public reporting of any performance data reported through an MVP on new improvement activity or Promoting Interoperability (PI) measure, objective, or activity during the first year in which it is included in such MVP. Under the removal of this requirement, performance information for new improvement activities and PI measures would be publicly reported on CMS Compare Tools during the first year in which the measures and activities are included in the program, regardless of reporting option.

We are also soliciting feedback on improvements to the current star rating assignment methodology for quality measure scores collected under the administrative claims collection type. With more information, we can determine whether an alternative methodology for star rating assignments is more appropriate for administrative claims quality measures prior to the public reporting of these scores on clinicians' profile pages on the Medicare.gov Compare Tool.

(2) Advanced APM Proposals

We are proposing to modify the application of the QP and partial QP status at § 414.1425 to ensure that only TINs participating in Advanced APMs receive additional incentive payments, both the APM Incentive Payment and the qualifying APM conversion factor.

We are proposing to clarify language at § 414.1425(c)(5) pertaining to when QP status is lost as a result of an APM Entity terminating participation from an Advanced APM.

We are proposing that for certain Alternative Payment Models where a participation list is not practicable that they would not provide a participation list for as a MIPS APM or APM participation for QPP purposes.

We are proposing to modify the conditions by which we award credit for Improvement Activities specified at § 414.1355 to ensure that participants receive credit.

We are proposing to modify the thresholds established at § 414.1430 in accordance with the Consolidated Appropriations Act, 2026.

2. Definitions

At § 414.1305, we are proposing to revise definitions of the following terms:

- APM Incentive Payment
- Collection type
- High priority measure
- MVP Participant
- Participation List

These terms and definitions are discussed in detail in the relevant sections of this proposed rule.

3. Transforming MIPS: MIPS Value Pathway (MVP) Strategy

We play a leading role in transitioning the Federal health care system from Original Medicare payment toward value-based payment, incentivizing higher quality of care over higher

quantity of care. MIPS aims to drive value through the collection, assessment, and public reporting of data that informs and rewards the delivery of high-value care. We continue to focus on transforming health care delivery, driving higher value care, and increasing alignment with other CMS programs and initiatives to reduce burden. We intend to continue our efforts to align the Quality Payment Program with the broader aims of CMS to ensure patients receive the care they want and deserve by promoting prevention, wellness, and chronic disease management. We are guided by the CMS National Quality Strategy [372] which focuses on achieving the best outcomes and safest care across the full care journey through innovation and collaboration. We are implementing meaningful improvements designed to strengthen healthcare delivery and advance patient outcomes. Through these efforts, we strive to create a healthcare system that not only responds to chronic disease but works proactively to prevent it.

In the CY 2022 PFS proposed rule and CY 2025 PFS final rule, we stated our intent to transform MIPS and obtain more meaningful, comparable performance data, and drive higher value care through MVPs (86 FR 39356 and 89 FR 98346) and that we intended to propose a full transition to MVP reporting along with the Alternative Payment Model (APM) Performance Pathway (APP) reporting to support movement towards value-based payment (86 FR 65394 through 65396, 87 FR 70034, and 89 FR 98346). As noted in the CY 2025 PFS proposed rule (89 FR 62012), robust MVP availability and clinician coverage would be a precursor to sunsetting traditional MIPS. Through this proposed rule and future rulemaking, we acknowledge that we will need to develop policies to support MVP reporting for all MIPS eligible clinicians by the CY 2029 performance period/2031 MIPS payment year. We will continue engaging with specialty societies to identify gaps and opportunities, and leveraging additional policy options, as needed.

In this section, we are proposing to phase out traditional MIPS reporting for MIPS eligible clinicians not participating in the APP and are proposing to sunset traditional MIPS reporting beginning with the CY 2029 performance period/2031 MIPS payment year. The MVP reporting option offers aligned measures and activities across quality, cost, improvement activities, and Promoting Interoperability performance categories. MVPs focus on specific specialties, conditions, or patient populations to make reporting more meaningful. With increased MIPS eligible clinicians reporting MVPs, MVP comparative performance data may become valuable to patients and caregivers in evaluating clinician performance and making choices about their care. We are proposing that MIPS eligible clinicians participating in MIPS and not the APP, would be required to report the measures and activities in the selected MVP beginning in the CY 2029 performance period/2031 MIPS payment year. We also propose to include virtual groups in MVP reporting to ensure all MIPS eligible clinicians can report MVPs.

a. Overview

In the CY 2022 PFS final rule, we finalized the MVP reporting option for MIPS eligible clinicians beginning in the CY 2023 performance period/2025 MIPS payment year to serve as an additional reporting option (86 FR 65391 through 65394). Currently there are three reporting options: MVPs, traditional MIPS, and the APP. We noted that we created the MVP reporting pathway to improve value, reduce burden, and inform patient choice in selecting clinicians. We also stated the MVP framework will move MIPS forward on the path to value by offering a reporting option that connects measures and activities across MIPS performance categories, better informing and empowering patients to make decisions about their healthcare, and by helping clinicians to achieve better outcomes using robust and accessible healthcare data and interoperability (86 FR 65392).

We intend to propose to transform MIPS through a full transition to MVP reporting to allow reporting of both MVPs and the APP to support movement towards value-based payment. If the proposal to phase out traditional MIPS reporting for MIPS eligible clinicians not participating in the APP is finalized, there would be two reporting options in the Quality Payment Program: MVPs and the APP. The transition from clinicians selecting from a large inventory of measures and activities in traditional MIPS to reporting more clinically relevant measures and activities in MVPs represents a necessary progression in MIPS if we are to achieve our intended goals of connecting measures and activities across MIPS and providing meaningful data to inform and empower patients to make decisions about their healthcare. We introduced the MVP reporting pathway in the CY 2020 PFS final rule (84 FR 62946). In the CY 2021 PFS final rule, we established MVP Guiding Principles (85 FR 84845 through 84849). In the CY 2022 PFS final rule, we finalized that MVP scoring policies would align with traditional MIPS unless exceptions were noted (86 FR 65419 through 65422). In the CY 2022 PFS proposed rule, we requested feedback on the potential sunset of traditional MIPS as a reporting option beginning with the CY 2028 performance period/2030 MIPS payment year (86 FR 65396). In the CY 2023 PFS final rule, we indicated our intention that MVPs would be the only pathway for participation in MIPS in the future (87 FR 70035). We have made continued and substantial progress in developing an MVP inventory offering clinicians the ability to report an MVP with clinically relevant measures. As discussed in section IV.A.4.a.(1) of this proposed rule, we previously finalized 27 MVPs and are proposing three additional MVPs for the CY 2027 performance period/2029 MIPS payment year. If the three newly proposed MVPs are finalized, our MVP inventory would increase to 30, potentially resulting in coverage of approximately 98 percent of specialties for MIPS eligible clinicians based upon self-reported specialty designations data and MVP topic. Please see section IV.A.4.a.(1) of this proposed rule for more information on MVP development. Phasing out traditional MIPS reporting and full implementation of MVPs for MIPS eligible clinicians not participating in the APP will move MIPS away from a fragmented reporting approach toward a more meaningful, specialty-aligned framework. Further, MVPs will continue to advance the overall goals of the Quality Payment Program of aligning quality and payment, fostering accountability, and improving care and outcomes for people served by Medicare.

b. Background on Full MVP Implementation

The MVP framework was introduced in the CY 2020 PFS final rule (84 FR 62946 through 62948). In the CY 2022 PFS proposed rule, we noted our intent to sunset traditional MIPS in a future performance period and solicited public comments on: 1) the length of time MVP reporting should be voluntary; 2) the timing for when we should fully implement MVPs; and 3) sunsetting the traditional MIPS reporting option (86 FR 39356). Responding interested parties

[372] *https://www.cms.gov/medicare/quality/meaningful-measures-initiative/cms-quality-strategy.*

supported MVP goals and a transparent, gradual transition to MVPs with voluntary MVP reporting, with adequate time to prepare for reporting an MVP (86 FR 65391 through 65396). In the CY 2022 PFS final rule, we finalized that voluntary reporting of MVPs would start in the CY 2023 performance period/2025 MIPS payment year. Additionally, we stated that we considered input from interested parties who encouraged implementation of MVPs through a gradual process that allows MVP participants and third-party intermediaries time to adapt to changes in policy, requirements, and programming updates that would need to occur in technology systems (86 FR 65394 to 65396).

In the CY 2025 PFS proposed rule, we issued a Request for Information (RFI) on the development of a timeline for the full transition to MVPs. We sought feedback on clinician readiness for MVP reporting and MIPS policies needed to sunset traditional MIPS to allow for full MVP implementation in the CY 2029 performance period/2031 MIPS payment year (89 FR 62011 and 62012). We noted full implementation of MVPs represents an evolution in MIPS towards value-based payment using meaningful sets of measures and activities reported by clinicians, including specialists. We stated MVPs would reduce the complexity of reporting burden associated with MIPS inventory of measures and activities through a targeted set of measures and activities that relate to specialties or conditions, aligning quality and cost measures, improvement activities, and a foundational layer of Promoting Interoperability measures and population health measures. We also noted that full implementation of MVPs would allow for closer comparisons of the performance of clinicians within the same specialty submitting an MVP and would provide improved data for patients.

In response to the RFIs that sought feedback on full MVP implementation, interested parties provided many comments regarding activities and policies that may support full MVP adoption. One key concern they noted was the limited ability of clinicians to choose the quality measures to report within an MVP. We recognize that full MVP implementation may limit the choice of measures and activities compared to those currently afforded by policies in traditional MIPS. However, MVPs include a set of clinically relevant measures and activities that provide an opportunity for MIPS performance data to better reflect clinicians' scope of care.

With the full implementation of MVPs, clinicians not reporting the APP would be able to select an MVP relevant to their scope of care and further choose the quality measures and improvement activities within the selected MVP that reflect the care provided. Widescale adoption of MVPs, using a standardized connected set of measures and activities for a specialty or medical condition, may generate important and meaningful information for patients to be able to compare the performance of clinicians on the same or similar sets of measures. Additionally, we refer readers to section IV.A.4.d.(1)(c)(i) of this proposed rule for details on the proposed MIPS core measure requirement for traditional MIPS and MVP reporting. The proposed MIPS core measure requirement would further clarify how MVPs would emphasize and increase reporting on select quality measures that are most important to clinicians and patients and reflect the care that is central to an applicable specialty, medical condition, or episode of care. Interested parties indicated that full implementation of MVPs requires the ability of all specialties to participate. In the CY 2026 PFS final rule, we finalized six new MVPs and updated 21 previously finalized MVPs. MVPs were developed and added to create a comprehensive inventory based on MVP clinical issues and targeted specialties/subspecialties (90 FR 49847). We refer readers to section IV.A.4.a.(1) of this proposed rule regarding the three new proposed MVPs for the CY 2027 performance period/2029 MIPS payment year.

In response to the RFIs that sought feedback on full MVP implementation (89 FR 62011 through 62016), some interested parties voiced concerns that full implementation of MVPs and subgroup policies would result in increased reporting burden. The commenters also expressed concern about the subgroup reporting requirement for multispecialty groups reporting an MVP beginning in the CY 2026 performance period/2028 MIPS payment year. As further discussed in this paragraph, we have modified our MVP and subgroup reporting policies to address some of these concerns. Our current MVP and subgroup reporting policies are aligned with the goal for full MVP implementation and would encourage increased participation from specialists. As we have greater MVP adoption and subgroup reporting, we anticipate specialist reporting through MVPs would increase the amount of performance data available to patients when selecting a clinician (89 FR 62012). In the CY 2022 PFS final rule (86 FR 65397), we finalized the subgroup reporting option for clinicians participating in MVP reporting. We noted that the intent of the subgroup reporting policies is to move away from large multispecialty groups reporting on the same set of measures, which may not be relevant or meaningful to all specialists that participate within a multispecialty group. In addition, subgroup reporting addresses feedback from interested parties over the prior years that large multispecialty groups tend to submit data that is not necessarily representative of all the clinicians that make up that group. To address concerns from interested parties on the MVP subgroup reporting burden, we finalized policies in the CY 2026 PFS final rule (90 FR 49842 through 49846) allowing a group practice to self-attest and identify the need to divide into subgroups based on the scope of care provided by clinicians in their group. We will continue to monitor subgroup participation in MVP reporting to determine potential policy changes in the future as we transition to full MVP implementation for MIPS eligible clinicians not participating in the APP.

Historically, we have received feedback from MIPS eligible clinicians in small group practices, defined at § 414.1305 as a TIN consisting of 15 or fewer eligible clinicians during the MIPS determination period, about the lack of adequate resources to successfully meet MIPS reporting requirements. To provide flexibility and to prevent additional burden for small groups we finalized a policy to maintain the MVP group reporting option for small practices, without the need for small practices to form subgroups (90 FR 49842 to 49843). We also note that MVP policies continue to offer the same scoring flexibilities for small group practices available to small group practices reporting traditional MIPS finalized at § 414.1380(b)(1) (86 FR 65419 through 65422). We refer readers to sections IV.A.4.d.(1)(c)(iii)(C) and IV.B.1.b.(2) of this proposed rule for details on the proposed exemption of small practices from the MIPS core measure reporting requirements and proposed scoring flexibilities for small practices.

Additionally, we will continue to monitor the subgroup reporting burden of larger group practices to determine if additional flexibilities are needed in the future for multispecialty groups that are not small practices to participate as subgroups. We believe the potential increase in the reporting burden for larger groups to divide into subgroups is outweighed by the benefit of additional

information clinicians and patients will receive through increased specialist reporting data (86 FR 65393 and 65394).

Finally, interested parties were interested in how scoring rules may work with full MVP implementation for clinicians with limited measure choices. MVP scoring policies, which rely on traditional MIPS scoring policies finalized at § 414.1380(b)(1), were established in the CY 2023 PFS final rule. More recently, in response to the RFI (89 FR 62011 through 62016) interested party feedback voiced concerns about quality measures within MVPs that cannot be scored for reasons beyond the clinician's control, such as measures without benchmarks, and the potential for some topped out measures to have a scoring cap. As noted previously, the existing scoring policies established in traditional MIPS specific to small group practices and the scoring policies related to measures without benchmarks, measures that do not meet case minimum, and measures that do not meet data completeness requirements also apply to MVP scoring (86 FR 65419 through 65420). We acknowledge concerns from clinicians with limited choice of measures and, in the CY 2026 PFS final rule, we finalized expansion of our approach for identifying measures impacted by limited choice and subject to topped-out measure benchmarks would extend to MVPs (90 FR 49903 through 49908). Additionally, we refer readers to section IV.B.1.b.(3) of this proposed rule for proposals on the scoring of topped out measures included in MVPs, to address concerns that interested parties raised with respect to those clinicians with limited measure choice and scoring caps for topped out measures. We will continue to evaluate the performance of clinicians impacted by limited measure choice as the program evolves and may refine the topped out scoring policies as needed in the future. Commenters responding to the RFI also requested that we develop scoring policies to ensure scoring between MVPs is equitable. We agree that ensuring scoring between MVPs is equitable is an important goal of MVP reporting. Therefore, we have solicited feedback on the future direction of MVP scoring in an RFI in section IV.B.1.e. of this proposed rule.

c. Proposal To Update Timeline for Full MVP Implementation

As discussed previously in section IV.A.3.a. of this proposed rule, MVP reporting became available for clinicians beginning in the CY 2023 performance period/2025 MIPS payment year (86 FR 65394 to 65396). In previous PFS rules, we have stated our intention to fully transition to MVPs and to sunset traditional MIPS (85 FR 50279 and 50284, 86 FR 65394 through 65396). We are concerned that continuing to maintain the traditional MIPS reporting option may impede MVP adoption for eligible clinicians. Additionally, it may cause slow adoption which may delay the intended benefits of MVPs, including simplification of MIPS and improving comparable clinician performance data that helps to drive value and inform clinician selection by patients. In addition, the availability of two MIPS reporting options, MVPs and traditional MIPS, creates challenges for developing and refining MVP policies over time due to limited MVP reporting resulting from continued clinician reliance on the traditional MIPS reporting option. However, in establishing the sunset date we are also cognizant of the need to provide ample time for clinicians to prepare for full MVP reporting. Therefore, we propose to phase out traditional MIPS reporting for MIPS eligible clinicians not participating in the APP beginning in the CY 2029 performance year/2031 MIPS payment year. Transitioning to MVP implementation alongside the option to participate through the APP would support efforts to transform MIPS for clinicians and patients who rely on program performance information. We note that traditional MIPS reporting will be available to clinicians through the CY 2028 performance period/2030 MIPS payment year. This proposed timeline will have provided a period of 6 years for voluntary MVP reporting, allowing clinicians time to engage in the development of the MVP inventory, update their systems and work processes to prepare for MVP reporting, and gain experience with MVP reporting. Clinicians would continue to be able to report through either traditional MIPS or via MVPs through the CY 2028 performance year/2030 MIPS payment year.

We currently believe that the CY 2029 performance year/2031 MIPS payment year would be an appropriate timeline for full implementation of MVPs. Since the current and proposed inventory of MVPs listed in section Appendix 2 of this proposed rule offers the opportunity for approximately 98 percent of MIPS eligible clinicians based on self-reported specialty designations and MVP topic to report through an MVP, we anticipate that nearly all MIPS eligible clinicians will be able to choose an applicable MVP. As discussed in section IV.A.4.a.(1) of this proposed rule, we continue developing new MVPs that are relevant and meaningful for MIPS eligible clinicians. We intend to explore a range of strategies for transitioning to full MVP reporting, including, but not limited to, proposing additional MVPs. We recognize that clinicians may currently lack applicable measures and may not have an applicable MVP or may be unable to report a sufficient number of measures in an MVP. However, for subspecialists without many applicable and available measures in the MIPS measure inventory, we are on track to developing reporting options or exploring alternatives to reporting MVPs by CY 2029. For example, we could consider developing a process for clinicians to indicate at the time of MVP registration that no available MVP in the MVP inventory includes applicable and available measures and activities. Alternatively, we could consider expanding measure denominators as applicable to strengthen specialty coverage for clinicians with limited applicable measures. We could also consider policies that allow us to review available and applicable measures for clinicians in the selected MVP to reduce the denominator of the quality performance category to score the quality performance category with fewer than four measures. Delaying the timeline for full implementation of MVPs would not result in a significantly greater availability of MVPs for the remaining specialists who currently lack applicable measures, since the MVPs are built on the measures and activities available in the current traditional MIPS measure inventory. With the majority of specialists having available MVPs, policies for clinicians with few quality measures, and 6 years of availability of MVPs we believe we should move forward with full implementation of MVPs.

Beginning in the CY 2029 performance period/2031 MIPS payment year, we propose that all MIPS eligible clinicians, with the exception of clinicians reporting through the APP, would report through an MVP. Specifically, we propose to add under § 414.1365(a)(2) that beginning in the CY 2029 performance period/2031 MIPS payment year, except for clinicians reporting under the APM performance pathway pursuant to § 414.1367, all MIPS eligible clinicians must report through an MVP.

We request public comment on this proposal.

d. Proposal to Include Virtual Groups in MVP Reporting

Section 1848(q)(5)(I) of the Act establishes the use of voluntary virtual

groups for certain assessment purposes. The statute requires the establishment and implementation of a process that allows an individual MIPS eligible clinician or a group consisting of not more than 10 MIPS eligible clinicians to elect to form a virtual group with at least one other such individual MIPS eligible clinician for a performance period. As determined in statute, individual MIPS eligible clinicians and groups forming virtual groups are required to make such election prior to the start of the applicable performance period under MIPS and cannot change their election during the performance period.

In the CY 2022 PFS final rule (86 FR 65394), we finalized a delay in the availability of MVP reporting for virtual groups. We noted that there are several considerations, such as implementation burden for interested parties and us, value of MVP reporting for these clinicians versus burden, scoring policies, and other issues that must be addressed prior to allowing clinicians in virtual groups to participate in MVP reporting. Therefore, we did not include virtual groups in the previously finalized definition of an MVP participant at § 414.1305 (86 FR 65392 through 65394). However, to comply with the statute, full implementation of MVPs must include a pathway for virtual groups to participate. For this reason, we propose to allow virtual groups to participate in MVP reporting beginning in the CY 2029 performance period/2031 MIPS payment year, aligning with the proposed timeline for full MVP implementation in section IV.A.3.c. of this proposed rule. This approach would allow time for us to further refine participation criteria and address potential barriers for virtual groups to participate in MVP reporting.

To include virtual groups in MVP reporting, we propose to revise the definition of an MVP participant at § 414.1305 to provide that, beginning in the CY 2029 performance period/2031 MIPS payment year, MVP participant means an individual MIPS eligible clinician, single specialty group, multispecialty group that meets the requirements of a small practice, virtual group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. As we update the definition of an MVP participant to include virtual groups, we are interested in feedback from virtual groups about any concerns they have regarding MVP reporting.

We considered including virtual groups in MVP reporting beginning in the CY 2028 performance period/2030 MIPS payment year. We recognize that we would need to evaluate additional related policies before including virtual groups in MVP reporting. Under the current policy at § 414.1365(b), MVP participants must register during the performance period. We recognize that the inclusion of virtual groups in MVP reporting would therefore require these groups to register for MVP reporting, which would be an addition to the existing registration requirement to form a virtual group prior to the performance period. We are exploring options to mitigate the need for virtual groups to register a second time for MVP reporting. Additionally, we note that even with the proposed inclusion of virtual groups in MVP reporting, clinicians in virtual groups would be unable to participate as subgroups because the definition of a subgroup at § 414.1305 is limited to clinicians within a single TIN and therefore excludes virtual groups, which, by definition, are composed of clinicians across two or more TINs. Under § 414.1305, a subgroup is a subset of a group that includes at least one MIPS eligible clinician and is identified by the group TIN, a subgroup identifier, and each eligible clinician's NPI.

We request public comment on this proposal.

4. QPP Reporting and Data Submission

a. CY 2027 MVP Development and Maintenance

(1) Development of New MIPS Value Pathways (MVPs)

The development of MVPs is informed by the framework established in prior rulemaking (85 FR 84849 through 84856). In the CY 2023 PFS final rule (87 FR 70035 through 70037), we expanded the MVP development process to provide interested parties more opportunities to submit feedback on new candidate MVPs prior to the notice and comment rulemaking process. Consistent with these policies, we posted three MVP candidates for interested parties to review and provide feedback for consideration in this proposed rule. We refer readers to the Quality Payment Program website to review public feedback for each 2027 MVP candidate (*https://qpp.cms.gov/mips/candidate-feedback*).

In alignment with the MVP development process (85 FR 84849 through 84856; 87 FR 70035 through 70037) and feedback received from interested parties, we are proposing to adopt three new MVPs:

- Diabetic Disease;
- Hospitalist; and
- Hypertension.

We aim to continue developing new MVPs that are relevant and meaningful for MIPS eligible clinicians. The Diabetic Disease and Hypertension MVPs are specifically designed to address the prevention of chronic illnesses by including measures and activities aimed at reducing the incidence and impact of long-term conditions. Disease-specific MVPs allow for more targeted interventions, improved measurement accuracy, and support clinicians in delivering evidence-based care for high-risk populations. We refer readers to Appendix 3: MVP Inventory, in this proposed rule for a detailed description of each proposed new MVP.

We continue to encourage interested parties to utilize our established pre-rulemaking processes to develop and submit candidate quality and cost measures relevant to their specialty. Furthermore, we continue to develop MVPs based on needs and priorities, as described in the MVP Needs and Priorities document (*https://qpp-cm-prod-content.s3.amazonaws.com/uploads/1803/MIPS%20Value%20Pathways%20(MVPs)%20Development%20Resources.zip*).

(2) MVP Maintenance Updates to Previously Finalized MVPs

Beginning with the CY 2022 PFS final rule (86 FR 65998 through 66031) and continuing through the CY 2026 PFS final rule (90 FR 50376 through 50405), we have expanded the MVP inventory to include the following 27 MVPs:

- Adopting Best Practices and Promoting Patient Safety within Emergency Medicine;
- Advancing Cancer Care;
- Advancing Care for Heart Disease;
- Advancing Rheumatology Patient Care;
- Complete Ophthalmologic Care;
- Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes;
- Dermatological Care;
- Diagnostic Radiology;
- Focusing on Women's Health;
- Gastroenterology Care;
- Improving Care for Lower Extremity Joint Repair;
- Interventional Radiology;
- Neuropsychology;
- Optimizing Chronic Disease Management;
- Optimal Care for Kidney Health;
- Pathology;
- Patient Safety and Support of Positive Experiences with Anesthesia;
- Podiatry; and
- Prevention and Treatment of Infectious Disorders Including

Hepatitis C and Human Immunodeficiency Virus (HIV);
- Pulmonology Care;
- Quality Care for Patients with Neurological Conditions MVP;
- Quality Care for the Treatment of Ear, Nose, and Throat Disorders;
- Quality Care in Mental Health and Substance Use Disorder; and
- Rehabilitative Support for Musculoskeletal Care;
- Surgical Care;
- Value in Primary Care; and
- Vascular Surgery.

In this proposed rule, we are proposing modifications to 23 previously finalized MVPs with the addition and removal of measures and improvement activities based on the MVP development criteria (85 FR 84849 through 84854). Through these modifications, we can expand upon clinical concepts, advance health and wellness, address maintenance requests from interested parties, and remove measures and activities that would either be replaced by more robust measures or activities or are being proposed for removal from their respective MIPS inventory. We are also proposing to rename the Rehabilitative Support for Musculoskeletal Care MVP to Rehabilitative Support MVP to better reflect the measures and activities it includes.

Additionally, we are proposing modifications to all 27 previously finalized MVPs in alignment with the proposed implementation of MIPS core measures. In section IV.A.4.d.(1) of this proposed rule, we propose modifications to the current MVP quality reporting requirements at § 414.1365 to replace the current requirement for an outcome/high priority measure with one MIPS core measure included in the MVP. We revised the format of the MVP tables in Appendix 3: MVP Inventory of this proposed rule to include MIPS core measures for each previously finalized MVP. We also added a MIPS core measure table to the newly proposed MVPs. We refer readers to sections IV.A.4.d.(1) and IV.B.1.b. of this proposed rule where we discuss the proposed policies for MIPS core measures.

We refer readers to Appendix 3: MVP Inventory of this proposed rule for the proposed modifications and detailed descriptions to the previously finalized MVPs and the newly proposed MVPs.

We request public comment on these proposals.

b. APM Performance Pathway (APP)

(1) Overview

In the CY 2021 PFS final rule (85 FR 84859 through 84866), we finalized the APM Performance Pathway (APP) at § 414.1367 beginning with the CY 2021 performance period/CY 2023 MIPS payment year. The APP was designed as a reporting and scoring pathway available only to MIPS eligible clinicians identified on the Participation List or Affiliated Practitioner List of an APM Entity participating in a MIPS APM as defined in § 414.1305 (MIPS APM participants) (§ 414.1367(a)). The APP provides a predictable and consistent MIPS reporting option to reduce reporting burden for, and encourage continued APM participation by, these clinicians. We also established in the APP for Shared Savings Program ACOs providing that, beginning with the Shared Savings Program performance year 2021 (CY 2021 performance period/CY 2023 MIPS payment year), ACOs were required to report quality data for purposes of the Shared Savings Program via the APP (42 CFR 425.512(a)(3); 85 FR 84722).

In that same rule, we finalized a quality measure set (85 FR 84860 and 84861) for purposes of quality performance category scoring for the APP. For those MIPS eligible clinicians, groups, or APM Entities for whom a given measure is unavailable due to the size of the available patient population or who are otherwise unable to meet the minimum case threshold for a measure, we established that such measure would be removed from the quality performance category score for such MIPS eligible clinician, group, or APM Entity (85 FR 84861).

In the CY 2025 PFS final rule (89 FR 98562), we finalized a second, optional quality measure set within the APP, called the APP Plus quality measure set, to align with the Universal Foundation measure set. The measure set for CY 2026 performance year includes the current APP quality measures and two additional quality measures from the Adult Universal Foundation measure set. As discussed in the CY 2025 PFS final rule, we intended to incrementally add the remaining three Adult Universal Foundation measures by the CY 2028 performance period/2030 MIPS payment year. We also finalized a 1-year delay to the CY 2026 performance year/CY 2027 MIPS payment year in the incorporation of the Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (Quality ID: 484) measure.

Further, for MIPS eligible clinicians, groups, and APM Entities reporting through the APP, we established in the CY 2021 PFS final rule (85 FR 84907) that we would not apply the quality measure scoring cap at § 414.1380(b)(1)(iv) in the event that a measure in the APP quality measure set is determined to be topped out. Because the APP quality measure set is fixed, we noted that it would not be appropriate to limit the maximum quality performance category score available to APP reporters. Should an APP quality measure be determined to be topped out, we would at that time consider amending the APP quality measure set through future rulemaking, if appropriate.

In the CY 2024 PFS final rule (88 FR 79329), we established the Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs) collection type in the APP quality measure set and finalized that the Medicare CQMs collection type would be available to only ACOs participating in the Shared Savings Program.

In the CY 2026 PFS final rule (90 FR 49849 through 49856) we updated quality measures in the original quality measure set and the APP Plus quality measure set, to reflect measures updates specified for the quality performance category.

(2) Updates to Quality Measures in the APP and APP Plus Quality Measure Set

In the CY 2021 PFS final rule, we adopted the original APP quality measure set (85 FR 84860 and 84861). In the CY 2025 PFS final rule, we finalized a phased approach to establish the APP Plus quality measure set over 4 years (89 FR 62024), including by incorporating into the APP Plus quality measure set the measures from the original APP quality measure set.

In the CY 2025 PFS final rule, we finalized a phased approach to establish the APP Plus quality measure set over 4 years (89 FR 62024). As finalized, the APP Plus quality measure set consisted of all the measures that were within the APP quality measure set (five Adult Universal Foundation measures and a separate quality measure) plus one additional measure from the Adult Universal Foundation measure set, with the intention of incrementally incorporating the remaining measures from the Adult Universal Foundation measure set by the CY 2028 performance year/CY 2030 MIPS payment year. We finalized this incremental approach in part to allow for both the eCQM and, for Shared

Savings Program ACOs, Medicare CQMs collection types to be developed and become available.

Because the APP is a feature within MIPS and therefore the quality measures used within the APP and APP Plus quality measure sets are all MIPS measures, any proposed updates we apply to MIPS measures also are incorporated into the APP and APP Plus quality measure sets, and proposed here accordingly. As discussed in Table Group D, in Appendix 1, of this proposed rule, we are proposing to adopt measure specification changes to the following measures that are part of the APP and APP Plus quality measure sets:

- *Diabetes:* Glycemic Status Assessment Greater Than 9% (Quality ID: 001) (eCQMs collection type)
- *Preventive Care and Screening*: Screening for Depression and Follow-up Plan (Quality ID: 134)
- Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups (Quality ID: 479)

In addition, we are proposing the removal of the following measures that, under the policies finalized in the CY 2025 PFS final rule (89 FR 98369 through 98371) are scheduled to be added to the APP Plus quality measure set for the CY 2027 performance period and for the CY 2028 performance period or the performance period that is 1 year after the eCQM specification becomes available, whichever is later, respectively:

- Initiation and Engagement of Alcohol and Other Drug Dependence Treatment measures (Quality ID: 305)
- Adult Immunization Status (Quality ID: 493)

We are proposing the removal of these two measures from the APP Plus quality measure set due to operational issues impacting the development of the collection types that were finalized in the CY 2025 PFS final rule for these two measures. Our proposal would address concerns expressed by ACOs with increasing the number of measures in the APP Plus quality measure set each year. ACOs have suggested maintaining a stable measure set as they transition to digital quality measurement. In the CY 2026 PFS dQM RFI, many commenters recommended that we maintain the APP Plus quality measure set as finalized without adding new measures to preserve resources for the transition to digital quality measurement and to consider challenges ACOs face in data aggregations for eCQM/MIPS CQM/Medicare CQM reporting (90 FR 49856).

These changes have been reflected in Tables C–BC2. Table C–BC2 also reflects the proposed creation of the new Medicare eCQMs collection type for Shared Savings Program ACOs reporting the APP Plus Quality measure set for performance year 2027 and subsequent performance years, as discussed in section XXX and Table Group D and DD, in Appendix 1, of this proposed rule.

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TABLE C-BC1: APM PERFORMANCE PATHWAY QUALITY MEASURE SET BEGINNING WITH THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR AND SUBSEQUENT PERFORMANCE PERIODS/MIPS PAYMENT YEARS

#	Measure Title	Collection Type	Submitter Type	Measure Type
001	Diabetes: Glycemic Status Assessment Greater Than 9%	eCQM/MIPS CQM/Part B Claims (all APP reporters)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Intermediate Outcome
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient Engagement/ Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Outcome

TABLE C-BC2: APP PLUS QUALITY MEASURE SET FOR THE CY 2027 PERFORMANCE PERIOD/CY 2029 MIPS PAYMENT YEAR AND SUBSEQUENT PERFORMANCE PERIODS/MIPS PAYMENT YEARS

QUALITY #	MEASURE TITLE	COLLECTION TYPE	SUBMITTER TYPE	MEASURE TYPE
001	Diabetes: Glycemic Status Assessment Greater Than 9%	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM/Medicare eCQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Intermediate Outcome
112	Breast Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM/Medicare eCQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Process
113	Colorectal Cancer Screening	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM /Medicare eCQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Process
134	Preventive Care and Screening: Screening for Depression and Follow-up Plan	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM/Medicare eCQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Process
236	Controlling High Blood Pressure	eCQM/MIPS CQM/Part B Claims (all APP reporters) Medicare CQM/Medicare eCQM (SSP ACOs only)	MIPS Eligible Clinician Representative of a Practice APM Entity Third Party Intermediary	Intermediate Outcome
321	CAHPS for MIPS	CAHPS for MIPS Survey	Third Party Intermediary	Patient Engagement/Experience
479	Hospital-Wide, 30-day, All-Cause Unplanned Readmission (HWR) Rate for MIPS Eligible Clinician Groups	Administrative Claims	N/A	Outcome
484	Clinician and Clinician Group Risk-standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions	Administrative Claims	N/A	Outcome

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c. Fast Healthcare Interoperability Resources®-Based Digital Quality Measurement in the Quality Payment Program and Other CMS Quality Programs—Request for Information

(1) Background

We are advancing quality measurement by transitioning existing quality measures and reporting processes to Fast Healthcare Interoperability Resources® (FHIR®)-based digital approaches. Digital quality measures [1] (dQMs) use standardized, interoperable digital data from multiple sources, including electronic health records (EHRs), to enable more comprehensive and timely assessment of care while reducing reporting burden. We continue to collaborate with Federal partners to advance health information technology and digital quality measurement policy, interoperability standards, and quality measurement infrastructure to support the transition to FHIR-based digital quality reporting. The establishment of the United States Core Data for Interoperability (USCDI)+ Quality Version 1 (V1), which identifies a common set of quality-related data elements to support more consistent and reusable data for quality measurement across programs, was released in 2026.[2] FHIR-based implementation guides and tools are also being developed to enable end-to-end FHIR-based digital quality measurement.[3] The 2026 US Quality Core Implementation Guide version 0.5.0 provides guidance for implementing USCDI+ Quality in FHIR to support consistent, interoperable

[1] Read more about the dQM transition in the Electronic Clinical Quality Improvement (eCQI) Resource Center here: *https://ecqi.healthit.gov/dqm/about-dqms.*

[2] Additional information on USCDI+ Quality Version 1, including the list of quality data elements and related implementation materials, is available at *https://uscdiplus.healthit.gov/uscdiplus?id=uscdi_record&table=x_g_sshh_uscdi_domain&sys_id=7ddf78228745b95098e5edb90cbb3525&view=sp#:~:text=of%20quality%20measures.-,Quality%20V1,-The%20USCDI%2B%20Quality.* The January 2026 announcement of the release of USCDI+ Quality Version 1 is available at *https://uscdiplus.healthit.gov/uscdiplus/en/announcing-the-release-of-uscdi-quality-version-1-january-2026?id=kb_article&table=kb_knowledge&sys_id=9ee9383c87f6fe108edc42e50cbb350b.*

[3] For example, see the eCQI Resource Center description of the FHIR Quality Measure Implementation Guide at *https://ecqi.healthit.gov/tool/hl7-quality-measure-ig.*

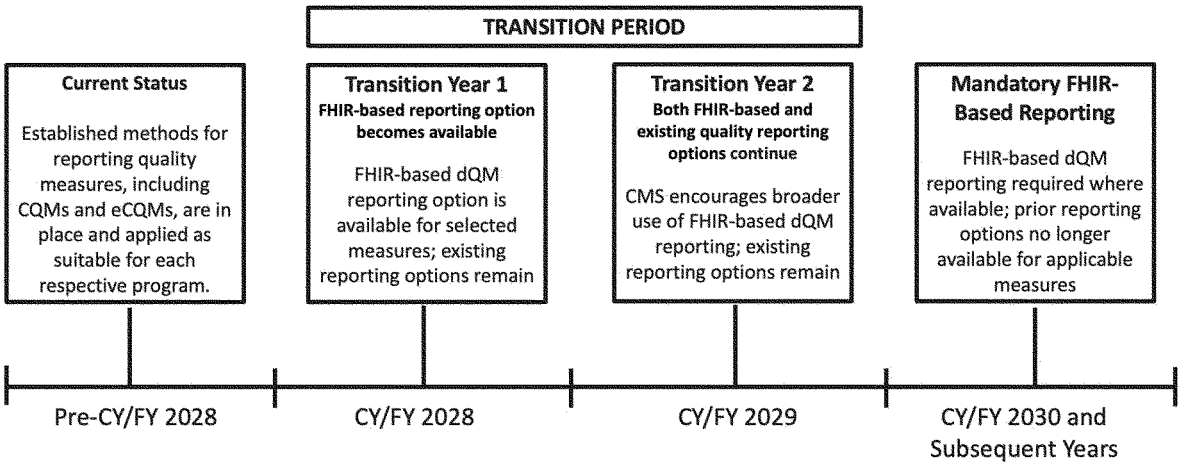
representation and exchange of quality data for quality measurement and reporting programs.[4] The Data Exchange for Quality Measures (DEQM) FHIR implementation guide provides guidance on how FHIR-based quality data can be reported and exchanged between providers, intermediaries, and payers.[5] Also available is the Measure Authoring Development Integrated Environment (MADiE), a software tool that enables creation and testing of eCQMs and FHIR-based dQMs within a single application, supporting modernized CMS quality measurement and reporting workflows.[6] Finally, the FHIR dQM specifications are also available.[7] Collectively, these developments are intended to provide a foundation for FHIR-based digital quality measurement and reporting. To further these goals, we seek public comment on the timeline for transitioning to FHIR-based quality measurement.

(2) Transition to FHIR-Based Quality Measurement in the Quality Payment Program and Other CMS Clinician and Hospital Quality Programs

The Quality Payment Program and other CMS clinician and hospital quality programs use clinical quality measures (CQMs) and electronic clinical quality measures (eCQMs), with current eCQM reporting supported through Quality Reporting Document Architecture (QRDA) files. We previously sought input on dQMs, including eCQMs, and FHIR-based quality measurement and reporting in multiple Medicare payment rules[8] and now seek input on a transition timeline, key milestones, and implementation considerations for FHIR-based quality reporting in the Quality Payment Program and other CMS clinician and hospital quality programs.

Subject to future notice and comment rulemaking, we are developing a phased transition to FHIR-based digital quality reporting for applicable measures that balances modernization goals with practical implementation considerations. Under this approach, for example, in the Quality Payment Program, we would introduce a 2-year transition period beginning with the CY 2028 performance period/2030 MIPS payment year during which existing quality collection types for CQMs and eCQMs, including eCQM reporting via QRDA files, would continue to be available while FHIR-based dQM options are introduced for selected measures, including both new and existing measures. Following this transition period, FHIR-based reporting would be required for those applicable measures that were available as FHIR-based dQM collection types during the transition period, beginning with the CY 2030 performance period/2032 MIPS payment year. An example of this timeline is illustrated in Figure C–C1.

Figure C-C1: TIMELINE FOR TRANSITION TO FHIR-BASED QUALITY REPORTING IN CMS QUALITY REPORTING PROGRAMS*



*We note that more specific adoption timelines may vary by measure and program based on feasibility, implementation complexity, and readiness of interested parties. Existing quality collection types for CQMs and eCQMs may include the following, as applicable by program: MIPS CQMs, Medicare CQMs, eCQM reporting via QRDA files, and proposed Medicare eCQMs. An additional timeline, titled "Transition Timeline for FHIR-based Digital Quality Measurement and Reporting," is also available on the QPP Resource Library at for more context.

We anticipate that the transition would begin with a limited set of measures for which FHIR-based digital specifications are available initially and would expand over time as technical infrastructure and implementation

[4] See the eCQI Resource Center description of the US Quality Core Implementation Guide (*https://ecqi.healthit.gov/qi-core/about*) and version 0.5.0 of the 2026 US Quality Core Implementation Guide (*http://fhir.org/guides/onc/us-quality-core/ImplementationGuide/fhir.onc.us-quality-core*).

[5] Additional information about the DEQM implementation guide is available at the eCQI Resource Center description: *https://ecqi.healthit.gov/tool/deqm-ig.*

[6] Additional information on MADiE is available at *https://www.emeasuretool.cms.gov/.*

[7] See *CMS https://ecqi.healthit.gov/sites/default/files/CMSdQMStrategicRoadmap_032822.pdfdigital* quality measurement specifications at .

[8] We have previously issued RFIs on digital quality measurement and FHIR-based reporting in multiple Medicare payment rules, including several Physician Fee Schedule (PFS) rules, such as CY 2022 PFS final rule (86 FR 65377 through 65382), CY 2023 PFS proposed rule (87 FR 46259 through 46262), and CY 2026 PFS final rule (90 FR 49855 through 49856). Additional requests for comment include the Health Technology Ecosystem RFI (90 FR 21034) and the Public Comment Period for Draft CMS FHIR® Digital Quality Measures (dQMs) request for comment available at*https://ecqi.healthit.gov/now-open-public-comment-period-draft-cms-fhir%C2%AE-digital-quality-measures-dqms.*

experience grow. Specific timelines for adopting FHIR-based digital quality reporting may need to vary by measure and program based on feasibility, implementation complexity, and program-specific requirements or reporting structures. We recognize that clear expectations and sufficient lead time are essential for successful implementation. Program-specific considerations for the Medicare Shared Savings Program (Shared Savings Program) are discussed in section IV.A.4.c.(3). In addition, we note that CMS Innovation Center models may have separate requirements and timelines related to FHIR-based digital quality measurement and reporting. We recognize resource constraints, and reporting burden may differ significantly for solo practitioners, small practices and provider facilities, and other practices and provider facilities in rural or underserved areas, and that these differences may warrant additional flexibilities or support.

TABLE C-C1: IMPLEMENTATION TIMELINE AND MILESTONES FOR TRANSITION TO FHIR-BASED DIGITAL QUALITY MEASUREMENT

Phase	Timeframe	Implementation Focus
Transition Period with FHIR-Based Reporting Options (Year 1)	CY and FY 2028*	Initial availability of FHIR-based digital quality measure (dQM) reporting option for selected measures, while existing quality reporting options for clinical quality measures (CQMs) and electronic clinical quality measures (eCQMs)** remain available for applicable measures and programs.
Transition Period with FHIR-Based Reporting Options (Year 2)	CY and FY 2029*	Continued availability of FHIR-based dQM reporting options for selected measures alongside existing quality reporting options for CQMs and eCQMs**, with CMS encouraging broader use of FHIR-based reporting.
Mandatory FHIR-Based Reporting	CY and FY 2030 and subsequent years*	FHIR-based dQM reporting required for measures that have been transitioned to FHIR-based digital quality specifications, with prior CQM and eCQM reporting options no longer available for those transitioned measures. Existing CQM and eCQM reporting options** would continue to be available for measures that have not yet transitioned to FHIR-based dQM reporting, as applicable under program-specific policies.

*Timeframes shown may correspond to performance periods, program years, reporting periods, or other CMS quality program-specific timeframes, as applicable. For example, CMS quality programs operate under both timings including CY and FY.

**Existing quality collection types for CQMs and eCQMs may include the following, as applicable by program: MIPS CQMs, Medicare CQMs, eCQM reporting via Quality Reporting Document Architecture (QRDA) files, and proposed Medicare eCQMs.

We invite public comment on the phased timeline, which we anticipate will start with a transition period with FHIR-based reporting options available alongside existing quality reporting options for the CY/FY 2028 and CY/FY 2029 performance periods, respectively. This transition period would then be followed by required FHIR-based reporting for applicable measures beginning with the CY 2030 performance period/2032 MIPS payment year.

- *Transition Approach and Design:* What factors should be considered in determining the structure of the 2-year transition period, during which FHIR-based reporting options and existing electronic quality reporting options for CQMs and eCQMs would be available concurrently? What are the scoring implications that CMS must consider during the transition period, when multiple reporting options are available? How should CMS approach data submission criteria, completeness, and other regulatory elements around quality measurement during the transition period?
- *Factors Affecting Readiness for FHIR-Based Reporting:* How does readiness for adopting FHIR-based quality measurement and reporting vary across different practice types, organizational settings, and supporting health IT entities (for example, EHR vendors, Qualified Clinical Data Registries (QCDRs), qualified registries, and other intermediaries)? What are the primary barriers and facilitators to adoption (for example, access to technology, workforce capacity, resources)? Specifically, what can be done to support technology readiness, testing needs, and measure availability? What strategies, technical assistance, policies, and scoring approaches would be most effective in helping reporting entities transition to FHIR-based reporting? In particular, how do these factors differ for solo practitioners, small practices and provider facilities, and other practices and provider facilities in rural or underserved areas, and what specific types of technical assistance, shared services, or policy flexibilities would be most helpful for these practices to successfully participate in FHIR-based quality reporting? We invite comment on existing clinician capabilities to begin the transition to FHIR-based quality reporting, challenges in using these approaches, and insights from early implementation that may inform future FHIR-based quality reporting activities.
- *General Solicitation of Comments:* We welcome comments on any additional issues, opportunities, or considerations related to the transition to FHIR-based digital quality measurement for the Quality Payment

Program and other CMS clinician and hospital quality programs for topics not specifically addressed earlier in this section.

(3) Additional Considerations for Shared Savings Program Transition to FHIR-Based Quality Measurement

As finalized in the CY 2025 PFS final rule, Shared Savings Program ACOs are required to report the Alternative Payment Model (APM) Performance Pathway (APP) Plus quality measure set beginning with the 2025 performance year (89 FR 98105).

We are seeking input from interested parties, ahead of future policy decisions, on a phased transition to FHIR-based digital quality reporting for applicable measures [9] under which we would introduce a 2-year transition period beginning with the 2028 performance period. During the transition period, existing quality reporting options [10] for Shared Savings Program ACOs would continue to be available while FHIR-based dQM options are introduced for selected measures. For the Shared Savings Program, the transition to FHIR-based dQMs builds upon the existing eCQM reporting infrastructure used for the APP Plus quality measure set (including APP/APP Plus measure alignment and current electronic reporting approaches) while introducing FHIR-based specifications for dQMs and related software tools, such as the Measure Authoring Development Integrated Environment (MADiE), so that Shared Savings Program ACOs would have a feasible pathway to adopt FHIR-based quality measurement. Following this transition period, FHIR-based reporting would be required for those applicable measures that were available as FHIR-based dQM reporting options during the transition period, beginning with the 2030 performance period. For example, Shared Savings Program ACOs would need to be prepared, by the 2030 performance period, to report each applicable APP Plus measure via FHIR-based digital quality reporting where a FHIR-based dQM specification exists for that measure. For APP Plus measures that do not have FHIR-based dQM specifications following the transition period, Shared Savings Program ACOs would continue to use applicable existing reporting mechanisms (for example, MIPS CQMs, Medicare CQMs, eCQM reporting via QRDA files, and proposed Medicare eCQMs) until FHIR-based dQM options are developed and adopted through future rulemaking. We recognize that clear expectations and sufficient lead time are essential for successful implementation, so we are clearly stating our planned timeline to avoid confusion among participants, in particular Shared Savings Program ACOs which, due to their organizational complexity, may require a longer lead time than MIPS reporting clinical groups.

As noted in section III.G.4.b.(2) of this proposed rule, we are also pursuing proposals in the Shared Savings Program to encourage the use of other pathways for using FHIR-enabled capabilities in certified health IT to support quality measurement reporting by ACOs and demonstrate use of CEHRT. This approach would offer another avenue for ACOs to gain experience with supporting quality measurement reporting using FHIR in anticipation of the transition to dQMs.

We invite public feedback on the phased timeline which starts with a 2-year transition period followed by required FHIR-based reporting for applicable measures.

- *Request for Information:* In addition to the questions included in section IV.A.4.of this proposed rule, we request public input on the technical assistance needed by organizations and on whether support and informational needs may differ for entities with more complex reporting environments, such as multi-taxpayer identification number (multi-TIN) ACOs, APM Entities, or providers operating across multiple EHR systems.

d. MIPS Performance Category Measures and Activities

(1) Quality Performance Category

(a) Background

Section 1848(q)(1)(A)(i) and (ii) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, to provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act provides that the Secretary must use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures that must be specified under the quality performance category.

We refer readers to §§ 414.1330 through 414.1340 and the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77097 through 77162 and 82 FR 53626 through 53641, respectively), and the CY 2019 through CY 2026 PFS final rules (83 FR 59754 through 59765, 84 FR 63949 through 62959, 85 FR 84866 through 84877, 86 FR 65431 through 65445, 87 FR 70047 through 70055, 88 FR 79329 through 79338, and 89 FR 98381 through 98390, and 90 FR 49856 through 49859, respectively) for a description of previously established policies and the statutory basis for policies regarding the quality performance category. In this proposed rule, we are proposing to:

- Amend the definition of the term ''collection type'' to include the Medicare Electronic Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs).
- Implement the MIPS core measure designations for quality measures in traditional MIPS and MVPs.
- Remove the high priority designation from MIPS quality measures.
- Remove the high priority designation from quality measure retention consideration.
- Replace the requirement to report a high priority measure with the requirement to report a MIPS core measure; and require an attestation process for cases in which a MIPS core measure is not available and applicable.
- Exempt clinicians in small practices from the MIPS core measure requirement and the attestation process.
- Amend the quality performance category data submission criteria at § 414.1335 and § 414.1365 to require MIPS core measure reporting with an attestation process.
- Amend the data submission criteria for the Medicare CQMs collection type.
- Establish the data submission criteria for the Medicare eCQMs collection type.
- Amend the data completeness criteria for the Medicare CQMs collection type.
- Establish data completeness criteria for the Medicare eCQMs collection type.
- Modify the MIPS quality measure set as described in Appendix 1 of this proposed rule, including the addition of new measures, updates to specialty sets, removal of existing measures, and substantive changes to existing measures.

(b) Proposal To Update Definition of Collection Type

With the proposed establishment of a new collection type, the Medicare Electronic Clinical Quality Measures for

[9] For Shared Savings Program ACOs, applicable measures include the five current eCQMs and proposed Medicare eCQMs in the APP Plus quality measure set.

[10] Existing quality reporting options for Shared Savings Program ACOS would include MIPS CQMs, Medicare CQMs, eCQM reporting via Quality Reporting Document Architecture (QRDA) files, and proposed Medicare eCQMs.

Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Medicare eCQMs) specific to the APM Performance Pathway (APP) as described in section XXX of this proposed rule, we are proposing to amend the definition of the term ''collection type'' to include Medicare eCQMs to account for the new collection type available only to Medicare Shared Savings Program ACOs meeting the reporting requirements of the APP. Specifically, starting with the CY 2027 performance period/2029 MIPS payment year, we are proposing to amend the definition of the term ''collection type'' in § 414.1305 to mean a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); Qualified Clinical Data Registry (QCDR) measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs); and Medicare Electronic Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs).

We request public comment on this proposal.

(c) Proposals To Modify Quality Data Submission Criteria

(i) Proposal To Designate MIPS Core Measures

In the CY 2026 PFS proposed rule (90 FR 32702), we published a Core Elements Request for Information (RFI) soliciting feedback on how to encourage MVP reporting on key quality measures, or ''core'' measures, that reflect the essential components of care. One goal of MIPS reporting, particularly with the transition to MVPs, is to provide patients with comparative clinician performance data so they can make the most informed decisions about their care. The number of MIPS quality measures available for clinicians to choose from in traditional MIPS reduces the standardization of performance data. While MVPs reduce the number of quality measures for clinicians to choose from, MVPs still provide a degree of measure choice that may not produce sufficient comparative performance data on standardized measures to support patient choice of care. In the Core Elements RFI in the CY 2026 PFS proposed rule (90 FR 37021 and 37022), we sought feedback on a potential reporting requirement in which clinicians reporting an MVP would be required to select and report one quality measure from a subset of ''core'' quality measures in each MVP, which would count as one of the four quality measures required in MVP reporting. MVP reporting requirements for the other performance categories would be unchanged. MIPS core measures would be limited to measures that are most reflective of the care that is unique to each MVP's specialty or medical condition. In response to the Core Elements RFI in the CY 2026 PFS proposed rule (90 FR 32702), commenters shared concerns that MIPS core measures may not be applicable to their scope of care and that a MIPS core measure reporting requirement could add complexity to MVP reporting. We have taken this commenter feedback into consideration in our proposal of the MIPS core measures policy and in our proposed modifications to the quality performance category data submission criteria for traditional MIPS and MVPs.

One of the goals of implementing MIPS core measures is to provide patients with comparative clinician performance data. This would enable patients to make better assessments of the quality of care provided by requiring clinicians within a given specialty to report on a narrower group of measures. This would also emphasize and increase reporting on select quality measures that we believe are the most reflective of the care central to an applicable specialty, medical condition, or episode of care. In developing the MIPS core measure policy, we evaluated several alternative approaches. First, when considering how to procure more robust comparative performance data, we considered mandating clinicians reporting an MVP be required to report the same MIPS quality measure. This approach was not consistent with section 1848(q)(2)(D)(i) of the Act, nor did it achieve intended policy goals of generating more comparative clinician performance data on key quality measures, since what matters most for high-quality care in one specialty may differ from another. Additionally, cross-cutting quality measures, while applicable to the majority of MIPS eligible clinicians, may not be applicable to all, especially bearing in mind subgroup reporting. Expanding upon this idea, we also examined the possibility of a uniform subset of quality measures that would be consistent across all MVPs, and from which clinicians would be required to report one to two quality measures. While having the same subset of measures provides better coverage of the variety of scopes of care provided by MIPS eligible clinicians, we remain concerned that a uniform subset of quality measures would not sufficiently account for the variety of MIPS eligible clinicians' scopes of care while meaningfully assessing quality performance.

In focusing on the goal of providing patients and clinicians with ''comparative performance data,'' particularly among clinicians practicing within the same clinical specialty or providing care to patients with a specific medical condition, we considered whether to use existing population health measures or to develop new administrative claims-based measures. While these approaches would allow for automatic capture of data, there are still constraints in applicability across MIPS eligible clinicians in addition to resources and feasibility. Given these findings, we determined that the most prudent way to capture meaningful comparative data and provide patients with better insight into the quality of care provided was to create a curated set of core quality measures for each MVP. The proposed list of MIPS core measures was selected because we determined these measures were most reflective of the care central to a clinical specialty or medical condition and would be the measures that the MIPS eligible clinician would be required to report from within that MVP.

For each MVP, we propose to select the MIPS core measures from the list of MIPS quality measures already assigned to the MVP because the quality measures within each MVP are the measures that are clinically relevant to the MVP's specialty or medical condition, and the proposed MIPS core measures are intended to be most reflective of the care that is central to the MVP's specialty or medical condition. The selection process focused on existing MIPS quality measures and quality measures proposed for the CY 2027 performance period/2029 MIPS payment year.

From this list, we then propose to select a minimum of three MIPS core measures per MVP. We may designate more than three MIPS core measures within an MVP if we determine more than three measures must be selected to reflect the care central to the subspecialties within that MVP.

Selection of the MIPS core measures would be based on the following factors:

- Whether the measure is an outcome-based measure;
- Measure collection type availability and the clinician's ability to meet reporting requirements to the extent practicable. Qualified Clinical Data Registry (QCDR) measures were not considered for MIPS core measure selection to ensure MIPS core measures are broadly available and accessible for all eligible clinicians;
- Measure adoption and current and historic performance rates for each measure, to be in alignment with section 1848(q)(3) of the Act which states that the Secretary shall consider historical performance standards and opportunity for continued improvement in establishing performance standards; and
- Whether the measure is most reflective of the care that is central to the clinical focus of the selected MVP, represents best practices essential to the MVP's specialty or medical condition, or addresses important areas for improving care.

We propose that the MIPS core measure designation would apply to quality measures in both traditional MIPS and MVPs. Establishing a set of unified key quality measures across both reporting pathways promotes alignment, reduced reporting complexity for clinicians reporting both traditional MIPS and MVPs and is operationally feasible. While the proposed MIPS core measures were selected from MVPs, the proposed MIPS core measure inventory would include over 70 quality measures. We believe these measures represent key aspects of care across a variety of specialties and medical conditions. The proposed MIPS core measures inventory also overlaps with the MIPS quality measures currently designated as high priority measures. Given the proposed removal of high priority designation for MIPS quality measures, the MIPS core measure inventory would not only support reporting within MVPs but would also be applicable to clinicians reporting via traditional MIPS. Additionally, it would provide sufficient data for benchmarking for the MIPS core measures once we phase out traditional MIPS reporting and transition to full implementation of MVP reporting, as proposed in section IV.A.3.c. of this proposed rule.

As detailed in section IV.A.4.d.(1)(c)(iii)(B) of this proposed rule, we are proposing that clinicians reporting through the traditional MIPS reporting option would select from the complete inventory of available MIPS core measures for the performance period. Whereas clinicians reporting through the MVP reporting option would select the applicable MIPS core measures from the core measures identified within their chosen MVP. As discussed in section IV.A.4.a.(2) of this proposed rule, we propose to revise the format of the MVP tables in Appendix 3: MVP Inventory of this proposed rule to include MIPS core measures for each previously finalized MVP. We also added a MIPS core measure table to the newly proposed MVPs. Further, we propose, beginning with the CY 2027 performance period/2029 MIPS payment year, to establish a MIPS core measure designation applicable to selected quality measures contained in the MIPS quality measure inventory and the MVP inventory found in the Appendices of this proposed rule.

We request public comment on these proposals.

(ii) Proposal To Remove High Priority Measure Designation and High Priority Quality Measure Retention Consideration

In the CY 2019 PFS final rule (83 FR 59761), we finalized that beginning with the CY 2019 performance period/2021 MIPS payment year, the term ''high priority measure'' is defined at § 414.1305 as an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure. In the CY 2023 PFS final rule (87 FR 70047 through 70049), we finalized an amended definition of the term ''high priority measure'' to include quality measurement pertaining to health equity. In the CY 2026 PFS final rule (90 FR 49857), we finalized at § 414.1305 an amended definition of the term ''high priority measure'' to mean an outcome (including intermediate-outcome and patient-reported outcome), appropriate use, patient safety, efficiency, patient experience, care coordination, or opioid-related quality measure, beginning with the CY 2026 performance period/2028 MIPS payment year.

In the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77785) and subsequent Quality Payment Program and PFS rules (82 FR 53965 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85368, 86 FR 65686 through 65968, 87 FR 70250 through 70633, 88 FR 79556 through 79964, 89 FR 98599 through 98957, and 90 FR 50036 through 50353), we designated certain quality measures as high priority in the MIPS quality measure inventory found in the Appendices of the rules for the applicable performance period to allow MIPS eligible clinicians to easily identify which measures meet the definition of a high priority measure at § 414.1305 and satisfy the reporting requirement. Additionally, in the CY 2022 PFS final rule (86 FR 65998 through 66031) and subsequent PFS rules we designated high priority quality measures in the MVP inventory found in the Appendices. The Explore Measures and Activities Tool on the QPP website (*https://qpp.cms.gov/reporting-requirements/measures-activities/explore*) also indicates which quality measures are designated as high priority in traditional MIPS and MVP reporting.

Given the proposed implementation of the MIPS core measure designation in section IV.A.4.d.(1)(c)(i) of this proposed rule, which identifies a subset of measures that reflect the essential components of care specific to a given specialty, medical condition, or episode of care, we are proposing to remove the high priority designation from MIPS quality measure inventory and the MVP inventory. The proposed MIPS core measures intend to increase reporting on select quality measures that are most reflective of the care central to a particular specialty, medical condition or episode of care, while providing patients with more comparative clinician performance data. We considered maintaining the high priority designation since many of the proposed MIPS core measures are high priority measures. However, the high priority designation does not appropriately capture a measure's relevance to a specific clinical specialty, medical condition or episode of care. We identify and designate quality measures that reflect agency-wide priorities as high priority in our programs through myriad ways such as using the MIPS high priority definition, developing the Universal Foundation, and implementing the Core Quality Measures Collaborative (CQMC). However, the proposed MIPS core measure designations specifically represent key quality measures that reflect the measure's relevance to a specific clinical specialty, medical condition or episode of care for clinicians and patients for each MVP and essential best practices to the MVP's clinical topic. The significant overlap in the proposed MIPS core measures with the MIPS high priority measures means we would still largely capture agency-wide priorities but with a greater emphasis on supporting intended MIPS policy goals of providing robust quality

measure data relevant to the scope of care for a specialty or medical condition. Additionally, maintaining the high priority measure designation could add complexity and confusion for clinicians given the overlap of the existing high priority measures and the proposed MIPS core measures. While we acknowledge the overlap in intended goals for high priority measures and MIPS core measures, we anticipate that the proposed MIPS core measures, with a selection emphasis on outcome-based measures, would provide a more targeted set of measures, focused on more meaningful improvement in the quality of care related to each MVP specialty or medical condition. Therefore, to implement the proposed MIPS core measure designation as described in section IV.A.4.d.(1)(c)(i) of this proposed rule, we are proposing to remove the high priority designation from the MIPS quality measure and the MVP inventory in Appendices 1 and 3 of this proposed rule.

Additionally, in the CY 2019 PFS final rule (83 FR 59765) at § 414.1330(c)(2), we revised the approach to remove quality measures to include considerations for retaining MIPS quality measures that otherwise meet the criteria for removal, including ''whether the MIPS quality measure is designated as high priority or not.'' To align with the proposed removal of high priority designation from MIPS quality measures, we would no longer include the use of a high priority measure designation as one of the considerations for retaining a MIPS quality measure. Therefore, we propose to update the existing quality measure retention consideration at § 414.1330(c)(2)(iv) to state that we would consider whether the quality measure is designated as high priority or not through the CY 2026 performance period/2028 MIPS payment year.

We request public comment on these proposals.

(iii) Proposal To Implement Data Submission Requirement for MIPS Core Measures

(A) Background

In the CY 2017 Quality Payment Program final rule (81 FR 77114), we finalized at § 414.1335(a)(1) that for the performance period, a MIPS eligible clinician will report at least six measures including at least one outcome measure. If an applicable outcome measure is not available, a MIPS eligible clinician will be required to report a high priority measure instead. Additionally, in the CY 2022 PFS final rule (86 FR 65412), we finalized at § 414.1365(c)(1), that except as provided in paragraph § 414.1365(c)(1)(i), an MVP participant must select and report, if applicable, 4 quality measures, including 1 outcome measure (or, if an outcome measure is not available, 1 high priority measure), included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii). We were concerned that small practices do not have the same resources to meet the quality reporting requirement of four measures if the MVP does not include four Medicare Part B claims measures. Therefore, we finalized at § 414.1365(c)(1)(i) that paragraph § 414.1365(c)(1) does not apply to a small practice that reports on an MVP that includes fewer than four Medicare Part B claims measures, provided that the small practice reports each such measure that is applicable.

(B) Proposal for MIPS Core Measure Data Submission Requirements With Self-Attestation

In conjunction with the proposed removal of the high priority designation for MIPS quality measures, and the proposed new designation of MIPS core measures beginning with the CY 2027 performance period/2029 MIPS payment year, we are proposing to remove the current quality measure data submission requirement of one outcome measure (or, if an outcome measure is not available, one high priority measure) for traditional MIPS and MVPs and replace the requirement with a MIPS core measure data submission requirement to emphasize the reporting on the proposed MIPS core measures. The requirement to report an outcome measure (or, if an outcome measure is not available, one high priority measure) would no longer be necessary, as the goals of that policy would be met by the proposed MIPS core measure reporting requirement, since the proposed MIPS core measure selection process considers outcome-based measures and measures that are integral in driving positive patient outcomes. Specifically, we are proposing that MIPS eligible clinicians reporting via traditional MIPS must submit data on at least six measures, including at least one MIPS core measure. Clinicians reporting a specialty measure set in traditional MIPS must report at least six measures and choose an applicable MIPS core measure, if available, within that specialty measure set. If the set contains fewer than six measures or fewer than six measures within the set apply, they must report on each measure that is applicable. Additionally, to be consistent with the existing reporting requirements for clinicians reporting a specialty measure set, as finalized in the CY 2017 Quality Payment Program final rule (81 FR 77114), if a specialty measure set does not contain a MIPS core measure, clinicians must still report on at least six measures within the specialty set. If the specialty set does not contain a MIPS core measure and contains fewer than six measures, or fewer than six measures within the set apply, they must report on each measure that is applicable within the specialty measure set. An MVP participant must select and report, if applicable, four quality measures, including at least one MIPS core measure. We note that clinicians submitting data for the quality performance category in traditional MIPS reporting would choose an applicable MIPS core measure from the full inventory of available MIPS core measures for the performance period. Clinicians reporting an MVP would choose the applicable MIPS core measures from those available in the selected MVP. Each MVP would include a minimum of three MIPS core measures for a clinician to select from. MVPs that encompass multiple specialties or subspecialties may include more than three MIPS core measures to ensure comprehensive coverage for the variety of clinicians reporting that MVP.

Since the proposed MIPS core measures were identified to reflect the care most central to a clinician specialty, medical condition, or episode of care within each MVP for clinicians and patients, we anticipate that clinicians could report the proposed MIPS core measures in the selected MVP. We acknowledge that due to the variety of clinician practices, specialties, and subspecialties reporting each MVP, there may be instances in which a clinician does not have an available and applicable MIPS core measure due to the limited inventory of the proposed MIPS core measures. If an individual eligible clinician, group, subgroup, or APM Entity does not have an available and applicable MIPS core measure that meets the numerator and denominator criteria as specified in the MIPS quality measure inventory for the applicable performance period, either in traditional MIPS or MVP reporting, we propose to establish a MIPS core measure self-attestation process. Under this process, the clinician would be required in good faith to attest during the data submission period that there was not an available and applicable MIPS core measure for them to report. The clinician would then be required to choose another measure to report in place of the MIPS core measure. A

clinician reporting via traditional MIPS could report any other applicable quality measure in the MIPS quality measure inventory. In MVP reporting, a clinician could report any other quality measure in the selected MVP. There may be instances in which a clinician attested to not having an applicable and available MIPS core measure, but new information or changing circumstances later made it so that the clinician does have an applicable and available MIPS core measure to report. To account for these cases, we would allow a clinician to attest that they do not have an applicable and available MIPS core measure and then submit a MIPS core measure. We refer readers to section IV.B.1.b.(1) for our proposals for scoring MIPS core measures. While we considered requiring clinicians without an available and applicable MIPS core measure to report an outcome or high priority measure, we determined that such a requirement would increase complexity for clinicians and would be unnecessary given that MVPs are already a collection of the key quality measures for a specialty, medical condition, or episode of care. We would not penalize a MIPS eligible clinician who provides a self-attestation to not having a MIPS core measure to report. We note that we may monitor attestations received for the MIPS core measure requirement and may, in future years, conduct random reviews to verify that there were no available and applicable MIPS core measures for reporting. We refer readers to section IV.B.1.b.(1) of this proposed rule for details on the proposed scoring policies for MIPS core measures.

For traditional MIPS reporting, we propose at § 414.1335(a)(1)(i) that beginning in the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians, except as provided in paragraphs (a)(1)(ii) and (a)(1)(iii) of this section, submits data on at least six quality measures, including at least one MIPS core measure. If there is not an available and applicable MIPS core measure, a MIPS eligible clinician must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure. If fewer than six measures apply, then the MIPS eligible clinician, group, virtual group, or APM Entity must report on each measure that is applicable.

Additionally, we propose at § 414.1335(a)(1)(ii) that beginning in the CY 2027 performance period/2029 MIPS payment year, except as provided in paragraph (a)(1)(iii) of this section, a MIPS eligible clinician that reports on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one MIPS core measure. If there is not an available and applicable MIPS core measure, a MIPS eligible clinician must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure within that set. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, report on each measure that is applicable.

For MVP reporting, we propose at § 414.1365(c)(1) that, beginning in the CY 2027 performance period/2029 MIPS payment year, except as provided in paragraphs (c)(1)(i) and (c)(1)(ii) of this section, an MVP participant must select and report, if applicable, four quality measures, including one MIPS core measure available in the MVP, excluding the population health measure required under paragraph (c)(4)(ii). If there is not an available and applicable MIPS core measure, an MVP participant must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure within the MVP.

We request public comment on these proposals.

(C) Proposal To Exempt Small Practices From MIPS Core Measure Reporting Requirement

We recognize that clinicians in small practices often face challenges in successfully participating in MIPS and MVP reporting due to limited financial, administrative, and health IT resources, when compared to medium and large practices. Historically, we have received feedback from small practices expressing concerns that meeting the MIPS reporting requirements can be challenging due to the limited resources of small practices, and we have implemented policies in MIPS to support clinicians in small practices to address these concerns. For example, in the CY 2022 PFS final rule (86 FR 65412), we finalized at § 414.1365(c)(1)(i) that the requirement to report four quality measures in an MVP does not apply to small practice clinicians reporting under the Medicare Part B claims collection type when the selected MVP contains fewer than four Medicare Part B claims-based quality measures. In addition, in MVPs, small practices reporting via Medicare Part B claims measures are currently exempt from the outcome/high priority reporting requirement if the MVP does not contain at least four Medicare Part B claims measures.

We considered several policy options for small practices with respect to reporting MIPS core measures. Initially, we considered whether to align the reporting requirements for small practices with the proposed MIPS core measure reporting requirements for clinicians in medium and large practices participating in traditional MIPS and MVP reporting. However, we anticipate that clinicians in small practices may continue to experience challenges with meeting the proposed MIPS core measure reporting requirement due to limited resources, difficulty reaching the case minimum requirement, and the limited inventory of proposed MIPS core measures, particularly the limited inventory of proposed MIPS core measures available via the Medicare Part B claims collection type, which is only available to small practices. While we also considered exempting small practices from the proposed MIPS core measure reporting requirement only if the selected MVP does not contain at least one MIPS core measure available via the Medicare Part B claims collection type, we remained concerned that such a policy would further limit measure choice for clinicians in small practices and could lead to confusion and unfairness if some MVPs contained Medicare Part B claims MIPS core measures and other MVPs did not. In recognition of these ongoing challenges, and to streamline reporting requirements for small practices while continuing to support clinicians in small practices, we want to provide flexibilities for clinicians in small practices to successfully report the MIPS quality performance category. Therefore, in both traditional MIPS and MVP reporting, we propose that small practices, as defined under § 414.1305, be exempt from the MIPS core measure data submission requirement. Under this proposal, clinicians in small practices would continue to report six quality measures for traditional MIPS or four quality measures as currently required for MVPs. It is important to note that while small practices are not required to report a MIPS core measure, they may choose to do so on a voluntary basis.

Specifically, we propose at § 414.1335(a)(1)(iii) that beginning with the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians in small practices are not required to submit at least one MIPS core measure or attest to not having an available and applicable MIPS core measure. MIPS eligible clinicians in

small practices must submit data on at least six measures, if applicable. Additionally, we propose at § 414.1365(c)(1)(ii) that beginning with the CY 2027 performance period/2029 MIPS payment year, an MVP participant that meets the requirements of a small practice is not required to submit at least one MIPS core measure or attest to not having an available and applicable MIPS core measure. Except as provided in paragraph (c)(1)(i) of this section, an MVP participant that meets the requirements of a small practice must select and report, if applicable, at least four quality measures included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section.

We request public comment on these proposals.

(iv) Proposal To Modify Data Submission Criteria for Medicare CQMs

In this proposed rule, we are proposing an amendment to the data submission criteria for the Medicare CQMs collection type in § 414.1335(a)(4) by including the availability of Medicare CQMs within the APP Plus measure set, as applicable. Specifically, in § 414.1335(a)(4)(i), we are proposing that the data submission criteria pertaining to Medicare CQMs would be met by a MIPS eligible clinician, group, and APM Entity reporting on the Medicare CQMs (reporting quality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set or APP Plus measure set (as applicable) and administering the CAHPS for MIPS Survey as required under the APP.

We are including the availability of Medicare CQMs under the APP Plus measure set to provide various options that would assist Medicare Shared Savings Program ACOs with reporting quality data and transition to the adoption of digital quality measures (dQMs). We encourage Medicare Shared Savings Program ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on their unique composition and technical infrastructure.

We request public comment on this proposal.

(v) Proposal To Implement Data Submission Criteria for Medicare eCQMs

In this proposed rule, we are proposing to establish the data submission criteria for the Medicare eCQMs collection type (as proposed under the APP in section III.G.3.d.(3) of this proposed rule) in § 414.1335(a)(5). Specifically, in § 414.1335(a)(5)(i), we are proposing that the data submission criteria pertaining to Medicare eCQMs would be met by a MIPS eligible clinician, group, and APM Entity reporting on the Medicare eCQMs (reporting quality data on beneficiaries eligible for Medicare eCQMs as defined at § 425.20) within the APP Plus measure set (as applicable) and administering the CAHPS for MIPS Survey as required under the APP.

Medicare eCQMs would serve to address concerns discussed in section III.G.3.d.(1) of this proposed rule by defining a population of beneficiaries that exists within the all payer/all patient eCQM specifications and tethering that population to a Medicare Shared Savings Program ACO's assigned beneficiary population. Medicare Shared Savings Program ACOs have noted challenges with quality data reporting as their list of eligible beneficiaries has often contained beneficiaries for whom the Medicare Shared Savings Program ACO is unable to identify a primary care relationship. Specifically, Medicare eCQMs would address the concern raised by Medicare Shared Savings Program ACOs with a higher proportion of specialty practices and/or multiple EHRs, the broader all payer/all patient eligible population would capture beneficiaries with no primary care relationship to the Medicare Shared Savings Program ACO. Medicare eCQMs would provide an additional optional collection type for reporting quality data and assist with the transition and adoption of dQMs. Also, we anticipate in future years when FHIR-based reporting becomes mandatory that Medicare Shared Savings Program ACOs would be able to continue to use the FHIR-based digital specifications to report only on their assigned beneficiary population. We encourage Medicare Shared Savings Program ACOs to evaluate all quality reporting options to determine which collection type is most appropriate based on their unique composition and technical infrastructure.

We request public comment on this proposal.

(d) Proposal To Modify Data Completeness Criteria

(i) Proposal To Modify Data Completeness Criteria for Medicare CQMs

As described in section III.G.3.c. of this proposed rule, we are extending the availability of the Medicare CQMs collection type and anticipating the sunsetting of the Medicare CQMs collection type starting with the CY 2030 performance period/2032 MIPS payment year when FHIR-based reporting becomes mandatory. We are proposing an amendment to the data completeness criteria for the Medicare CQMs collection type in § 414.1340(d)(1) by modifying the duration of availability for the Medicare CQMs collection type as a means for meeting data completeness criteria requirements, which would eliminate the specific duration of availability (from the CY 2024 performance period/2026 MIPS payment year to the CY 2028 performance period/2030 MIPS payment year) and extend the duration of the availability of the Medicare CQMs collection type. Such modification would extend the availability of the Medicare CQMs collection type for meeting the data completeness criteria threshold requirements under the APP until CMS identifies the sunsetting of the Medicare CQMs collection type in future rulemaking.

Specifically, in § 414.1340(d), respectively, we are proposing the following modification to the data completeness criteria threshold pertaining to the Medicare CQMs collection type:

At paragraph (d)(1), starting with the CY 2024 performance period/2026 MIPS payment year, an APM Entity, specifically a Medicare Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare CQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria.

We request public comment on this proposal.

(ii) Proposal To Implement Data Completeness Criteria for Medicare eCQMs

As we propose to establish a new collection type, Medicare eCQMs specific to the APP as described in section III.G.3.d.(3) of this proposed rule, we are also proposing to establish the data completeness criteria threshold for the Medicare eCQMs collection type. Specifically, in § 414.1340(e), respectively, we are proposing the following data completeness criteria threshold pertaining to the Medicare eCQMs collection type:

At paragraph (e)(1), starting with the CY 2027 performance period/2029 MIPS payment year, an APM Entity, specifically a Medicare Shared Savings Program ACO that meets the reporting requirements under the APP, submitting quality measure data on Medicare

eCQMs must submit data on at least 75 percent of the APM Entity's applicable beneficiaries eligible for the Medicare eCQM, as proposed to be defined at § 425.20, who meet the measure's denominator criteria.

Also, for the data completeness criteria pertaining to the quality performance category, we are proposing a technical amendment to recognize the former paragraph (e) as new paragraph (f) due to the proposal to establish the data completeness criteria for the new collection type, Medicare eCQM, in § 414.1340(e) as discussed in the following XXX section of this proposed rule.

We request public comment on this proposal.

(e) Addition of New Quality Measures

(i) Pre-Rulemaking Process

Prior to introducing a new MIPS quality measure in a proposed rule, we receive public input on measures through the pre-rulemaking process (referred to as the Pre-Rulemaking Measure Review (PRMR)) established in accordance with section 1890A of the Act. Although section 1848(q)(2)(D)(viii) of the Act provides that the pre-rulemaking process under section 1890A of the Act is not required to apply to the selection of MIPS quality measures, we have found that the pre-rulemaking process provides a comprehensive review of measures from multi-stakeholder workgroups and have accordingly elected for such measures to be reviewed utilizing the PRMR process (87 FR 70048). Under the established PRMR process (additional information regarding the PRMR process is available at *https://p4qm.org/PRMR*), CMS has contracted with a Consensus-Based Entity (CBE), which is responsible for convening a multi-stakeholder panel comprised of clinicians, patients, measure experts, and health information technology specialists to provide input on measures CMS is considering for use in Medicare.

The PRMR process begins with CMS's publication of measures under consideration for use in Medicare (the Measures Under Consideration (MUC) List). Each measure on the MUC List is reviewed by one of several committees convened by the CBE for the purpose of providing multi-stakeholder input to the Secretary. The PRMR process includes opportunities for public comments through a 21-day public comment period, as well as public listening sessions. The CBE posts the compiled comments and listening session inputs received during the public comment period and the listening sessions within 5 days of the close of the public comment period. More details regarding the PRMR process may be found in the PQM Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review and Measure Set Review (available at *https://p4qm.org/sites/default/files/2025-07/OP2-PRMR-MSR-Final-Multi-Stakeholder-Group-Guidebook-of-Policies-and-Procedures-508_1.pdf*).

Per the PQM Guidebook, the final vote of the multistakeholder committee convened by the CBE may result in the following disposition of a measure: The committee recommends that this measure be added to the CMS program or the committee does not recommend that this measure be added to the CMS program. A ''does not recommend'' voting result signals continued disagreement among the committee despite being presented with perspectives from public comments and committee member feedback and discussion and highlights the multi-faceted assessments of quality measures. There may be cases in which the CBE does not recommend a measure to move forward to the rulemaking process and eventual implementation but we go forth with proposing a measure. We note that section 1848(q)(2)(D)(iii)(v)(III) of the Act does not preclude the Secretary from proposing and implementing measures that are not endorsed by a CBE as long as the measure is evidence-based.

Quality measures considered for potential implementation in MIPS starting with CY 2027 performance period/2029 MIPS payment year were informed, in part, by the measures included on the 2025 MUC List (available at *https://mmshub.cms.gov/sites/default/files/2025-MUC-List.xlsx*). We refer readers to Table Group A of Appendix 1: MIPS Quality Measures of this proposed rule for detailed descriptions of the new MIPS quality measures proposed. We note that we are advancing quality measurement by transitioning existing quality measures and reporting processes to Fast Healthcare Interoperability Resources® (FHIR®)-based digital approaches. We refer readers to section IV.A.4.c. of this proposed rule, where we seek input on the anticipated transition timeline, key milestones, and implementation considerations for FHIR-based quality reporting.

(ii) Removal of Quality Measures

In the CY 2025 PFS final rule, we codified previously established criteria for the removal of MIPS quality measures from the MIPS quality measure inventory at § 414.1330. In the CY 2017 Quality Payment Program final rule (81 FR 77136 through 77137), we established the following criteria for measure removal to include: If the Secretary determines that the MIPS quality measure is no longer meaningful, such as MIPS quality measures that are topped out; and, if a measure steward is no longer able to maintain the quality measure. In the CY 2019 PFS final rule (83 FR 59763), we expanded the criteria for measure removal to include MIPS quality measures that reached an extremely topped-out status (for example, a measure with an average mean performance within the 98th to 100th percentile range). The MIPS quality measure may be proposed for removal in the next rulemaking cycle, regardless of whether or not it is in the midst of the topped-out measure lifecycle, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made, after taking into account any other relevant factors.

Also, in the CY 2019 PFS final rule (83 FR 59764), we established other criteria for measure removal, specifically MIPS quality measures that are: duplicative; not maintained or updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice; and low-bar, standard of care process measures. As described in the CY 2019 PFS final rule (83 FR 59765), we established an approach to incrementally remove process measures where prior to removal, consideration will be given to, but will not be limited to, the following:

- Whether the removal of the process measure impacts the number of measures available for a specific specialty.
- Whether the MIPS quality measure addresses a priority area highlighted in the Measure Development Plan: *https://www.cms.gov/medicare/quality/value-based-programs/quality-payment-program/measure-development.*
- Whether the MIPS quality measure promotes positive outcomes in patients.
- Considerations and evaluation of the measure's performance data.
- Whether the MIPS quality measure is designated as high priority or not.
- Whether the MIPS quality measure has reached extremely topped-out status within the 98th to 100th percentile range, due to the extremely high and unvarying performance where meaningful distinctions and improvement in performance can no longer be made.

In the CY 2020 PFS final rule (84 FR 62958 through 62959), we expanded the

criteria for measure removal to include MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods and are not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians. For MIPS quality measures that do not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods, we noted that we will factor in other considerations (such as, but not limited to, the robustness of the measure; whether it addresses a measurement gap; if the measure is a patient-reported outcome; and consideration of the MIPS quality measure in developing MVPs) prior to determining whether to remove the MIPS quality measure. We refer readers to section IV.A.4.d.(1)(c)(ii) of this proposed rule for our proposals regarding removing references to the high priority measure designation from MIPS quality measures and MIPS quality measure retention consideration.

(iii) Inventory of Quality Measures

Section 1848(q)(2)(D)(i) of the Act requires the Secretary, through notice and comment rulemaking, to establish an annual final list of quality measures from which MIPS eligible clinicians may choose for the purpose of assessment under MIPS. Section 1848(q)(2)(D)(i)(II) of the Act requires that the Secretary annually update the list by removing measures from the list, as appropriate; adding new measures to the list, as appropriate; and determining whether measures that have undergone substantive changes should be included on the updated list.

Previously finalized MIPS quality measures can be found in the CY 2017 and CY 2018 Quality Payment Program final rules (81 FR 77558 through 77816 and 82 FR 53966 through 54174, respectively), and the CY 2019 through CY 2026 PFS final rules (83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, 87 FR 70250 through 70633, 88 FR 79556 through 79964, 89 FR 98599 through 98957, and 90 FR 50036 through 50353, respectively). We are proposing changes to the MIPS quality measure inventory, as outlined in Appendix 1 of this proposed rule, including the following: the addition of new measures; updates to specialty sets (that is, creation of new specialty sets; addition and/or removal of measures; and substantive changes to existing measures within specialty sets, as appropriate); removal of existing measures; and substantive changes to existing measures. For the CY 2027 performance period/2029 MIPS payment year, we are proposing an inventory of 180 MIPS quality measures.

The new MIPS quality measures that we are proposing to include in MIPS for the CY 2027 performance period/2029 MIPS payment year and future years can be found in Table Group A of Appendix 1 of this proposed rule. For the CY 2027 performance period/2029 MIPS payment year, we are proposing 10 new MIPS quality measures, which include measures focused on patient-reported outcomes and chronic disease management.

On January 14, 2026, we solicited recommendations for potential new specialty measure sets or revisions to existing specialty measure sets for the CY 2027 performance period/2029 MIPS payment year.[376] The recommendations we received were based on the MIPS quality measures finalized in the CY 2026 PFS final rule and the 2025 MUC List. The recommendations include the addition or removal of current MIPS quality measures from existing specialty sets, and/or the creation of new specialty sets. All specialty set recommendations submitted for consideration were assessed and vetted, and as a result, the recommendations that we agree with are proposed in this proposed rule.

We are proposing modifications to existing specialty sets as described in Table Group B of Appendix 1 of this proposed rule. Modifications to specialty sets include the addition of new measures and/or existing measures within the MIPS quality measure inventory, removal of measures, and/or substantive changes to previously finalized measures. Specialty and subspecialty sets are not inclusive of every specialty or subspecialty. We develop and maintain specialty measure sets to assist MIPS eligible clinicians with selecting quality measures that are most relevant to their scope of practice.

In addition to establishing new individual MIPS quality measures and modifying existing specialty sets as described in Tables Group A and Group B of Appendix 1 of this proposed rule, we refer readers to Table Group C of Appendix 1 of this proposed rule for a list of MIPS quality measures proposed for removal and detailed discussion of our rationale for each measure. Of the 20 MIPS quality measures proposed for removal, two MIPS quality measures are extremely topped out, four MIPS quality measures have reached the end of the topped-out lifecycle, three MIPS quality measures are no longer being maintained by the measure steward, eight MIPS quality measures are duplicative of new or current measures, one MIPS quality measure has limited adoption and therefore no benchmark, one MIPS quality measure is a low bar process measure, and one MIPS quality measure lacks robustness. The proposal to remove the MIPS quality measures described in Table Group C of Appendix 1 of this proposed rule would lead to a more parsimonious inventory of meaningful, robust measures in the program.

Further, in Appendix 1 of this proposed rule, we are proposing substantive changes to 43 MIPS quality measures, which can be found in Table Group D and Table Group DD of Appendices of this proposed rule. Of the proposed substantive changes to the 43 MIPS quality measures, two MIPS quality measures are only available for use in relevant MVPs, which can be found in Table Group DD of Appendix 1 of this proposed rule. We have previously established criteria that would apply when we are considering making substantive changes to a quality measure (81 FR 77137 and 86 FR 65441 through 65442). On an annual basis, we review the established MIPS quality measure inventory to consider updates to the measures. Possible updates to measures may be minor or substantive. The proposed inventory of 180 MIPS quality measures for the CY 2027 performance period/2029 MIPS payment year includes 177 MIPS quality measure available for utilization in traditional MIPS and MVPs, and 3 MIPS quality measures available only for utilization in MVPs (as finalized in the CY 2024 PFS final rule (88 FR 79897 through 77902)).

In summary, in the CY 2027 PFS proposed rule, we are proposing to modify the quality performance category measure inventory to include a set of 180 MIPS quality measures for the CY 2027 performance period/2029 MIPS payment year, which includes the following:

- Implementation of 10 new MIPS quality measures including measures focused on patient-reported outcomes and chronic disease management;
- Removal of 20 MIPS quality measures: Two MIPS quality measures that are extremely topped out, four MIPS quality measures that have reached the end of the topped-out

[376] Message to the Quality Payment Program listserv on January 14, 2026, entitled ''The Centers for Medicare & Medicaid Services (CMS) is Soliciting Interested Party Recommendations for Potential Consideration of New Specialty Measure Sets and/or Revisions to the Existing Specialty Measure Sets for the 2027 Performance Year of the Merit-based Incentive Payment System (MIPS).''

measure lifecycle, three MIPS quality measures that are no longer being maintained by the measure steward, eight MIPS quality measures that are duplicative of new or current measures, one MIPS quality measure that has limited adoption and therefore no benchmark, one MIPS quality measure that is a low bar process measure, and one MIPS quality measure lacking robustness, and;

- Substantive changes to 43 current MIPS quality measures.

We refer readers to Table Groups A through DD of Appendix 1 of this proposed rule for a summary of the new measures proposed, the measures proposed for removal, and the substantive changes proposed as well as specialty set changes proposed.

We request public comment on these proposals.

(2) Cost Performance Category

(a) Background

Section 1848(q)(2)(A)(ii) of the Act includes resource use as a performance category under MIPS. We refer to this performance category as the cost performance category. As required by sections 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians are evaluated under all four of the MIPS performance categories, including the cost performance category.

Section 1848(q)(2)(B)(ii) of the Act provides that, for the cost performance category, the measurement of resource use (that is, cost) for such period must be in accordance with section 1848(p)(3) of the Act, using the methodology under section 1848(r) of the Act as appropriate, and, as feasible and applicable, accounting for the cost of drugs under Medicare Part D. Section 1848(p)(3) of the Act provides that costs shall be evaluated, to the extent practicable, based on a composite of appropriate measures of costs established by the Secretary that eliminate the effect of geographic adjustments in payment rates, and take into account risk factors (such as socioeconomic and demographic characteristics, ethnicity, and health status of individuals) and other factors determined appropriate by the Secretary. Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and Advanced APMs under section 1833(z) of the Act. Specifically, section 1848(r)(2)(H) of the Act provides that, not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, make revisions to the operational lists of care episode and patient condition codes as the Secretary determines may be appropriate.

We are proposing the following update to the cost performance category beginning with the CY 2027 performance period/2029 MIPS payment year:

- Update the operational list of care episode and patient condition groups and codes to reflect changes to service and diagnosis codes that define care episodes and patient condition groups, as identified through the annual maintenance of episode-based measures.

For a description of the statutory authority for and existing policies pertaining to the cost performance category, we refer readers to §§ 414.1350 and 414.1380(b)(2) and the CY 2017 Quality Payment Program final rule (81 FR 77162 through 77177), CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), CY 2023 PFS final rule (87 FR 70055 through 70057), CY 2024 PFS final rule (88 FR 79339 through 79349), CY 2025 PFS final rule (89 FR 98390 through 98408), and CY 2026 PFS final rule (90 FR 49859 through 49864).

More details on the proposal in this section, which we invite comments on, are provided in section IV.A.4.d.(2)(b) through section IV.A.4.d.(2)(d) of this proposed rule.

(b) Selection of Cost Measures

In accordance with our statutory authority as described in section IV.A.4.d.(2)(a) of this proposed rule and our regulation at § 414.1350(a), we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category.

We consider adoption of cost measures to capture new clinical areas, which furthers our goals to transition from traditional MIPS to MVPs and expands the Medicare spending that is captured by the cost performance category assessment. MVPs require the inclusion of at least one cost measure, so adoption of cost measures for new clinical areas allows us to create new MVPs for clinical areas that do not yet have MVPs or to increase the amount of applicable cost measures in existing MVPs. Additionally, adopting cost measures that assess new clinical areas moves us closer towards the statutory goal of covering 50 percent of costs under Medicare Parts A and B, as specified under section 1848(r)(2)(D)(i)(I) of the Act.

In the CY 2022 PFS final rule (86 FR 65455 through 65459), we established common standards for potential episode-based measures to ensure consistency across episode-based measures being considered for potential use in MIPS. Specifically, the CY 2022 PFS final rule requires that any episode-based measure for the cost performance category include the following: (1) episode definition based on trigger codes that determine the patient cohort; (2) attribution; (3) service assignment; (4) exclusions; and (5) risk adjustment.

Additionally, in the CY 2025 PFS final rule (89 FR 98405), we codified criteria that must be met for a cost measure to be removed from the MIPS cost measure inventory at § 414.1350. Under the criteria, we may remove a cost measure from MIPS based on one or more of the following factors; provided, however, that we may retain a cost measure that meets one or more of the following factors if we determine the benefit of retaining the measure outweighs the benefit of removing it.

- It is not feasible to implement the measure specifications.
- A measure steward is no longer able to maintain the cost measure.
- The implementation costs or negative unintended consequences associated with a cost measure outweigh the benefit of its continued use in the MIPS cost performance category.
- The measure specifications do not reflect current clinical practice or guidelines.
- The availability of a more applicable measure, including a measure that applies across settings, applies across populations, or is more proximal in time to desired patient outcomes for the particular topic.

We are not proposing to adopt any new measures for the CY 2027 performance period/2029 MIPS payment year. We are also not proposing to remove any measures for the CY 2027 performance period/2029 MIPS payment year.

(c) Inventory of Cost Measures

As discussed previously, we specify cost measures for a performance period to assess the performance of MIPS eligible clinicians on the cost performance category. There are currently 35 cost measures in the cost performance category for the CY 2026 performance period/2028 MIPS

payment year, comprising 33 episode-based measures covering a range of conditions and procedures and 2 population-based measures. Previously finalized MIPS cost measures can be found in the CY 2018 Quality Payment Program final rule (82 FR 53641 through 53648), CY 2019 PFS final rule (83 FR 59765 through 59776), CY 2020 PFS final rule (84 FR 62959 through 62979), CY 2021 PFS final rule (85 FR 84877 through 84881), CY 2022 PFS final rule (86 FR 65445 through 65461), CY 2023 PFS final rule (87 FR 70055 through 70057), CY 2024 PFS final rule (88 FR 79339 through 79349), and CY 2025 PFS final rule (89 FR 98390 through 98408). We refer readers to the CY 2026 PFS proposed rule (90 FR 32718 through 32719) for more context on how we establish the inventory of cost measures, including the pre-rulemaking requirements.

We are neither proposing any new MIPS cost measures nor proposing to remove any MIPS cost measures for the CY 2027 performance period/2029 MIPS payment year. We are also not proposing substantive changes to any existing MIPS cost measures for the CY 2027 performance period/2029 MIPS payment year.

(d) Proposal To Update the Operational List of Care Episode and Patient Condition Groups and Codes

Generally, to calculate MIPS eligible clinicians' performance on cost measures, we use codes from claims data to identify and apply the applicable cost measure's specifications, which govern the attribution, scope, and calculation of the cost measure. We are proposing to revise the operational list of care episode and patient condition groups and codes to reflect coding changes that are identified during the annual measure maintenance of implemented cost measures. This section of this proposed rule provides context on the statutory requirements for care episode and patient condition groups and proposes changes to the operational list.

Section 1848(r) of the Act specifies a series of steps and activities for the Secretary to undertake to involve physicians, practitioners, and other interested parties in enhancing the infrastructure for cost measurement, including for purposes of MIPS and Advanced APMs under section 1833(z) of the Act. Section 1848(r)(2) of the Act requires the development of care episode and patient condition groups, and classification codes for such groups, and provides for care episode and patient condition groups to account for a target of an estimated one-half of expenditures under Medicare Parts A and B (with this target increasing over time as appropriate). Sections 1848(r)(2)(E) through (G) of the Act require the Secretary to post on the CMS website a draft list of care episode and patient condition groups and codes for solicitation of input from interested parties, and subsequently, post an operational list of such groups and codes. Section 1848(r)(2)(H) of the Act requires that not later than November 1 of each year (beginning with 2018), the Secretary shall, through rulemaking, revise the operational list of care episode and patient condition codes as the Secretary determines may be appropriate, and that these revisions may be based on experience, new information developed under section 1848(n)(9)(A) of the Act, and input from physician specialty societies and other interested parties.

For more information about past revisions to the operational list that we made as we developed, proposed, and finalized episode-based measures, we refer readers to the CY 2023 PFS final rule (87 FR 70056 and 70057), CY 2024 PFS final rule (88 FR 79348), and CY 2025 PFS final rule (89 FR 98404). Prior operational lists are available at the QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.*

In accordance with section 1848(r)(2)(H) of the Act, we are proposing to revise the operational list beginning with the CY 2027 performance period/2029 MIPS payment year to reflect changes to codes used to identify existing care episode and patient condition groups, based on new information gathered during annual maintenance of MIPS cost measures. We conduct annual maintenance for measures implemented in MIPS to ensure that the codes used for the measure specifications remain up to date. For example, we may update the service or diagnosis codes associated with a cost measure's specifications to retain the intent of the measure when these codes are changed in, added to, or deleted from the applicable code sets. During our annual maintenance review process for MIPS cost measures, we work with the measure developer to identify non-substantive changes to service and diagnosis codes that should be reflected in the operational list of care episode and patient condition groups so that, to the extent feasible, there is alignment between the operational list and measure specifications. More information on the annual maintenance process is available at the CMS Measures Management System (MMS) page at *https://mmshub.cms.gov/measure-lifecycle/measure-use/maintenance/annual-update.*

Our proposed revisions to the operational list are available for review on our QPP Cost Measure Information page at *https://www.cms.gov/medicare/quality/value-based-programs/cost-measures/about.* We seek interested party feedback on the service and diagnosis codes used in MIPS care episode and patient condition groups to inform any non-substantive changes to the operational list in tandem with CMS's annual maintenance efforts for the CY 2027 performance period/2029 MIPS payment year.

We request public comment on this proposal.

(3) Improvement Activities Performance Category

(a) Background

Section 1848(q)(2)(A)(iii) of the Act includes clinical practice improvement activities as a performance category under MIPS. We refer to this performance category as the improvement activities performance category. As required by section 1848(q)(2) and (5) of the Act, the four performance categories of MIPS are used in determining the MIPS final score for each MIPS eligible clinician. In general, MIPS eligible clinicians are evaluated under all four of the MIPS performance categories, including the improvement activities performance category.

Section 1848(q)(2)(C)(v)(III) defines the term ''clinical practice improvement activities'' as activities that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes.

Section 1848(q)(2)(B)(iii) of the Act provides that, for the improvement activities category, the Secretary shall specify subcategories of clinical practice improvement activities, including at least six subcategories as specified in section 1848(q)(2)(B)(iii)(I) through (VI) of the Act. These statutorily enumerated subcategories are: (1) expanded practice access (such as same day appointments for urgent needs and afterhours access to clinician advice); (2) population management (such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry); (3) care coordination (such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use

of remote monitoring or telehealth); (4) beneficiary engagement (such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms); (5) patient safety and practice assessment (such as through use of clinical or surgical checklists and practice assessments related to maintaining certification); and (6) participation in an alternative payment model, as defined in section 1833(z)(3)(C) of the Act (section 1848(q)(2)(B)(iii)(I) through (VI) of the Act).

For previous discussions on the general background of the improvement activities performance category, we refer readers to the CY 2017 Quality Payment Program final rule (81 FR 77177 and 77178), the CY 2018 Quality Payment Program final rule (82 FR 53648 through 53661), the CY 2019 Physician Fee Schedule (PFS) final rule (83 FR 59776 and 59777), the CY 2020 PFS final rule (84 FR 62980 through 62990), CY 2021 PFS final rule (85 FR 84881 through 84886), the CY 2022 PFS final rule (86 FR 65462 through 65466), the CY 2023 PFS final rule (87 FR 70057 through 70061), the CY 2024 PFS final rule (88 FR 79350 and 88 FR 79351), CY 2025 PFS final rule (89 FR 98408 through 98413), and CY 2026 PFS final rule (90 FR 49846 through 49868). We also refer readers to § 414.1305 for the relevant definitions of improvement activities and attestation, § 414.1320 for standards establishing the performance period, § 414.1325 for the data submission requirements, § 414.1355 for standards related to the improvement activity performance category generally, § 414.1360 for data submission criteria for the improvement activity performance category, and § 414.1380(b)(3) for improvement activities performance category scoring.

We are proposing various updates to the Improvement Activities Inventory (the Inventory) beginning with the CY 2027 performance period/2029 MIPS payment year, as described further in section IV.A.4.d.(3)(b)(ii) of this proposed rule. First, we propose adding six new improvement activities in two performance categories: (1) Care Coordination and (2) Advancing Health and Wellness, our newest subcategory. Second, we propose modifying five existing improvement activities currently specified for the performance category. Third, we propose removing 11 improvement activities currently specified for the performance category.

(b) Improvement Activities Inventory

(i) Annual Call for Activities

Background

In the CY 2017 Quality Payment Program final rule (81 FR 77190), for the first year of MIPS, we implemented the initial Inventory consisting of approximately 95 activities (81 FR 77817 through 77831). We took several steps to ensure the Inventory was inclusive of activities aligned with statutory and program requirements. As part of this process, we conducted numerous interviews with high performing organizations of all sizes and conducted an environmental scan to identify existing models, activities, or measures that met all or part of the improvement activities performance category.

Beginning with the CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659), we introduced an informal process for interested parties to submit new improvement activities or modifications for our consideration and potential inclusion in the comprehensive Inventory. In the CY 2018 Quality Payment Program final rule (82 FR 53656 through 53659), beginning with the CY 2019 performance period/2021 MIPS payment year, we finalized a formal Annual Call for Activities process for the addition of possible new activities and for possible modifications to current activities in the Inventory. This process requires interested parties to submit a nomination form similar to the one we used for the CY 2018 performance period/2020 MIPS payment year (82 FR 53656 through 53659). In order to submit a request for a new activity or a modification to an existing activity, the interested party must submit a nomination form (OMB control # 0938–1314) available at *https://qpp.cms.gov/resources/resource-library* during the Annual Call for Activities.

(ii) Proposals To Update the Improvement Activities Inventory

In the CY 2018 Quality Payment Program final rule (82 FR 53660), we finalized that we would establish improvement activities through notice-and-comment rulemaking. For our previously finalized Improvement Activities Inventories, we refer readers to Table H in the CY 2017 Quality Payment Program final rule (81 FR 77817) Appendix, Tables F and G in the CY 2018 Quality Payment Program final rule (82 FR 54175 through 54229) Appendix, Tables A and B in the CY 2019 PFS final rule (83 FR 60286 through 60303) Appendix 2, Tables A, B, and C in the CY 2020 PFS final rule (84 FR 63514 through 63538) Appendix 2, Tables A, B, and C in the CY 2021 PFS final rule (85 FR 85370 through 85377) Appendix 2, Tables A, B, and C in the CY 2022 PFS final rule (86 FR 65969 through 65997) Appendix 2, Tables A, B, and C in the CY 2023 PFS final rule (87 FR 70633 through 70650) Appendix 2, Tables A, B, and C in the CY 2024 PFS final rule (88 FR 79965 and 88 FR 79977) Appendix 2, Tables A, B, and C in the CY 2025 PFS final rule (89 FR 98958 through 98971) Appendix 2, and Tables A, B, and C in the CY 2026 PFS final rule (90 FR 50354 through 50369) Appendix 2. We also refer readers to the Quality Payment Program website at *https://qpp.cms.gov/* and the Explore Measures and Activities tool at *https://qpp.cms.gov/reporting-requirements/measures-activities/explore?tab=improvement Activities&py=2026* for a complete list of the current improvement activities.

(iii) Proposals To Adopt New Improvement Activities

We propose adding six new improvement activities beginning with the CY 2027 performance period/2029 MIPS payment year. We propose that IA_CC_XX (Use of Data to Improve Practice Workflows) and IA_CC_XX (Understand and Improve Diagnostic Performance) be included in the Care Coordination subcategory. We propose that IA_AHW_XX (Systematic Screening and Intervention for Nutrition and other Health-Impacting, Non-Clinical Issues), IA_AHW_XX (Advance Care Planning Conversations to Support Patient Wellness and Care Preferences), IA_AHW_XX (Clinician Use of Artificial Intelligence (AI) to Improve Patient Care), and IA_AHW_XX (Lifestyle Approaches to Diabetes Remediation) would be included in the Advancing Health and Wellness subcategory.

The first new improvement activity, IA_CC_XX, titled ''Use of Data to Improve Practice Workflows'', would allow MIPS-eligible clinicians to improve integration of evidence-based guidelines into care by developing and refining clinical pathways and workflows. If gaps are identified through data, clinicians would update and implement changes, monitor adoption and outcomes, and reassess performance regularly.

The second new improvement activity, IA_CC_XX, titled ''Understand and Improve Diagnostic Performance'', supports clinicians in improving patient safety by reducing diagnostic safety events and miscommunication through standardized processes for tracking

discrepancies, near-misses, and data accuracy. If issues are identified, teams would conduct root-cause analyses, implement corrective actions such as workflow changes or training, and monitor performance regularly to ensure improvement.

The third new improvement activity, IA_AHW_XX, titled ''Systematic Screening and Intervention for Nutrition and other Health-Impacting, Non-Clinical Issues'', would allow MIPS-eligible clinicians to implement standardized screening tools for nutrition, housing, transportation, and financial strain within clinical workflows. If needs are identified, clinicians would initiate referrals to appropriate community resources, track follow-up and resolution, and reassess screening processes and outcomes regularly to improve effectiveness.The fourth new improvement activity, IA_AHW_XX, titled ''Advance Care Planning Conversations to Support Patient Wellness and Care Preferences'', would allow MIPS-eligible clinicians to engage patients and caregivers in advance care planning and end-of-life discussions using structured communication tools while documenting goals of care, symptom management, and patient priorities. If care preferences or needs change, clinicians would update care preferences, coordinate across specialties, and reassess regularly to ensure alignment with the patient's goals and clinical status.

The fifth new activity, IA_AHW_XX, titled ''Clinician Use of Artificial Intelligence (AI) to Improve Patient Care'', would allow MIPS-eligible clinicians to implement and participate in organizational initiatives that improve patient care through the responsible and transparent use of artificial intelligence (AI) in clinical and operational workflows. Clinicians would establish policies for evaluating and monitoring AI tools or participate in developing and refining AI-enabled resources, such as predictive analytics, clinical decision support, and risk-stratification models, to improve patient outcomes, care-team efficiency, and population health management. Examples may include using AI tools to summarize medical literature for clinical decision-making, assist with documentation (*e.g.,* AI-generated notes with clinician review), support population health management by identifying care gaps, determine patient eligibility for clinical trials, or generate draft responses to patient questions for clinician review.

The sixth new activity, IA_AHW_XX, titled ''Lifestyle Approaches to Diabetes Remediation'', engages clinicians in delivering structured, evidence-based lifestyle interventions for diabetes management, addressing nutrition, physical activity, sleep, stress, and behavior change through programs such as; Lifestyle Empowerment Approach for Diabetes Remission (LEADR) or the Diabetes Self-Management Education and Support (DSMES). Clinicians provide education and coaching, track patient progress, and adjust interventions as needed to improve health outcomes.

See Table F–B1 in Appendix 2 for more information regarding each of these proposed new improvement activities.

We are seeking public comments on our proposals to add each of these activities to the Inventory beginning with the CY 2027 performance period/2029 MIPS payment year.

(iv) Proposals To Modify Existing Improvement Activities

We are proposing to modify five existing improvement activities beginning with the CY 2027 performance period/2029 MIPS payment year. First, IA_BMH_4 ''Depression screening'', IA_CC_8 ''Implementation of documentation improvements for practice/process improvements'', IA_CC_9 ''Implementation of practices/processes for developing regular individual care plans'', and IA_PM_4 ''Glycemic management services'' will be combined with elements of similar improvement activities in the Inventory to make their descriptions more robust. IA_BMH_4, will be combined with elements from IA_BMH_5 ''Major depressive disorder (MDD) prevention and treatment interventions''. The proposed description modification involves clinicians using a coordinated, team-based approach to screen for depression, assess suicide risk, and provide evidence-based follow-up care, with ongoing monitoring and documentation to support safe, effective management of patients.

IA_CC_8, will be combined with elements from IA_CC_10 ''Care transition documentation practice improvements'', IA_CC_11 ''Care transition standard operational improvements'', and IA_CC_12 ''Care coordination agreements that promote improvements in patient tracking across settings''. The proposed description modification promotes proactive, patient-centered care coordination across all settings by improving communication, tracking referrals and transitions, and documenting actions to ensure continuity, reduce fragmentation, and support better outcomes.

IA_CC_9 will be combined with elements from IA_BE_15 ''Engagement of Patients, Family, and Caregivers in Developing a Plan of Care''. The proposed description modification highlights creating and regularly updating individualized care plans for at-risk patients in collaboration with the patient and their family or caregivers. It emphasizes aligning care with the patient's goals, priorities, and desired outcomes while ensuring clear communication and shared understanding.

IA_PM_4, will be combined with elements from IA_PM_19 ''Glycemic Screening Services'' and IA_PM_20 ''Glycemic Referring Services''. The proposed description modification requires clinicians to attest to screening for abnormal blood glucose, referring eligible patients to prevention programs, and setting individualized glycemic goals that are regularly reassessed. Documentation must meet 60 percent in the first year and 75 percent thereafter, including patients treated for at least 90 days.

Second, IA_PSPA_16 ''Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools, including AI-enabled predictive decision-support interventions—and standardized treatment protocols to manage workflow on the care team to meet patient needs,'' would be modified to explicitly incorporate AI-enabled decision support and strengthen oversight requirements, including monitoring, root cause analysis, and mitigation of AI-related risks. The proposed description modification specifies that MIPS-eligible clinicians use interoperable, AI-enabled clinical decision support tools to guide care-team workflows and support evidence-based, patient-centered care, while also implementing safeguards for safe use, ongoing monitoring, and evaluation of tool performance and patient safety.

See Table F–B2 in Appendix 2 for more information regarding each of these proposed modifications to existing improvement activities.

We are seeking public comments on our proposals to modify each of these activities currently specified for the Inventory beginning with the CY 2027 performance period/2029 MIPS payment year.

(v) Proposals To Remove Existing Improvement Activities

Additionally, we are proposing to remove eleven previously finalized improvement activities beginning with

the CY 2027 performance period/2029 MIPS payment year: IA_BMH_5 ''MDD prevention and treatment interventions'', IA_CC_10 ''Care transition documentation practice improvements'', IA_CC_11 ''Care transition standard operational improvements'', IA_CC_12 ''Care coordination agreements that promote improvements in patient tracking across settings'', IA_PSPA_2 ''Participation in MOC Part IV'', IA_CC_16 ''Primary Care Physician and Behavioral Health Bilateral Electronic Exchange of Information for Shared Patients'', IA_BE_15 ''Engagement of Patients, Family, and Caregivers in Developing a Plan of Care'', IA_PM_19 ''Glycemic Screening Services'', IA_PM_20 ''Glycemic Referring Services'', IA_EPA_4 ''Additional improvements in access as a result of QIN/QIO TA'', and IA_PM_2 ''Anticoagulant management improvements''. We are proposing removal of these specific improvement activities in accordance with our activity removal policy set forth at § 414.1355(d). Specifically, we propose to remove each of these eleven improvement activities under Removal Factor(s) 1 or 7, which provides that we may remove an improvement activity if we determine it is duplicative of another activity (§ 414.1355(d)(1)) or the activity is obsolete (§ 414.1355(d)(7)).

Our proposal to remove IA_BMH_5, IA_CC_10, IA_CC_11, IA_CC_12, IA_BE_15, IA_PM_19, and IA_PM_20 would align with Removal Factor 1, as these activities are similar to other improvement activities in the Inventory and can be considered duplicative. Additionally, our proposal to remove IA_PSPA_2, IA_CC_16, IA_EPA_4, and IA_PM_2 would align with Removal Factor 7, as the activities are no longer relevant or useful in current clinical practice or policy and can be considered obsolete. See Table F–B3 in Appendix 2 for more information regarding our proposals to remove each of these existing improvement activities.

We are seeking public comments on our proposals to remove each of these activities from the improvement activities performance category beginning with the CY 2027 performance period/2029 MIPS payment year.

(4) MIPS Promoting Interoperability Performance Category

(a) Background

Section 1848(q)(2)(A)(iv) of the Act includes the meaningful use of certified electronic health record (EHR) technology (CEHRT) as a performance category under MIPS. We refer to this performance category as the MIPS Promoting Interoperability performance category (formerly the advancing care information performance category).

Section 1848(q)(2)(B)(iv) of the Act provides that the requirements established under section 1848(o)(2) of the Act for determining whether a MIPS eligible clinician is a meaningful EHR user also applies to our assessment of a MIPS eligible clinician's performance on measures and activities with respect to the MIPS Promoting Interoperability performance category. Section 1848(o)(2)(D) of the Act generally provides that the requirements for being a meaningful EHR user under section 1848(o)(2) continue to apply for purposes of MIPS.

Under section 1848(o)(2)(A) of the Act, a MIPS eligible clinician must meet three requirements related to the meaningful use of CEHRT during a performance period for a MIPS payment year. Specifically, under section 1848(o)(2)(A) of the Act, the MIPS eligible clinician must: (1) Demonstrate to the satisfaction of the Secretary the use of CEHRT in a meaningful manner, which shall include the use of electronic prescribing as determined to be appropriate by the Secretary; (2) Demonstrate to the satisfaction of the Secretary that their CEHRT is connected in a manner that provides, in accordance with law and standards applicable to the exchange of information, for electronic exchange of health information to improve the quality of care, such as promoting care coordination, and demonstrates (through a process specified by the Secretary), that they have not knowingly and willfully taken action (such as to disable functionality) to limit or restrict the compatibility or interoperability of the CEHRT; and (3) Use CEHRT to submit information on clinical quality measures and such other measures as selected by the Secretary.

For previously established policies regarding the MIPS Promoting Interoperability performance category, we refer readers to §§ 414.1305 (includes definitions pertaining to the MIPS Promoting Interoperability performance category), 414.1375 (MIPS Promoting Interoperability performance category provisions), and 414.1380(b)(4) (includes scoring provisions pertaining to the MIPS Promoting Interoperability performance category); and the CY 2017 Quality Payment Program final rule (81 FR 77199 through 77245), CY 2018 Quality Payment Program final rule (82 FR 53663 through 53688), CY 2019 PFS final rule (83 FR 59785 through 59820), CY 2020 PFS final rule (84 FR 62991 through 63006), CY 2021 PFS final rule (85 FR 84886 through 84895), CY 2022 PFS final rule (86 FR 65466 through 65490), CY 2023 PFS final rule (87 FR 70060 through 70087), CY 2024 PFS final rule (88 FR 79308 through 79312 and 79351 through 79365), the 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking final rule (89 FR 54662 through 54718), CY 2025 PFS final rule (89 FR 98414 through 98427), and CY 2026 PFS final rule (90 FR 49868 through 49902).

In this proposed rule, we are proposing to—

- Update the definition of CEHRT to align with ONC Health IT Certification Program proposed updates relevant to the MIPS Promoting Interoperability performance category;
- Remove the ONC Direct Review and ONC-Authorized Certification Bodies (ACB) Surveillance attestations;
- Remove the Security Risk Analysis measure;
- Add an Electronic Prior Authorization for Prescription Drugs measure; and
- Update the previously adopted Electronic Prior Authorization measure.

(b) Proposal To Modify the Definition of Certified Electronic Health Record Technology in the MIPS Promoting Interoperability Performance Category

(i) Background

In accordance with § 414.1375(b)(1), to earn a performance category score for the MIPS Promoting Interoperability performance category, a MIPS eligible clinician must be a meaningful EHR user for MIPS and use CEHRT during the performance period, as both terms are defined in § 414.1305. In the CY 2025 PFS final rule, we discussed previously finalized modifications related to the CEHRT definition for the Quality Payment Program, including for the MIPS Promoting Interoperability performance category at § 414.1305 (89 FR 98414 and 98415). Currently, we define CEHRT, for purposes of MIPS, as EHR technology (which could include multiple technologies) certified under the Office of National Coordinator for Health Information Technology's (ONC) Health Information Technology (IT) Certification Program that meets the Base EHR definition at 45 CFR 170.102 and certified as meeting additional ONC health IT certification criteria as adopted and updated in 45 CFR 170.315 as enumerated in paragraph (2)(i) of the CEHRT definition at § 414.1305, including as necessary to report on applicable measures specified for the MIPS Promoting Interoperability

performance category. In section IV.A.4.d.(4)(g)(iv) of this proposed rule, Table C–G 8 outlines the measures for the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year and the associated ONC health IT certification criteria set forth at 45 CFR 170.315 impacting the definition of CEHRT, as applicable as of the publication date of this proposed rule.

In the Health Data, Technology, and Interoperability: ASTP/ONC Deregulatory Actions to Unleash Prosperity proposed rule (90 FR 60970) (HTI–5 proposed rule) published in the **Federal Register** on December 29, 2025, ONC [377] proposed a wide-ranging set of updates to the ONC Health IT Certification Program. The HTI–5 proposed rule focuses on deregulatory actions in 45 CFR part 170 (Health Information Technology Standards, Implementation Specifications, and Certification Criteria and Certification Programs for Health Information Technology) and 45 CFR part 171 (Information Blocking). The HTI–5 proposed rule seeks to reduce burden, offer flexibility to developers and providers, and support innovation through the removal and revision of certain certification criteria and regulatory provisions. The following summarizes proposals in the HTI–5 proposed rule that are relevant to MIPS eligible clinicians.

In the HTI–5 proposed rule, ONC identified 34 certification criteria for removal and 7 certification criteria for revision. ONC stated that removing or revising these criteria would reduce burden and costs for health IT developers and clinicians, partly due to the decreased necessity to maintain ongoing conformance with certification requirements (90 FR 60973).

Table C–G 1 of this proposed rule summarizes the potential impacts the proposed removal and revisions of the ONC health IT certification criteria may have on MIPS eligible clinicians reporting the MIPS Promoting Interoperability performance category. Table C–G 1 of this proposed rule describes how the criteria subject to HTI–5 proposals are incorporated into the definition of CEHRT in § 414.1305. In addition to the ONC health IT certification criteria included in the definition of CEHRT in § 414.1305, the definition includes EHR technology certified under the ONC Health IT Certification Program that meets the Base EHR definition at 45 CFR 170.102 and technology certified to the health IT criteria necessary to report on applicable measures specified for the MIPS Promoting Interoperability performance category.

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[377] ASTP/ONC is now referred to as ONC, pursuant to a notice published in the **Federal Register** on April 1, 2026 (91 FR 16204). Although at the time of specific references noted herein, ONC was either referenced as ASTP/ONC or as ONC; for clarity, all references in this proposed rule are noted as ONC.

TABLE C-G 1 HTI-5 PROPOSED RULE PROPOSALS TO REMOVE AND REVISE ONC HEALTH IT CERTIFICATION CRITERIA THAT IMPACT THE CEHRT DEFINITION FOR THE MIPS PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY

ONC Health IT Certification Criteria as Defined in the Following Sections of Title 45 CFR 170.315	Remove/Revise	Timing	Relevance to the CEHRT Definition for the MIPS Promoting Interoperability Performance Category
Patient Demographics and Observations - (a)(5)	Revise	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Implantable Device List - (a)(14)	Remove	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Decision Support Interventions - (b)(11)	Revise	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Direct Project - (h)(1)	Remove	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Direct Project, Edge Protocol, and XDR/XDM - (h)(2)	Remove	Effective date of HTI-5 final rule.	Specified in Base EHR definition.
Family Health History - (a)(12)	Remove	Effective January 1, 2027.	Specified in CEHRT definition.
Patient Health Information Capture - (e)(3)	Remove	Effective January 1, 2027.	Specified in CEHRT definition.
Automated Numerator Recording - (g)(1)	Remove	Effective January 1, 2027.	Specified in CEHRT definition.
Automated Measure Calculation – (g)(2)	Remove	Effective January 1, 2027.	Specified in CEHRT definition.
Clinical Quality Measures – Report – (c)(3)(i)	Revise	Effective January 1, 2027.	Specified in CEHRT definition.
Clinical Quality Measures – Report – (c)(3)(ii)	Remove	Effective January 1, 2027.	Specified in CEHRT definition.
Clinical Quality Measures – Filter – (c)(4)	Remove	Effective January 1, 2027	Specified in CEHRT definition
Transitions of Care - (b)(1)	Revise	Effective January 1, 2027.	Specified criterion for the Support Electronic Referral Loops by Sending Health Information, Support Electronic Referral Loops by Receiving and Reconciling Health Information, Health Information Exchange Bi-Directional Exchange, and Enabling Exchange Under TEFCA measures.
Clinical Information Reconciliation and Incorporation - (b)(2)	Remove	Effective January 1, 2027.	Specified criterion for the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure.
View, Download, and Transmit to 3rd Party - (e)(1)	Revise	Effective date of HTI-5 final rule.	Specified criterion for the Provide Patients Electronic Access to Their Health Information measure.
Transmission to cancer registries – (f)(4)	Remove	Effective January 1, 2027	Specified criterion for the Public Health Registry Reporting measure.
Transmission to public health agencies – Electronic Case Reporting - (f)(5)	Revise	Effective date of HTI-5 final rule.	Specified criterion for the Electronic Case Reporting measure.
Transmission to public health agencies – Health Care Surveys - (f)(7)	Remove	Effective January 1, 2027.	Specified criterion for the Public Health Registry Reporting measure.
Application access — patient selection - (g)(7)	Remove	Effective January 1, 2027.	Specified criterion for the Provide Patients Electronic Access to Their Health Information and Health Information Exchange Bi-Directional Exchange measures.
Application Access – All Data Request - (g)(9)	Remove	Effective January 1, 2027.	Specified criterion for the Provide Patients Electronic Access to Their Health Information and Health Information Exchange Bi-Directional Exchange measures.

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Proposed changes in the HTI–5 proposed rule would affect ONC health IT certification criteria included in the definition of CEHRT in 42 CFR 414.1305, which applies to the MIPS Promoting Interoperability performance category in several ways. First, several ONC proposals either revise or remove certain ONC Health IT Certification Program certification criteria included within the Base EHR definition at 45 CFR 170.102, which is incorporated into the definition of CEHRT at § 414.1305. Removal of these criteria from the ONC Health IT Certification Program and the Base EHR definition would therefore remove the requirement that a MIPS eligible clinician must use CEHRT that includes health IT certified to the removed criteria Specifically, ONC proposed to remove the following ONC health IT certification criteria from the Base EHR definition at:, 45 CFR 170.315(a)(14)—''implantable device list'' (90 FR 60983), 45 CFR 170.315(h)(1)—''transport methods and

other protocols—direct project'' (90 FR 60998), and 45 CFR 170.315(h)(2)—''transport methods and other protocols—Direct Project, Edge Protocol, and XDR/XDM'' (90 FR 60999). ONC also proposed to revise the following criteria referenced in the Base EHR definition: 45 CFR 170.315(b)(1)—''transitions of care'' (90 FR 60984), 45 CFR 170.315(a)(5)—''patient demographics and observations'' (90 FR 60981 through 60982) and 45 CFR 170.315(b)(11)—''decision support interventions'' (90 FR 60986 through 60987).

Also, ONC proposed to remove the following five ONC health IT certification criteria specified in the text of the definition of CEHRT at § 414.1305. Specifically, ONC proposed to remove: 45 CFR 170.315(a)(12)—''family health history,'' 45 CFR 170.315(e)(3)—''patient health information capture,'' 45 CFR 170.315(g)(1)—''automated numerator recording,'' 45 CFR 170.315(g)(2)—''automated measure calculation,'' and 45 CFR 170.315(c)(4)—''clinical quality measures—filter'' (90 FR 60982, 60991, 60994, 60995, and 60988, respectively). Also, ONC proposed to revise 45 CFR 170.315(c)(3)—''clinical quality measures—report'' (90 FR 60988). Such ONC health IT certification criteria are discussed further in section IV.A.4.d.(4)(b)(ii) of this proposed rule.

In addition, ONC proposed to remove and/or revise other ONC health IT certification criteria that directly support certain MIPS Promoting Interoperability performance category measures. For example, ONC proposed to revise the ''transitions of care'' criterion in 45 CFR 170.315(b)(1), which supports the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures and remove the ''clinical information reconciliation and incorporation'' criterion in 45 CFR 170.315(b)(2), which supports the Support Electronic Referral Loops by Receiving and Reconciling Health Information measure (90 FR 60984). In addition, of the four ONC health IT certification criteria that are identified as supporting the Provide Patients Electronic Access to Their Health Information measure: 45 CFR 170.315(e)(1), 45 CFR 170.315(g)(7), 45 CFR 170.315(g)(9), and 45 CFR 170.315(g)(10), three are impacted by the proposals in the HTI–5 proposed rule. ONC proposed to revise 45 CFR 170.315(e)(1) (90 FR 60990 through 60991) and remove 45 CFR 170.315(g)(7) and 45 CFR 170.315(g)(9) (90 FR 60998). MIPS eligible clinicians would only need to implement the remaining heath IT certification criteria identified for the Provide Patients Electronic Access to Their Health Information measure (the revised 45 CFR 170.315(e)(1) and unaltered 45 CFR 170.315(g)(10)), if ONC finalizes such proposals. Similarly, for the Support Electronic Referral Loops by Sending Health Information and Support Electronic Referral Loops by Receiving and Reconciling Health Information measures, MIPS eligible clinicians would only need to implement the remaining ONC health IT certification criteria if applicable ONC health IT certification criteria proposed for removal are finalized as proposed in the HTI–5 proposed rule. In section IV.A.4.d.(4)(g)(iv) of this proposed rule, Table C–G 8 contains a complete list of the MIPS Promoting Interoperability performance category measures, and the applicable ONC health IT certification criteria, including the impact to individual ONC health IT certification criteria if the proposals in the HTI–5 proposed rule are finalized.

Regarding the Public Health Registry Reporting measure, ONC has proposed to remove both ONC health IT certification criteria that support the measure: 45 CFR 170.315(f)(4)—''transmission to cancer registries'' and 45 CFR 170.315(f)(7)—''transmission to public health agencies—health care surveys'' (90 FR 60992 and 60994). If the proposed removal of the ONC health IT certification criteria is finalized as proposed in the HTI–5 proposed rule, there would be no specific ONC health IT certification criteria identified for this measure. Consistent with existing policy, a MIPS eligible clinician would still be able to use any available data exchange standard specified in 45 CFR part 170 subpart B to meet the measure. For example, the transmission could be in the form of a Consolidated Clinical Document Architecture (C–CDA) as adopted in 45 CFR 170.205(a)(4), or Quality Reporting Document Architecture (QRDA) as adopted in 45 CFR 170.205(h)(2).

Regarding the Electronic Case Reporting measure, ONC proposed to revise the following health IT criterion that supports the measure: at 45 CFR 170.315(f)(5)—''transmission to public health agencies—electronic case reporting'' (90 FR 60992 through 60993). This proposal would update the ONC health IT certification criterion to focus on functional, rather than standards-based requirements. While ONC's proposal, if finalized, would revise the requirements for health IT products certified to this health IT criterion, MIPS eligible clinicians would continue to need to use health IT certified to this criterion to report the Electronic Case Reporting measure.

Also, we note that ONC proposed to remove certain ONC health IT certification criteria such as 45 CFR 170.315(g)(3)—''safety-enhanced design,'' 45 CFR 170.315(g)(4)—''quality management system,'' (90 FR 60995 through 60997), and a series of criteria related to privacy and security functionality in 45 CFR 170.315(d)(1)–(13) (90 FR 60989 and 60990), most of which are included in the Health IT Module certification requirements at 45 CFR 170.550. Such ONC health IT certification criteria represent capabilities commonly found in certified health IT products used by MIPS eligible clinicians. Furthermore, we note that the proposed removal of such health IT criteria from the ONC Health IT Certification Program would not affect a MIPS eligible clinician's obligation to ensure the privacy and safety of patient electronic health information under the Health Insurance Portability and Accountability Act of 1996 and other applicable laws. We refer readers to Table C–G 8 in section IV.A.4.d.(4)(g)(iv) of this proposed rule for a complete list of ONC health IT certification criteria that support each MIPS Promoting Interoperability performance category measure, including ONC health IT certification criteria ONC proposed to remove and/or revise. In most cases, the ONC health IT certification criteria that support measure reporting would remain part of the ONC Health IT Certification Program. For additional information regarding ONC's proposals in the HTI–5 proposed rule, we refer readers to the HTI–5 proposed rule (90 FR 60970).

(ii) Proposal To Modify the Definition of Certified Electronic Health Record Technology in the MIPS Promoting Interoperability Performance Category

Beginning with the CY 2019 performance period and subsequent performance periods, the definition of CEHRT for the MIPS Promoting Interoperability performance category in § 414.1305 requires the use of EHR technology certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to specific ONC health IT certification criteria as adopted and updated in 45 CFR 170.315. In paragraph (2)(i) of the definition of CEHRT, the definition further specifies that EHR technology must be certified to criteria for ''family health history'' (45 CFR 170.315(a)(12)) and ''patient health information

capture'' (45 CFR 170.315(e)(3)). In paragraph (2)(ii) of the definition of CEHRT, the definition specifies that EHR technology must be certified to ONC health IT certification criteria that are necessary to report on applicable objectives and measures specified for the MIPS Promoting Interoperability performance category. Paragraph (2)(ii)(A) of the definition of CEHRT includes the applicable measure calculation certification criteria at 45 CFR 170.315(g)(1) or (2) for all ONC health IT certification criteria that support an objective with a percentage-based measure. Paragraph (2)(ii)(B) includes clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii) and optionally (c)(4).

We are proposing to amend the definition of CEHRT (specified as ''Certified electronic health record technology (CEHRT)'') in § 414.1305, by modifying paragraphs (2)(i), (2)(ii)(A), and (2)(ii)(B) to align with the applicable ONC proposals to remove and revise certain ONC health IT certification criteria as proposed in the HTI–5 proposed rule. Specifically, we are proposing to remove references to the following ONC health IT certification criteria for the CY 2027 performance period/2029 MIPS payment year:

- ''family health history''—45 CFR 170.315(a)(12);
- ''patient health information capture''—45 CFR 170.315(e)(3);
- ''automated numerator recording''—45 CFR 170.315(g)(1);
- ''automated measure calculation''—45 CFR 170.315(g)(2); and
- ''clinical quality measures—filter''—45 CFR 170.315(c)(4).

If the ONC proposals to remove such ONC health IT certification criteria are finalized as proposed, the ONC health IT certification criteria at 45 CFR 170.315(a)(12), 45 CFR 170.315(e)(3), 45 CFR 170.315(g)(1), and 45 CFR 170.315(g)(2) would no longer be required and ONC health IT certification criteria at 45 CFR 170.315(c)(4) would no longer be included as an optional criterion to meet the definition of CEHRT, effective January 1, 2027. As part of this proposed modification to the definition of CEHRT, we would also specify a limited timeframe, from CY 2019 through CY 2026, for the following ONC health IT certification criteria to be included in the CEHRT definition; ''family health history'' (45 CFR 170.315(a)(12)), ''patient health information capture'' (45 CFR 170.315(e)(3)), ''automated numerator recording'' (45 CFR 170.315(g)(1)), ''automated measure calculation'' (45 CFR 170.315(g)(2), and ''clinical quality measures'' (45 CFR 170.315(c)(4)). Additionally, as part of the proposed modification to the definition of CEHRT, we would modify the reference to the ''clinical quality measures—report'' (45 CFR 170.315(c)(3)) ONC health IT certification criterion from ''(c)(3)(i) and (ii)'' to (c)(3), which would align with the proposed revisions in the HTI–5 proposed rule to modify (c)(3) to include the provision of (c)(3)(i), and remove subparagraphs (c)(3)(i) and (c)(3)(ii). Lastly, we are proposing to amend the definition of CEHRT in § 414.1305 by modifying paragraphs 2(i), (2)(i)(A), and (2)(i)(B).

While the proposal is consistent with the proposals in the HTI–5 proposed rule (90 FR 60970), we note that our proposal is not contingent upon the final actions that ONC will make regarding their proposals to remove and revise ONC health IT certification criteria as proposed in the HTI–5 proposed rule.

We believe that the longstanding presence of the ONC health IT certification criteria for ''family health history'' at 45 CFR 170.315(a)(12) and ''patient health information capture'' at 45 CFR 170.315(e)(3) in the ONC Health IT Certification Program (adopted in 2015 at 80 FR 62602 and 80 FR 62624 respectively) and their incorporation into the MIPS Promoting Interoperability performance category requirements means functionality reflected in such ONC health IT certification criteria is likely to be fully embedded in certified health IT and is widely available for use by MIPS eligible clinicians. Further, ONC anticipates that health IT developers will continue to retain such capabilities in their Health IT Modules despite the absence of ONC health IT certification criteria for such functionalities (90 FR 60982 and 60991). Such ONC health IT certification criteria are not identified as supporting any specific measures within the MIPS Promoting Interoperability performance category and as a result, we do not anticipate any modifications to the measure specifications due to the removal of these criteria from the definition.

If the ONC health IT certification criteria needed for measure calculation (''automated numerator recording'' and ''automated measure calculation'' ONC health IT certification criteria in 45 CFR 170.315(g)(1) and 45 CFR 170.315(g)(2)) is finalized for removal, then EHR technology used by MIPS eligible clinicians would not need to be certified to such two ONC health IT certification criteria in order to meet the requirement for MIPS eligible clinicians to use CEHRT; however, we anticipate that health IT developers seeking to support customers participating in the MIPS Promoting Interoperability performance category will continue to support the functionality of these criteria by reporting of numerators and denominators for certain MIPS Promoting Interoperability performance category measures, including the e-Prescribing measure and Provide Patients Electronic Access to Their Health Information measure. Removing the requirements for ONC health IT certification criteria at 45 CFR 170.315(g)(1) and 45 CFR 170.315(g)(2) from the definition of CEHRT in § 414.1305 would reduce administrative burden for health IT developers associated with testing and certifying to such functionality without impacting reporting requirements for the MIPS Promoting Interoperability performance category.

Additionally, for the optional ONC health IT certification criterion pertaining to ''clinical quality measures—filter'' in 45 CFR 170.315(c)(4), we do not believe that this criterion is a meaningful addition to the CEHRT definition for health care providers. The optional designation for this ONC health IT certification criterion has led to limited uptake while health care providers and health IT developers have indicated that this functionality is available in EHRs without relying on a regulatory requirement. Also, ONC has stated that it anticipates that health IT systems will continue to retain the clinical quality measure filtering functionality despite the absence of the ONC health IT certification criterion for such functionality (90 FR 60988).

In summary, we are proposing to amend the definition of CEHRT, specified as ''Certified electronic health record technology (CEHRT)'' in § 414.1305, by modifying paragraphs (2)(i), (2)(i)(A), and (2)(i)(B). Specifically—

- In paragraph (2)(i), we are proposing to remove for CY 2027 and subsequent years, the certification criteria for ''family health history'' (as adopted and updated at 45 CFR 170.315(a)(12)) and ''patient health information capture'' (as adopted and updated at 45 CFR 170.315(e)(3));
- In paragraph (2)(ii)(A), we are proposing to remove for CY 2027 and subsequent years, the ONC health IT certification criteria for ''automated numerator recording'' (as adopted and updated at 45 CFR 170.315(g)(1)) and ''automated measure calculation'' (as

adopted and updated at 45 CFR 170.315(g)(2)); and

• In paragraph (2)(ii)(B), we are proposing to remove for CY 2027 and subsequent years, the ONC health IT certification criterion for ''clinical quality measures—filter'' (as adopted and updated at 45 CFR 170.315(c)(4)).

The revised text would read as follows:

''Certified electronic health record technology (CEHRT) [. . .]

(2) For 2019 and subsequent years, EHR technology (which could include multiple technologies) certified under the ONC Health IT Certification Program that meets the 2015 Edition Base EHR definition, or subsequent Base EHR definition (as defined at 45 CFR 170.102) and has been certified to the ONC health IT certification criteria, as adopted and updated in 45 CFR 170.315—

(i) For CY 2019 through CY 2026, at 45 CFR 170.315(a)(12) (family health history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) Necessary to report on applicable objectives and measures specified for MIPS including the following:

(A) For CY 2019 through CY 2026, the applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3), and for CY 2019 through CY 2026, optionally (c)(4), and can be electronically accepted by CMS.''

The proposed modifications would be effective January 1, 2027, which aligns with the effective date of ONC's proposal to remove such ONC health IT certification criteria from the Code of Federal Regulations as proposed in the HTI–5 proposed rule. If our proposed modifications are finalized, a MIPS eligible clinician's EHR technology would no longer be required to meet the ONC health IT certification criteria at 45 CFR 170.315(a)(12), (e)(3), (g)(1), or (g)(2), the ONC health IT certification criteria at 45 CFR 170.315(c)(4) would no longer be included as optional in paragraph (2)(ii)(B), and paragraph (2)(ii)(B) would reference the entirety of the certification criterion at 45 CFR 170.315(c)(3) in the definition of CEHRT at 42 CFR 414.1305. All other remaining ONC health IT certification criteria included in the definition of CEHRT would continue to be a requirement for a MIPS eligible clinician's EHR technology. We note that there is a similar proposal to remove certain ONC health IT certification criteria from the definition of CEHRT for the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs) in the ''Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2027 Rates; Requirements for Quality Programs; and Other Policy Changes'' (FY 2027 IPPS/LTCH PPS) proposed rule (91 FR 19620 through 19621).

We request public comment on this proposal.

(c) Proposal To Remove ONC Direct Review and ONC-Authorized Certification Bodies (ACB) Surveillance Attestations

(i) Background

In the CY 2017 Quality Payment Program final rule, we finalized policies to support MIPS eligible clinicians in ONC health IT surveillance and direct review activities through requiring two attestations, specifically, the ONC Direct Review attestation and the ONC-Authorized Certification Bodies (ACB) Surveillance attestation (81 FR 77019 through 77027). The purpose of ONC surveillance and direct review is to provide greater assurance that health IT meets certification requirements not only in a controlled testing environment, but also when used by health care providers in actual production environments (80 FR 62707). When such attestations were finalized as requirements for the MIPS Promoting Interoperability performance category (formerly the advancing care information performance category) in the CY 2017 Quality Payment Program final rule, we intended for the attestations to complement and strengthen recent updates to ONC's ability to perform surveillance and direct review activities.

Specifically, in October 2015, ONC finalized the 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications final rule, which added requirements for ONC–ACBs to conduct more frequent and more rigorous surveillance of certified technology and capabilities in the field (80 FR 62707). Additionally, in October 2016, ONC published the ONC Health IT Certification Program: Enhanced Oversight and Accountability final rule, which established regulatory processes to facilitate ONC's direct review and evaluation of the performance of certified health IT in certain circumstances (81 FR 72406). In the CY 2017 Quality Payment Program final rule, we determined that surveillance and direct review activities provided greater assurance to health care providers that their certified EHR technology would perform in a manner that meets their expectations, but that such surveillance and direct review would not be effective unless health care providers cooperated with such activities, including by granting access to and assisting ONC–ACBs and ONC to observe the performance of production systems (81 FR 77020).

In § 414.1375(b)(3)(i)(A), we require an attestation that acknowledges the requirement to cooperate in good faith with ONC direct review of his or her health IT certified under the ONC Health IT Certification Program if a request to assist in ONC direct review is received. A MIPS eligible clinician must attest that he or she, if requested, cooperated in good faith with ONC direct review of his or her health IT certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the MIPS eligible clinician in the field. Also, we specified at § 414.1375(b)(3)(i)(B) an optional attestation that acknowledges the option to cooperate in good faith with ONC–ACB surveillance of his or her health IT certified under the ONC Health IT Certification Program if a request to assist in ONC–ACB surveillance is received. A MIPS eligible clinician may attest that he or she, if requested, cooperated in good faith with ONC–ACB surveillance of his or her health IT certified under the ONC Health IT Certification Program as authorized by 45 CFR part 170, subpart E, to the extent that such technology meets (or can be used to meet) the definition of CEHRT, including by permitting timely access to such technology and demonstrating its capabilities as implemented and used by the MIPS eligible clinician in the field.

The ONC Direct Review attestation is a required element of the MIPS Promoting Interoperability performance category. Submitting a ''Yes'' response is the only means to fulfill the requirement of the attestation. If a MIPS eligible clinician submits a ''No'' response or does not submit any

attestation for the ONC Direct Review attestation, the MIPS eligible clinician will receive a score of zero for the MIPS Promoting Interoperability performance category. The ONC–ACB Surveillance attestation is optional. A MIPS eligible clinician can submit a ''Yes'' or ''No'' response or not submit any attestation for the ONC–ACB Surveillance attestation. No scenario for the ONC–ACB Surveillance attestation would impact a MIPS eligible clinician's score for the MIPS Promoting Interoperability performance category. Scoring implications for the proposal to remove the ONC Direct Review and ONC–ACB Surveillance attestations are discussed in section IV.A.4.d.(4)(g)(ii)(A) of this proposed rule.

(ii) Proposal To Remove the ONC Direct Review and ONC–ACB Surveillance Attestations Beginning With the CY 2026 Performance Period/2028 MIPS Payment Year

We are proposing to remove the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation in § 414.1375(b)(3)(i)(A) and (B), respectively, beginning with the CY 2026 performance period/2028 MIPS payment year to reduce administrative burden. For the CY 2026 performance period, MIPS eligible clinicians would not be reporting on such attestations until the applicable submission period, which starts on January 1, 2027. Because these two attestations are reported during the applicable submission period, we have determined that it would be feasible for CMS to implement and operationalize these modifications to the MIPS Promoting Interoperability performance category requirements prior to the start of the submission period associated with the CY 2026 performance period. We continue to recognize the importance of ONC direct review and ONC–ACB surveillance activities and consider such mechanisms important for mitigating issues with health IT products that may pose serious risks to public health or safety, and we continue to collaborate with ONC to support the ONC Health IT Certification Program. As stated in the CY 2017 Quality Payment Program final rule (81 FR 77020), efforts to strengthen surveillance and direct review of certified health IT are critical to the success of HHS programs and initiatives that require the use of certified health IT to improve health care quality and the efficient delivery of care. We do not anticipate that the commitment from ONC and the ONC–ACBs toward such goals will change.

While ONC–ACB surveillance and ONC direct review activities remain important to being a user of certified health IT, we no longer consider the administrative step of attesting to cooperating and/or participating in such activities to be necessary. Since 2016 (1 year prior to the enactment of MACRA, in which the MIPS Promoting Interoperability performance category replaced the Medicare EHR Incentive Program for eligible professionals), the ONC–ACB surveillance and ONC direct review activities and processes have become known to MIPS eligible clinicians and as a result, the value of participation has become evident without dependence on an ongoing need to conduct annual attestations. Therefore, the administrative burden associated with such attestations outweighs their value compared to when they were originally adopted.

The proposal to remove the ONC Direct Review attestation and ONC–ACB Surveillance attestation aligns with the goals of reducing administrative burden while simultaneously focusing on high-value, outcome-oriented measures. Specifically, the removal of such attestations from the MIPS Promoting Interoperability performance category requirements provides an opportunity to reduce the number of discrete manual steps and reporting fields required for successful adherence to reporting requirements without diminishing the integrity or central goals of the MIPS Promoting Interoperability performance category. Although we are proposing to remove such attestations, we strongly encourage MIPS eligible clinicians to continue participating in the surveillance and direct review processes when assistance is requested by ONC or an ONC–ACB. CMS will continue to support surveillance and direct review activities as appropriate.

We are proposing to amend § 414.1375(b)(3)(i) by modifying the requirements to include a specific allotted timeframe (CY 2017 performance period/2019 MIPS payment year through CY 2025 performance period/2027 MIPS payment year) for requiring the reporting of attestations pertaining to the ONC Direct Review attestation and ONC–ACB Surveillance attestation. Specifically, we are proposing to amend § 414.1375(b)(3)(i) as follows: ''Supporting providers with the performance of CEHRT (SPPC). To engage in activities related to supporting providers with the performance of CEHRT beginning with the 2019 MIPS payment year through the 2027 MIPS payment year, the MIPS eligible clinician—. . .'' We are proposing to remove the required ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation beginning with the CY 2026 performance period/2028 MIPS payment year to reduce burden. If the proposal to remove the ONC Direct Review attestation and ONC–ACB Surveillance attestation is finalized as proposed, for the CY 2026 performance period/2028 MIPS payment year, MIPS eligible clinicians would not, in the case of the ONC Direct Review attestation, be required to report on such attestation, and in the case of the ONC–ACB Surveillance attestation, have the option of reporting on such attestation during the applicable submission period (January 1, 2027 through March 1, 2027). The proposed removal of such attestations would not affect a MIPS eligible clinician's score for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year, respectively. We note that the proposals to remove the ONC Direct Review attestation and optional ONC–ACB Surveillance attestation align with the same proposals for the Medicare Promoting Interoperability Program as proposed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19621).

We refer readers to Tables C–G 2, C–G 3, and C–G 6 in sections IV.A.4.d.(4)(g)(i) and IV.A.4.d.(4)(g)(ii)(D) of this proposed rule for information regarding the reporting requirements and scoring methodology of the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year, if the proposal to remove the ONC Direct Review attestation and ONC–ACB Surveillance attestation is finalized as proposed. We note that if the proposal is finalized as proposed, the CY 2025 performance period/2027 MIPS payment year would be the last performance period/MIPS payment year in which the ONC Direct Review attestation and ONC–ACB Surveillance attestation would be included under the MIPS Promoting Interoperability performance category.

We request public comment on these proposals.

(d) Proposal To Remove Security Risk Analysis Measure

(i) Background

The HIPAA Security Rule [378] (45 CFR part 160 and subparts A and C of part

[378] On January 6, 2025, the U.S. Department of Health and Human Services published the HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information proposed

164) contains, among other things, the administrative safeguards that covered entities and business associates (45 CFR 164.308) must implement, such as the standard and implementation specifications for security management processes. Among such safeguards are implementation specifications that require covered entities and business associates to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information (ePHI) held by the covered entity or business associate (45 CFR 164.308(a)(1)(ii)(A)). Safeguards also include implementing security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with the general requirements of the HIPAA Security Rule at 45 CFR 164.306(a).

Ensuring the privacy and security of ePHI is essential for demonstrating meaningful use of CEHRT (90 FR 49871). Since 2010, we adopted and maintained the Security Risk Analysis measure based on the HIPAA Security Rule risk analysis requirement in 45 CFR 164.308(a)(1)(ii)(A) for the Medicare EHR Incentive Program for Eligible Professionals,[379] the predecessor to the MIPS Promoting Interoperability performance category.[380] In the CY 2017 Quality Payment Program final rule (81 FR 77219 through 77220), we adopted the Protect Patient Health Information objective for the MIPS Promoting Interoperability performance category and included the Security Risk Analysis measure within this objective. We subsequently modified this measure in the CY 2019 PFS final rule (83 FR 59790) and the CY 2026 PFS final rule (90 FR 49871 through 49874).

As described in the CY 2026 PFS final rule, the MIPS Promoting Interoperability Security Risk Analysis measure requires MIPS eligible clinicians to attest ''Yes'' to having conducted security risk management and attest ''Yes'' to having conducted or reviewed a security risk analysis as required by the HIPAA Security Rule (90 FR 49870 through 49874). The scoring implications associated with the proposal to remove the Security Risk Analysis measure are discussed in section IV.A.4.d.(4)(g)(ii)(B) of this proposed rule.

(ii) Proposal To Remove the Security Risk Analysis Measure Beginning With the CY 2027 Performance Period/2029 MIPS Payment Year

We are proposing to remove the Security Risk Analysis measure beginning with the CY 2027 performance period/2029 MIPS payment year to reduce reporting burden. The HIPAA Security Rule (45 CFR part 160 and subparts A and C of part 164) contains, among other requirements, the administrative safeguards that covered entities and business associates (45 CFR 164.308) must implement, such as the standard and implementation specifications for security risk analysis and risk management processes. The administrative safeguards also require implementation of security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with the general requirements of the HIPAA Security Rule at 45 CFR 164.306.

Given that MIPS eligible clinicians are covered entities under the HIPAA Security Rule and the requirements of the Security Risk Analysis measure derive from the HIPAA Security Rule requirements, removal of the Security Risk Analysis measure will not weaken any cybersecurity requirements for MIPS eligible clinicians. When the Security Risk Analysis measure was adopted in the CY 2017 Quality Payment Program final rule, we determined that requiring an attestation regarding HIPAA Security Rule requirements promoted awareness of these requirements among MIPS eligible clinicians (81 FR 77219 through 77220).

However, we have considered the ongoing applicability of the measure given its longstanding presence in the MIPS Promoting Interoperability performance category and the established awareness of HIPAA Security Rule requirements among MIPS eligible clinicians. In assessing whether it remains appropriate to maintain the Security Risk Analysis measure from the MIPS Promoting Interoperability performance category, we considered the extent to which the measure continues to advance its goals relative to the costs associated with its continued use. We believe these costs include not only the burden associated with reporting the requisite attestations, but also the costs associated with administering and maintaining the measure within the program. These costs may include but are not limited to the following: clinician burden associated with information collection and submission; clinician burden associated with complying with overlapping programmatic and regulatory requirements, including the HIPAA Security Rule; and CMS resources associated with oversight, maintenance, education, and operational support for the measure. In the case of the Security Risk Analysis measure, because the underlying security risk analysis and risk management activities are already required under the HIPAA Security Rule, we believe it may be unnecessarily costly and of limited incremental benefit to retain this measure where its continued inclusion no longer meaningfully advances the objectives of the MIPS Promoting Interoperability performance category beyond the separate regulatory requirements that already apply. For these reasons, we believe removal of the Security Risk Analysis measure at this time would balance the goals of reducing unnecessary administrative burden, maintaining a parsimonious and meaningful measure set, and preserving the focus of the MIPS Promoting Interoperability performance category on high-value measures that more directly support program objectives.

This proposal aligns with our goals of reducing administrative burden while simultaneously focusing on high-value, outcome-oriented measures. Specifically, the removal of the Security Risk Analysis measure from the MIPS Promoting Interoperability performance category provides an opportunity to reduce the number of discrete manual steps and reporting fields required for successful adherence to reporting requirements without diminishing the integrity or central goals of the MIPS Promoting Interoperability performance category. Although we are proposing to remove the Security Risk Analysis measure, we remind MIPS eligible clinicians to continue to conduct security risk analysis and security risk management to safeguard ePHI as required under the HIPAA Security Rule. We anticipate that MIPS eligible clinicians will continue to conduct security risk analysis and security risk management activities to comply with the requirements pertaining to the security of data created and maintained

rule (90 FR 898). The proposed rule has not been finalized as of the publication of this proposed rule.

[379] Medicare and Medicaid Programs: Electronic Health Record Incentive Program final rule (75 FR 44368 and 44369); established at 42 CFR 495.6(d)(15)(ii).

[380] Section 101(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) sunset the Medicare EHR Incentive Program for Eligible Professionals, set forth at section 1848(o) of the Act. As discussed previously, section 1848(o)(2) of the Act has been incorporated into the MIPS Promoting Interoperability performance category's requirements via section 1848(q)(2)(B)(iv) of the Act. *See* CY 2017 Quality Payment Program final rule (81 FR 77018 and 77019) for more information regarding the sunsetting of the Medicare EHR Incentive Program for Eligible Professionals.

by CEHRT in accordance with the HIPAA Security Rule.

Retirement of the Security Risk Analysis measure from the MIPS Promoting Interoperability performance category beginning with the CY 2027 performance period/2029 MIPS payment year would reduce burden by removing the attestation requirement and supporting a more parsimonious and outcomes-oriented measure set. Specifically, we propose in § 414.1375(b)(2)(ii)(A) to specify a limited timeframe, through the 2028 MIPS payment year for which a MIPS eligible clinician would be required to report that they completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs.

We refer readers to Tables C–G 2, C–G 4, C–G 6 and C–G 8 in sections IV.A.4.d.(4)(g)(i), IV.A.4.d.(4)(g)(ii)(D), and IV.A.4.d.(4)(g)(iv) of this proposed rule for more information regarding the reporting requirements and scoring methodology of the MIPS Promoting Interoperability performance category starting with the CY 2027 performance period/2029 MIPS payment year, which is contingent upon the finalization of the proposal to remove the Security Risk Analysis measure.

We request public comment on this proposal.

(e) Proposal To Adopt a New Electronic Prior Authorization for Prescription Drugs Measure Beginning With the CY 2028 Performance Period/2030 MIPS Payment Year

(i) Background

Under section 1848(o)(2)(A) of the Act, the MIPS Promoting Interoperability performance category assesses whether MIPS eligible clinicians use CEHRT in a meaningful manner. By statute, such demonstration includes the use of electronic prescribing as determined to be appropriate by the Secretary. The MIPS Promoting Interoperability performance category has therefore included measures related to electronic prescribing since its inception (75 FR 44337; and 81 FR 77229 through 77237). Separately from the MIPS Promoting Interoperability performance category, we have also advanced the adoption of electronic prescribing through authority under section 1860D–4(e) of the Act, which requires that prescriptions for covered Medicare Part D drugs transmitted electronically comply with a uniform transaction standard specified by CMS. Under the same authority under section 1860D–4(e) of the Act, we also generally require that Schedule II, III, IV, and V controlled substances under Medicare Part D and Medicare Advantage prescription drug plans be prescribed electronically in accordance with an electronic prescription drug program. That required standard includes transactions for the electronic prior authorization of Part D-covered drugs prescribed to Part D-eligible individuals (85 FR 86827 through 86832 and 89 FR 51242 through 51247).

Historically, the ONC Health IT Certification Program and the Part D Program have maintained complementary policies of aligning ONC health IT certification criteria and associated standards related to electronic prescribing, medication history, and electronic prior authorization for prescriptions (89 FR 51257). In successive rules supporting the ONC Health IT Certification Program, ONC has adopted the National Council for Prescription Drugs Program (NCPDP) SCRIPT standard as the required exchange standard for the electronic prescribing certification criterion at 45 CFR 170.315(b)(3). In the ''Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications'' final rule (89 FR 51242 through 51247), the Part D Program finalized at § 423.160(b)(1) the requirement that Part D sponsors, prescribers and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, must comply with the standard in 45 CFR 170.205(b). Taken in conjunction with the standards and expiration date adopted by ONC in the same rule (89 FR 51258 through 51259), § 423.160(b)(1) will require Part D sponsors, prescribers and dispensers to use NCPDP SCRIPT standard version 2023011, which ONC adopted at 45 CFR 170.205(b)(2), beginning January 1, 2028, and expire NCPDP SCRIPT standard version 2017071, which ONC previously adopted at 45 CFR 170.205(b)(1) as of January 1, 2028. The NCPDP SCRIPT standard version 2023011 includes enhancements to support electronic prescribing and transmission of prescription-related and electronic prior authorization information.

On April 14, 2026, the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability Standards and Prior Authorization for Drugs for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, and Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges'' (2026 CMS Interoperability Standards and Prior Authorization for Drugs) proposed rule was published and introduced proposals that require Medicare Advantage organizations, state Medicaid and CHIP FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plans offered on the Federally-facilitated Exchanges (collectively ''impacted payers'') to support certain exchange standards for the electronic prior authorization of prescription drugs (91 FR 19890). We proposed that, beginning on October 1, 2027, impacted payers be required to support electronic prior authorization for all drugs that require prior authorization. Two separate sets of standards were proposed for payers to facilitate electronic prior authorization for drugs: three NCPDP standards (NCPDP SCRIPT Standard©, NCPDP Formulary and Benefit (F&B) Standard©, and NCPDP Real-Time Prescription Benefit (RTPB) Standard©) for prescription drugs covered under a pharmacy benefit; and six Fast Healthcare Interoperability Resources® (FHIR®) standards including the HL7 FHIR Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide (IG), the HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) IG, the HL7 FHIR Da Vinci—Prior Authorization Support (PAS) IG) for prescription drugs covered under a medical benefit.

Concurrent with other CMS efforts to promote standards adoption in electronic prior authorization, the MIPS Promoting Interoperability performance category has placed increasing emphasis on prior authorization through its adoption of the Electronic Prior Authorization measure (89 FR 8909) as established in the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program'' (2024 CMS Interoperability and Prior Authorization) final rule. The Electronic Prior Authorization measure assesses

MIPS eligible clinicians on the use of a Prior Authorization application programming interface (API) to request prior authorization for medical items and services. However, the measure does not assess the use of electronic prior authorization for prescription drugs, in part because the Prior Authorization API requirements finalized in the 2024 CMS Interoperability and Prior Authorization final rule excluded prescription drugs (89 FR 8918).

(ii) Proposal To Adopt Electronic Prior Authorization for Prescription Drugs Measure

Across the healthcare industry, a majority of prior authorizations for prescription drugs covered under a pharmacy benefit remain a separate manual process outside of the EHR workflow, not connected to e-prescribing, and could cause major points of friction and delay in the prescribing and prior authorization workflow. In 2023, approximately 38 percent of prescription drug prior authorizations were fully electronic and 15 percent were fully manual, indicating continuing capacity for improvement in the domain.[381] This current level of adoption of electronic prior authorization for prescription drugs contributes to a reliance on payer portals and manual processes, including processes based on phone, or fax, which are entirely outside the EHR and that may delay patients' access to needed medications, increase administrative complexity for clinicians and staff, and undermine the efficiency and clinical value of electronic prescribing. As more payers support standardized electronic prior authorization, we have determined that measuring the use of prior authorization for prescription drugs would be a valuable addition to our assessment of meaningful use of CEHRT under the MIPS Promoting Interoperability performance category. Standards-based electronic prior authorization should improve timeliness and transparency of medication access by facilitating document-gathering and tracking of prior authorization status within clinician EHR workflows to support care coordination and help close the prescriber-to-dispenser loop. Thus, we believe that incorporating electronic prior authorization for prescription drugs is an appropriate aspect of demonstrating meaningful use of CEHRT by MIPS eligible clinicians.

Action in this area is further supported by longstanding efforts to promote standards adoption for prescription-related transactions under the Part D Program and the ONC Health IT Certification Program. As previously noted, CMS and ONC have maintained complementary policies aligning electronic prescribing and prescription-related standards at 42 CFR 423.160(b)(1) for Part D transactions and 45 CFR 170.315(b)(3) for the ONC Health IT Certification Program. Health IT developers also have experience with the underlying transaction standards because of their use in Part D transactions. Therefore, we believe that MIPS eligible clinicians and their health IT vendors have a foundation to implement the functionality for a new measure we are proposing in this proposed rule, the Electronic Prior Authorization for Prescription Drugs measure.

We are proposing to adopt a new measure, Electronic Prior Authorization for Prescription Drugs, for the MIPS Promoting Interoperability performance category beginning with the CY 2028 performance period/2030 MIPS payment year. We intend for the new Electronic Prior Authorization for Prescription Drugs measure to be included in the Health Information Exchange objective for the MIPS Promoting Interoperability performance category to emphasize the role of prior authorization in promoting care coordination and collocate the new measure in the same objective as the previously adopted Electronic Prior Authorization measure. The new Electronic Prior Authorization for Prescription Drugs measure aims to assess a MIPS eligible clinician's utilization of standards-based electronic prior authorization. We are proposing the specifications of the Electronic Prior Authorization for Prescription Drugs measure to be as follows:

- *Measure Description:* For at least one prescription drug ordered by the MIPS eligible clinician during the performance period for which prior authorization is required, the prior authorization is requested electronically using CEHRT.
- *Reporting Requirements:* ''Yes''/''No'' response.
- *Exclusion:* Any MIPS eligible clinician who—

++ Does not prescribe drugs that require prior authorization during the applicable performance period;

++ Only prescribes drugs requiring prior authorization where the payer does not support the specified electronic prior authorization standard during the applicable performance period; or

++ Prescribes fewer than 100 permissible prescription drugs during the performance period.

We note that the last exclusion matches an exclusion in the Electronic Prescribing measure. For this exclusion, ''permissible prescriptions'' means all drugs that meet the current definition of a prescription as ordered by a MIPS eligible clinician to dispense a drug that would not be dispensed without such order. ''Permissible prescriptions'' may include electronic prescriptions of controlled substances where creation of an electronic prescription for the medication is feasible using CEHRT and where allowable by state and local law. Additionally, for purposes of this exclusion, permissible prescriptions include any prescription, not only those requiring prior authorization. To successfully report this measure, MIPS eligible clinicians must submit a ''Yes'' response, in which they are affirmatively attesting to having requested prior authorization electronically using CEHRT for at least one prescription drug ordered by the MIPS eligible clinician during the performance period or (if applicable) claim an exclusion. We expect that once a MIPS eligible clinician has the capability of requesting prior authorization electronically, that MIPS eligible clinician would do so more frequently, though we are not proposing to measure frequency of use at this time with this initial version of the measure. The new measure would apply to prescription drugs covered under a pharmacy benefit, as functionally defined by whether prior authorization can be requested for the drug can be authorized using the NCPDP SCRIPT standard.

The proposal to use CEHRT for this measure would require use of health IT certified to the ONC health IT certification criteria at 45 CFR 170.315(b)(3)—''Electronic prescribing'' and at 45 CFR 170.315(b)(4)—''Real-time prescription benefit'' to support any electronic prior authorization requests used to satisfy this measure. Use of both ''electronic prescribing'' and ''real-time prescription benefit'' certification criteria ensures that MIPS eligible clinicians use standards-based capabilities within their health IT systems to successfully complete the measure. Beginning January 1, 2028, the specified standards within the certification criteria in 45 CFR 170.315(b)(3) and 45 CFR 170.315(b)(4) would be the same versions of the NCPDP SCRIPT Standard and NCPDP

[381] For more information, see: *https://www.caqh.org/hubfs/Issue%20Briefs/CAQH_Insights_NCPDP_SCRIPT_Issue_Brief.pdf.*

RTPB Standard, respectively, required for Medicare Part D sponsors and proposed to be required for other impacted payers in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 19925 through 19927). For purposes of the proposed new Electronic Prior Authorization for Prescription Drugs measure, ''requested electronically'' means initiating and submitting an electronic prior authorization request from within CEHRT using health IT certified under 45 CFR 170.315(b)(3) and 45 CFR 170.315(b)(4). Using health IT certified to the ''real-time prescription benefit'' criterion in 45 CFR 170.315(b)(4) allows a MIPS eligible clinician to ascertain the patient-specific out-of-pocket cost of a prescription drug, the cost of suitable alternatives, compare prescription costs at different pharmacies, and learn whether prior authorization for a specific prescription drug is required.

The 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule also proposed that impacted payers support the NCPDP F&B standard (91 FR 19926). We are not including this standard as part of required CEHRT for this measure at this juncture. However, we believe that the NCPDP F&B standard complements the NCPDP SCRIPT and RTPB standards certification criteria for Health IT Modules in 45 CFR 170.315(b)(3) and 45 CFR 170.315(b)(4), respectively, and we encourage MIPS eligible clinicians to use the F&B standard functions within their EHRs as part of an electronic prior authorization workflow as well.

We note that adoption of the new Electronic Prior Authorization for Prescription Drugs measure is not contingent upon the finalization of the proposals in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule. We note the proposed new Electronic Prior Authorization for Prescription Drugs measure includes an exclusion for cases in which no applicable payer supports the specified electronic prior authorization standard.

Electronic prior authorization requests for prescription drugs covered under a pharmacy benefit, which would leverage the NCPDP SCRIPT Standard and NCPDP RTPB Standard, are often for those prescription drugs dispensed at a retail pharmacy. We recognize that other prescription drugs may be covered under a medical benefit and are usually administered or dispensed by a medical provider in a health care setting. Those drugs covered under a medical benefit generally use FHIR-based electronic prior authorization processes, such as those supported by the Da Vinci CRD, DTR, and PAS implementation guides finalized under ONC health IT certification criteria, and therefore are not in scope for the proposed new Electronic Prior Authorization for Prescription Drugs measure. A MIPS eligible clinician that only needs prior authorization for prescription drugs covered under a medical benefit and not a pharmacy benefit would be eligible to claim an exclusion for not ordering an applicable prescription drug during the performance period.

For purposes of the new Electronic Prior Authorization for Prescription Drugs measure, ''one prescription drug ordered by the MIPS eligible clinician'' includes a new prescription and, where applicable, a prescription renewal or refill request that generates a prior authorization requirement at the time of prescribing. A prescription drug ''for which prior authorization is required'' is one for which the applicable payer rules indicate a prior authorization requirement at the point of prescribing for the patient and plan. We believe the NCPDP F&B Standard would help inform MIPS eligible clinicians when a prior authorization is required or not, even if not a mandate of the Electronic Prior Authorization for Prescription Drugs measure. We recognize that coverage for certain prescription drugs may fall under either the pharmacy or medical benefit and we will continue to consider future policies to reduce workflow fragmentation across prior authorization approaches. In section IV.A.4.d.(4)(f)(vii) of this proposed rule, we request public comment on the potential to expand the scope of the Electronic Prior Authorization to include prescription drugs covered under a medical benefit.

We are proposing that the Electronic Prior Authorization for Prescription Drugs measure would require an attestation of ''Yes'' or ''No'' response from a MIPS eligible clinician. Starting with the CY 2028 performance period/2030 MIPS payment year and subsequent years for MIPS eligible clinicians, a MIPS eligible clinician would be required to submit a ''Yes'' response for the measure or claim an applicable exclusion in order to earn a score for the MIPS Promoting Interoperability performance category. If a MIPS eligible clinician submits a ''No'' response, fails to submit any attestation, or does not claim an applicable exclusion for the Electronic Prior Authorization for Prescription Drugs measure, the MIPS eligible clinician would receive a score of zero for the MIPS Promoting Interoperability performance category (weighted at 25 percent of the MIPS final score), and would not be considered a meaningful EHR user for purposes of the MIPS Promoting Interoperability performance category for an applicable performance period. We refer readers to Tables C–G 2, C–G 5, C–G 6, and C–G 8 in sections IV.A.4.d.(4)(g)(i), IV.A.4.d.(4)(g)(ii)(D), and IV.A.4.d.(4)(g)(iv) of this proposed rule for information regarding the reporting requirements and scoring methodology of the MIPS Promoting Interoperability performance category, which is contingent upon the finalization of the proposal to adopt the new Electronic Prior Authorization for Prescription Drugs measure.

We propose that this measure would initially require an attestation of a ''Yes'' or ''No'' response to allow MIPS eligible clinicians to gain familiarity with electronic prior authorization for prescription drugs and measure reporting. We anticipate a future conversion of the Electronic Prior Authorization for Prescription Drugs measure to numerator/denominator reporting once standardized data capture and reporting have further progressed. We would monitor the measure's feasibility and consider updates, including volume-based thresholds or rate-based scoring, to ensure the measure reflects meaningful use at scale.

We request public comment on these proposals.

(f) Proposal To Modify the Electronic Prior Authorization Measure

(i) Background

In the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we adopted the Electronic Prior Authorization measure under the Health Information Exchange objective in the MIPS Promoting Interoperability performance category. We finalized that MIPS eligible clinicians would be required to attest to the Electronic Prior Authorization measure beginning with the CY 2027 performance period/2029 MIPS payment year (89 FR 8910); and subsequently, once the measure would become effective as a required measure in the MIPS Promoting Interoperability performance category, MIPS eligible clinicians would be required to satisfactorily report on the measure (and meet the other reporting requirements) in order to earn a score for the MIPS Promoting Interoperability performance category. For purposes of the Electronic Prior Authorization measure, a prior authorization request would need to be made using a Prior Authorization API using data from CEHRT to submit a

''Yes'' response for the measure, unless a MIPS eligible clinician claims an applicable exclusion. We finalized the following measure description for the Electronic Prior Authorization measure (89 FR 8916):

For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the prior authorization is requested electronically from a Prior Authorization API using data from CEHRT.

Exclusions: Any MIPS eligible clinician who:

(1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance period; or

(2) Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets CMS's Prior Authorization API requirements during the applicable performance period.

In addition to becoming a required measure beginning with the CY 2027 performance period/2029 MIPS payment year, we finalized that the Electronic Prior Authorization measure would not be scored (that is, not assigned points for successful completion) for the CY 2027 performance period/2029 MIPS payment year. For the MIPS Promoting Interoperability performance category, satisfactory performance on the Electronic Prior Authorization measure can be demonstrated only by submitting a ''Yes'' response to affirmatively attest to the measure or by claiming an applicable exclusion. MIPS eligible clinicians who submit a ''No'' response, fail to submit any attestation response, or do not claim an applicable exclusion for the Electronic Prior Authorization measure will receive a score of zero for the MIPS Promoting Interoperability performance category (weighted at 25 percent of the MIPS final score), and will not be considered a meaningful EHR user for purposes of the MIPS Promoting Interoperability performance category for the applicable performance period (89 FR 8911).

The 2024 CMS Interoperability and Prior Authorization final rule also finalized that Medicare Advantage plans, state Medicaid Fee-for-service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plans (QHP) issuers on the Federally-Facilitated Exchange (collectively referred to as ''impacted payers'') must implement and maintain a Prior Authorization API beginning in CY 2027. The compliance date is January 1, 2027, for MA organizations and state Medicaid and CHIP FFS programs; by the first rating period beginning on or after January 1, 2027 for Medicaid managed care plans and CHIP managed care entities; and for plan years beginning on or after January 1, 2027, for individual market QHP issuers on the FFEs (89 FR 8759 through 8760). In that rule, we recommended, rather than required, specific FHIR Implementation Guides (IGs) to support the APIs (89 FR 8937).

In the Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule (HTI–4 final rule), which was published as part of the FY 2026 IPPS/LTCH PPS final rule (90 FR 37164 through 37182), ONC finalized three ONC health IT certification criteria for electronic prior authorization:

- ''Provider prior authorization API—coverage requirements discovery'' in 45 CFR 170.315(g)(31);
- ''Provider prior authorization API—documentation templates and rules'' in 45 CFR 170.315(g)(32); and
- ''Provider prior authorization API—prior authorization support'' in 45 CFR 170.315(g)(33).

These certification criteria are based on three IGs developed by the HL7 Da Vinci project which ONC adopted in the HTI–4 final rule [382] at 45 CFR 170.215(j)(1), (2), and (3)—

- HL7® FHIR® Da Vinci—Coverage Requirements Discovery (CRD) IG;
- HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) IG; and
- HL7 FHIR Da Vinci—Prior Authorization Support (PAS) IG.

Together, these ONC health IT certification criteria can enable electronic prior authorization for healthcare providers. We refer readers to the HTI–4 final rule (90 FR 37162 through 37175) for more information regarding ONC's finalized certification criteria at 45 CFR 170.315(g)(31) through (33) and section XI.B.4.b. of the HTI–4 final rule (90 FR 36541 through 36542) for a summary of all ONC finalized policies.

In the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, we proposed to require impacted payers to implement and maintain Prior Authorization APIs that conform to the CRD, DTR, and PAS IGs adopted by ONC on behalf of the Secretary at 45 CFR 170.215(j)(1), (2), and (3). We proposed compliance dates for impacted payers to conform to the proposed standards and IGs beginning October 1, 2027 (however, impacted payers must still implement Prior Authorization APIs beginning in CY 2027). Finally, in section II.J.6 of the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule (91 FR 20002), ONC proposed to adopt updated versions of the CRD, DTR, and PAS IGs. If finalized, these proposed updated versions will enable payers and health IT developers to implement Prior Authorization APIs and Health IT Modules conforming to the finalized ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33) to utilize the latest versions of these specifications.

The 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule includes proposals for impacted payers to implement and maintain Prior Authorization APIs using the CRD, DTR, and PAS IGs. Those proposals, along with the provisions ONC finalized in the HTI–4 final rule to adopt the CRD, DTR, and PAS IGs and establish electronic prior authorization certification criteria for health IT developers, collectively support the Electronic Prior Authorization measure for MIPS eligible clinicians and advance interoperability by applying consistent standards across HHS programs. We refer readers to the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule and the HTI–4 final rule (90 FR 37169) for more information regarding the three ONC health IT certification criteria to support electronic prior authorization at 45 CFR 170.315(g)(31), (32), and (33).

(ii) Proposal To Modify the Electronic Prior Authorization Measure for the CY 2027 Performance Period/2029 MIPS Payment Year

We are proposing to amend the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year by modifying the measure description.

Specifically, the new measure description would be: For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT.

For the proposed modification to the measure description, we are amending the phrase from ''using data from CEHRT'' to ''using CEHRT'' to clarify that MIPS eligible clinicians must use certified Health IT modules where

[382] In the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, ONC has proposed updated versions of such Implementation Guides (91 FR 19910 and 19911).

necessary to support the electronic prior authorization processes specified in this measure. When we adopted the Electronic Prior Authorization measure, we did not identify specific ONC health IT certification criteria required to complete the actions specified in the measure (89 FR 8910 through 8915). We stated that gathering structured data from CEHRT would be achievable without additional certification criteria (89 FR 8925) that had not been proposed or finalized at the time of the 2024 CMS Interoperability and Prior Authorization final rule. The proposed update to the measure description to require that a prior authorization be requested electronically ''using CEHRT'' is consistent with the availability of certified Health IT Modules that must be used to complete the action specified in the Electronic Prior Authorization measure. At this juncture, we are not proposing to modify the exclusion criteria that were finalized when we adopted the Electronic Prior Authorization measure (89 FR 8916). The proposal to amend the Electronic Prior Authorization measure by modifying the measure description for the CY 2027 performance period/2029 MIPS payment year aligns with the same proposal for the Medicare Promoting Interoperability Program as proposed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19621).

We request public comment on this proposal.

(iii) Proposal To Modify the Electronic Prior Authorization Measure Beginning With the CY 2028 Performance Period/2030 MIPS Payment Year

We are proposing to amend the Electronic Prior Authorization measure description beginning with the CY 2028 performance period/2030 MIPS payment year to include a complete set of actions necessary to support robust prior authorization and require use of Health IT modules certified to the ONC health IT certification criteria at 45 CFR 170.315(g)(31),[383] (32),[384] and (33) [385] as part of the measure requirements. We are proposing to update the measure in order to take a step-wise approach to the certified health IT capabilities necessary to complete the measure and ensure that MIPS eligible clinicians continue to progress towards adoption of capabilities necessary to fully support electronic prior authorization.

Specifically, we are proposing to modify the measure description as follows beginning with the CY 2028 performance period/2030 MIPS payment year: For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the MIPS eligible clinician uses CEHRT to electronically request and receive coverage requirements, request and populate prior authorization documentation using templates and rules, submit the prior authorization request, and receive the payer response through a provider Prior Authorization API.

We are proposing to modify the measure description to explicitly delineate the requirement to use ONC health IT certification criteria for the Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year. We propose to modify the measure description to specify the following actions required for meeting the requirement of the measure: ''electronically request and receive coverage requirements,'' ''request and populate prior authorization documentation using templates and rules,'' ''submit the prior authorization request,'' and ''receive the payer response'' (does not require the approval of the prior authorization request by the payer, but does require that the MIPS eligible clinician receive a prior authorization decision or determination response from the payer) to reflect the specific capabilities supported by Health IT Modules certified to the ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33). We note that we would interpret this requirement to mean that each of these specific actions should occur within the same prior authorization request.

We request public comment on this proposal.

(iv) ONC Health IT Certification Criteria To Support the Electronic Prior Authorization Measure

If the proposal to require that an electronic prior authorization must be requested using CEHRT to satisfy the Electronic Prior Authorization measure is finalized, we would require MIPS eligible clinicians to use Health IT Modules certified to the ONC health IT certification criteria in 45 CFR 170.315(g)(31), (32), and/or (33) as finalized in the HTI–4 final rule. Specifically, for the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians would be required to use CEHRT for electronic prior authorization requests that includes the utilization of one, or more than one, Health IT Modules certified to the ONC health IT certification criteria in 45 CFR 170.315(g)(31), (32), or (33) to meet the requirements of the Electronic Prior Authorization measure. Beginning with the CY 2028 performance period/2030 MIPS payment year, MIPS eligible clinicians would be required to use CEHRT for electronic prior authorization requests that includes the utilization of all three Health IT Modules certified to the ONC health IT certification criteria in 45 CFR 170.315(g)(31), (32), and (33) to meet the requirements of the Electronic Prior Authorization measure. Using certified health IT to support these electronic prior authorization transactions ensures that MIPS eligible clinicians have standards-based capabilities within their health IT systems to interact with Prior Authorization APIs impacted payers are required to implement and maintain.

Specifically, the three criteria at 45 CFR 170.315(g)(31), (32), and (33) are based on the HL7 Da Vinci CRD, DTR, and PAS IGs, and address different parts of the electronic prior authorization workflow. The ''provider prior authorization API—coverage requirements discovery'' in 45 CFR 170.315(g)(31) enables a healthcare provider to request information from payers about coverage requirements. Where further information is needed to support a prior authorization request, the ''provider prior authorization API—documentation templates and rules'' criterion in 45 CFR 170.315(g)(32) provides a mechanism for providers to assemble the documentation needed to support a prior authorization request according to a payer's requirements. Finally, the ''provider prior authorization API—prior authorization support'' in 45 CFR 170.315(g)(33) enables submission of prior authorization requests from health IT systems as well as to check the status of a previously submitted request. By finalizing each component of the workflow as a separate ONC health IT certification criterion, ONC sought to support a more dynamic health IT marketplace in which a health IT developer could develop Health IT Modules demonstrating conformance to all three IGs or focus on a specific element or elements (90 FR 37169).

For the CY 2027 performance period/2029 MIPS payment year, we are proposing modifications to the Electronic Prior Authorization measure

[383] *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-C/section-170.315#p-170.315(g)(31).*

[384] *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-C/section-170.315#p-170.315(g)(32).*

[385] *https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-D/part-170/subpart-C/section-170.315#p-170.315(g)(33).*

in section IV.A.4.d.(4)(f)(ii) of this proposed rule such that a MIPS eligible clinician could submit a ''Yes'' response, in which they are affirmatively attesting to the measure, if a ''prior authorization is requested electronically through a Prior Authorization API using CEHRT.'' Different prior authorization scenarios that allow a MIPS eligible clinician to successfully attest to the measure, as proposed for CY 2027 performance period/2029 MIPS payment year, may require the functionality of one, or more than one, Health IT Modules certified to the criteria in 45 CFR 170.315(g)(31), (32), and (33). For instance, a MIPS eligible clinician could successfully report on the measure for the CY 2027 performance period/2029 MIPS payment year using CEHRT that includes a Health IT Module that is only certified to the ''provider prior authorization API—coverage requirements discovery'' criterion in 45 CFR 170.315(g)(31), but not to the ONC health IT certification criteria at 45 CFR 170.315(g)(32) or (33).

Consider an example in which a patient is a Medicare Advantage (MA) enrollee who has stable coronary artery disease and new exertional dyspnea (feeling shortness of breath during physical exertion). The patient's cardiologist wants to order an outpatient transthoracic echocardiogram (TTE) to assess left ventricular function and valvular disease. When the cardiologist places an order for a TTE in the EHR, a Health IT Module certified to the ''provider prior authorization API—coverage requirements discovery'' criterion (45 CFR 170.315(g)(31)) automatically sends a real-time query to the patient's MA plan endpoint to determine whether prior authorization is required for the requested service (the TTE) and, if so, what documentation is needed. The MA plan returns a CRD response (via CDS Hooks ''card'') indicating that prior authorization is necessary and has been approved under the beneficiary's plan benefits and network status, including information such as the prior authorization number and assumed billing codes.

In this first example, the prior authorization request is satisfied using only the capabilities represented with the ''provider prior authorization API—coverage requirements discovery'' (45 CFR 170.315(g)(31)). The MIPS eligible clinician submitted a query for prior authorization, the payer responded that prior authorization was required, the prior authorization was approved, and the MIPS eligible clinician received a response indicating this approval from the payer through the payer's Prior Authorization API. In this case, the receipt of an approval indicates that the MIPS eligible clinician effectively submitted a request for prior authorization, consistent with the requirements of the Electronic Prior Authorization measure. Conversely, if the MIPS eligible clinician receives a response that no prior authorization is required, that query would not fulfill the requirements of the measure. Also, we considered whether the allowance of using CEHRT to conduct a check to determine if an item or service requires prior authorization should be able to satisfy the measure when the MIPS eligible clinician successfully submits a prior authorization coverage requirements determination query, regardless of whether the payer's response indicates that prior authorization is required. We request comment on whether such additional flexibility would benefit MIPS eligible clinicians.

Based on feedback we have received from implementers about their likely approach to phasing in electronic prior authorization capabilities, we expect that the use of health IT certified to the ''provider prior authorization API—coverage requirements discovery'' (45 CFR 170.315(g)(31)), as described in the example above, may be a common approach for the CY 2027 performance period/2029 MIPS payment year. However, we note that under the approach to use certified Health IT Modules for the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year as described in this proposed rule, there could be additional scenarios that would qualify for the measure in which a MIPS eligible clinician uses only the certified Health IT Module in 45 CFR 170.315(g)(32) or (g)(33) as part of the workflow for submitting a prior authorization request.

For the following second example, the case illustrates a prior authorization workflow that would meet the requirements of the Electronic Prior Authorization measure as proposed for the CY 2027 performance period/2029 MIPS payment year and also meet the more stringent requirements for the measure proposed beginning with the CY 2028 performance period/2030 MIPS payment year, as described in section IV.A.4.d.(4)(f)(iii) of this proposed rule, when all three certified Health IT Modules in 45 CFR 170.315(g)(31), (32) and (33) would be required. The initial prior authorization query from a MIPS eligible clinician to a payer could result in a response indicating the need for additional information before a determination as to whether prior authorization is approved or denied can be provided, based on the coverage requirements identified. Additional certified Health IT Modules supporting additional elements of the electronic prior authorization workflow would then need to be used to submit the prior authorization request after collecting the necessary documentation.

Consider an example in which the patient is an MA enrollee who has been diagnosed with metastatic colorectal cancer. The patient's oncologist has ordered a PET–CT scan and immunotherapy infusion. The oncologist places the order for a PET–CT scan and immunotherapy infusion in the EHR, which is certified to the ''provider prior authorization API—coverage requirements discovery'' criterion (45 CFR 170.315(g)(31)) and automatically queries the patient's MA plan's FHIR API. The EHR receives a response via CDS Hooks card indicating that prior authorization is required for both services and describes coverage criteria and documentation needs. Because the EHR is also certified to 45 CFR 170.315(g)(32), the certified health IT enables the oncologist to complete prior authorization following the DTR IG. An embedded Substitutable Medical Applications and Reusable Technologies (SMART) on FHIR app fetches the payer's specific documentation template and rules for oncology prior authorizations. For the PET–CT, the payer's documentation rules ask for the cancer staging information and previous imaging results; the immunotherapy, the payer's documentation rules require the patient's biomarker (for example, PD–L1 expression) status, prior treatment history, and recent lab results. Much of this information can be auto-populated because the embedded DTR app uses Clinical Quality Language (CQL) logic and FHIR queries to pull the patient's latest CT scan report and lab results from her medical record, and it confirms her cancer diagnosis and stage from the problem list. The oncologist answers a few additional questions (such as confirming the patient has no contraindications and that a required biomarker test was positive). By the end of this step, the EHR has compiled all necessary supporting documentation for the prior authorization, ensuring the request will be complete.

Next, the oncologist's office submits the prior authorization request electronically using the capabilities under the ''provider prior authorization API-prior authorization support'' criterion (45 CFR 170.315(g)(33)) to bundle the request and documentation and send it to the MA plan's prior

authorization endpoint. This bundle is transmitted via a FHIR RESTful interaction to the payer, as defined by the PAS IG. The EHR's certified Health IT Module ensures the request conforms to the required FHIR structure and sends it securely. Because all required information was provided up front and matched the plan's coverage criteria, the MA plan's system could potentially automatically adjudicate and approve the requests in near real-time. If that happened, the oncologist could now schedule the patient's therapy without delay, confident that the services are covered.

Both examples result in a prior authorization request that would meet the proposed modification to Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year because in each case, the MIPS eligible clinician requests prior authorization electronically using CEHRT. However, each example utilized different combinations of Health IT Modules certified to electronic prior authorization certification criteria in 45 CFR 170.315(g)(31), (32), and (33). In the first example, the MIPS eligible clinician used a single Health IT Module certified to the ''provider prior authorization API—coverage requirements discovery'' criterion (45 CFR 170.315(g)(31)) to complete actions necessary to successfully attest ''Yes'' to the Electronic Prior Authorization measure. In the second example, the MIPS eligible clinician used Health IT Modules certified to all three of the electronic prior authorization certification criteria to complete all actions for the MIPS eligible clinician to successfully attest ''Yes'' to the Electronic Prior Authorization measure as proposed for CY 2027 performance period/2029 MIPS payment year.

Consistent with the hypothetical examples, we note that a MIPS eligible clinician would be able to successfully attest ''Yes'' to the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year using only those certified Health IT Modules necessary to meet the requirements of the measure. MIPS eligible clinicians would not be required to adopt additional electronic prior authorization certified Health IT Modules if they are not needed for the purposes of successfully reporting the Electronic Prior Authorization measure. We expect that the ability to utilize different combinations of certified Health IT Modules to meet the measure for the CY 2027 performance period/2029 MIPS payment year would afford MIPS eligible clinicians and health IT developers flexibility in how they deploy, adopt, and use different aspects of certified health IT functionality for electronic prior authorization.

Beginning with the CY 2028 performance period/2030 MIPS payment year, we are proposing to modify the measure language to state that a MIPS eligible clinician must use CEHRT to ''electronically request and receive coverage requirements, request and populate prior authorization documentation using templates and rules, submit the prior authorization request, and receive the payer response through a provider prior authorization API.'' In order for a MIPS eligible clinician to attest ''Yes'' to the Electronic Prior Authorization measure, all three certified health IT modules at 45 CFR 170.315(g)(31), (32), and (33) would be required, consistent with the actions associated with the proposed modifications to the measure, which require capabilities corresponding to each of the certified Health IT Modules. Only the second example described above, in which a prior authorization request is submitted after obtaining additional documentation necessary for the request and utilizing health IT certified to the complete set of ONC health IT certification criteria for electronic prior authorization, would be relevant if the proposal for the CY 2028 performance period/2030 MIPS payment year is finalized.

We request public comment on the proposal to use certified health IT to support the Electronic Prior Authorization measure.

(v) Proposal To Modify the Electronic Prior Authorization Measure to an Optional Measure for the CY 2027 Performance Period/2029 MIPS Payment Year

We are proposing to amend our previously finalized requirement that MIPS eligible clinicians must report the Electronic Prior Authorization measure to be considered a meaningful EHR user for the CY 2027 performance period/2029 MIPS payment year (89 FR 8919).

Subsequent to the Electronic Prior Authorization measure being established, we proposed in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule to require that impacted payers implement and maintain Prior Authorization APIs that use HL7 FHIR and conform to the HL7 FHIR Da Vinci CRD, DTR, and PAS implementation guides, as adopted by ONC, with compliance generally beginning October 1, 2027 (91 FR 19910 through 19911). We expect additional implementation complexity for MIPS eligible clinicians, who are downstream from impacted payers and health IT developers who will be required to implement these API standards version requirements in CY 2027 if the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule is finalized as proposed (91 FR 19910 through 19911). As a result, we believe that MIPS eligible clinicians may need additional time and flexibility before requiring the Electronic Prior Authorization measure to account for these changes to the underlying transaction standards occurring in CY 2027. First, we recognize that MIPS eligible clinicians and health IT developers will need additional time for procurement, integration, and testing to operationalize standards-based electronic prior authorization capabilities that support the Electronic Prior Authorization measure. Second, interested parties have indicated that achieving widespread implementation and routine use of these capabilities in CY 2027 may be challenging, particularly for small, rural, and otherwise under-resourced MIPS eligible clinicians. Third, there may be additional implementation complexity for MIPS eligible clinicians because the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule includes proposals to update the versions of underlying transaction standards within the relevant ONC health IT certification criteria. For these reasons, we propose that a year of optional reporting will both incentivize adoption of Health IT Modules certified to ONC criteria for electronic prior authorization through bonus points and offer flexibility to those MIPS eligible clinicians that could benefit from additional time to test, implement, and deploy the CEHRT functionality that is required to support the Electronic Prior Authorization measure. We note that we do not believe that finalization of this proposal is contingent on finalization of proposals in the CMS Interoperability Standards and Prior Authorization for Drugs proposed rule because health care providers, payers, and health IT developers have already begun to adopt and test standards-based electronic prior authorization capabilities, and we expect standards adoption, conformance testing, and validation for the relevant Health IT Modules to continue.[386]

Therefore, in section IV.A.4.d.(4)(f)(v) of this proposed rule, we are proposing

[386] For example, CMS has announced early adopters advancing electronic prior authorization solutions; see *https://www.cms.gov/newsroom/press-releases/cms-announces-early-adopters-advance-solutions-electronic-prior-authorization-accelerating-momentum.*

to modify the Electronic Prior Authorization measure, with the proposed measure updates, to be an optional measure. The measure would be eligible for 10 bonus points for MIPS eligible clinicians who submit a ''Yes'' response for the measure indicating that they have requested a prior authorization electronically using CEHRT from a payer's Prior Authorization API for at least one medical item or service (excluding drugs) ordered within the CY 2027 performance period. To account for the Electronic Prior Authorization measure being an optional measure for the CY 2027 performance period/2029 MIPS payment year with an allocation of 10 bonus points, we are proposing to modify the scoring methodology for optional measures under the MIPS Promoting Interoperability performance category as described in section IV.B.1.d. of this proposed rule. If the proposal to modify the Electronic Prior Authorization measure from a required measure to an optional measure is finalized as proposed, a MIPS eligible clinician who submits a ''No'' response would not have an affected score for the MIPS Promoting Interoperability performance category, and their response would not impact the MIPS eligible clinician being considered a meaningful EHR user for the CY 2027 performance period/2029 MIPS payment year.

Such proposed modification would change the policy adopted for the Electronic Prior Authorization measure as finalized in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8911). The optional reporting of the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year may be particularly beneficial for MIPS eligible clinicians in small, rural, or otherwise under-resourced clinical practice settings navigating new measure requirements while minimizing and balancing operational and reporting burden and demand. If the proposal to amend the Electronic Prior Authorization measure by modifying the measure from a required measure to an optional measure is finalized as proposed, exclusions would not be available for the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year because there will be no negative consequences for MIPS eligible clinicians who do not report on the optional measure. Given the allocated timeframe for MIPS eligible clinicians to become familiar with the Electronic Prior Authorization measure since the CY 2024 performance period as provided in the 2024 CMS Interoperability and Prior Authorization final rule, we believe that proposing to amend the Electronic Prior Authorization measure by modifying it from being a required measure to being as an optional bonus measure solely for the CY 2027 performance period/2029 MIPS payment year would provide MIPS eligible clinicians sufficient time to adopt and begin utilizing the certified health IT necessary to successfully report the Electronic Prior Authorization measure.

We refer readers to Tables C–G 2, C–G 4, C–G 6, and C–G 8 in sections IV.A.4.d.(4)(g)(i), IV.A.4.d.(4)(g)(ii)(D), and IV.A.4.d.(4)(g)(iv) of this proposed rule for information regarding the reporting requirements and scoring methodology of the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year, which is contingent upon the finalization of the proposal to amend the Electronic Prior Authorization by modifying the measure from being a required measure to being an optional measure. We note that the proposal to amend the Electronic Prior Authorization by modifying the measure from being a required measure to an optional measure for the CY 2027 performance period/2029 MIPS payment year aligns with the same proposal for the Medicare Promoting Interoperability Program as proposed in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19625).

We request public comment on this proposal.

(vi) Proposal To Require the Electronic Prior Authorization Measure Beginning With the CY 2028 Performance Period/2030 MIPS Payment Year

When the Electronic Prior Authorization measure was adopted in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we finalized that for a MIPS eligible clinician to satisfactorily meet the requirements of the measure, they would be required to affirmatively attest or claim an applicable exclusion for the Electronic Prior Authorization measure beginning with the CY 2027 performance period/2029 MIPS payment year (89 FR 8910). If a MIPS eligible clinician submits a ''No'' response, fails to submit any attestation, or does not claim an applicable exclusion for the Electronic Prior Authorization measure, the MIPS eligible clinician would receive a score of zero for the MIPS Promoting Interoperability performance category (weighted at 25 percent of the MIPS final score) and would not be considered a meaningful EHR user for purposes of the MIPS Promoting Interoperability performance category for the applicable performance period (89 FR 8911).

We are proposing to amend the Electronic Prior Authorization measure by modifying the measure to require MIPS eligible clinicians to report the Electronic Prior Authorization measure beginning with the CY 2028 performance period/2030 MIPS payment year. Specifically, beginning with the CY 2028 performance period/2030 MIPS payment year, we are proposing that a MIPS eligible clinician must use CEHRT to electronically request and receive coverage requirements, request and populate prior authorization documentation using templates and rules, submit the prior authorization request, and receive the payer response through a Prior Authorization API for at least one medical item or service (excluding drugs) ordered within the applicable performance period. A MIPS eligible clinician would submit a ''Yes'' response, or alternatively claim an applicable exclusion, to satisfy the requirements of the Electronic Prior Authorization measure. In each case, the Electronic Prior Authorization measure would not affect the total score for the MIPS Promoting Interoperability performance category. If a MIPS eligible clinician submits a ''No'' response, fails to submit any attestation, or does not claim an applicable exclusion for the Electronic Prior Authorization measure, the MIPS eligible clinician would receive a score of zero for the MIPS Promoting Interoperability performance category (weighted at 25 percent of the MIPS final score) and would not be considered a meaningful EHR user for purposes of the MIPS Promoting Interoperability performance category for the applicable performance period (89 FR 8911). This proposal reflects the measure reporting requirements that were first adopted for the Electronic Prior Authorization measure as described in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8911), but it would modify the measure to being a required measure for the MIPS Promoting Interoperability performance category beginning with the CY 2028 performance period/2030 MIPS payment year instead of beginning with the CY 2027 performance period/2029 MIPS payment year as originally finalized.

The measure exclusions originally adopted in the 2024 CMS

Interoperability and Prior Authorization final rule (89 FR 8916 through 8923) would be available to MIPS eligible clinicians for the CY 2028 performance period/2030 MIPS payment year and subsequent years. The available exclusions would be for any MIPS eligible clinician who: (1) Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance period; or (2) Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets CMS's Prior Authorization API requirements during the applicable performance period. A MIPS eligible clinician would also be able to claim the first exclusion if none of its prior authorization requests required the functionality described in the certification criteria at 45 CFR 170.315(g)(31), (32) and (33) for electronic prior authorization. For instance, if no prior authorization request submitted by a MIPS eligible clinician during the performance period required gathering and submitting additional documentation to support the request, which is supported by health IT certified to the criteria in 45 CFR 170.315(g)(32) and 45 CFR 170.315(g)(33), then no prior authorization request that MIPS eligible clinician performed would fulfill the measure and the MIPS eligible clinician would be able to claim an exclusion. More broadly, if the MIPS eligible clinician is unable to use CEHRT to effectively exchange information and submit a prior authorization request with any payer from which they are seeking an authorization, we believe that would be sufficient for a MIPS eligible clinician to claim that the payer does not have a functioning Prior Authorization API for the purpose of the reporting and exclusion eligibility.

We note that CMS's specified payer Prior Authorization API requirements are proposed to include conformance to the three IGs underlying the ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33). Therefore, if those Prior Authorization API requirements are finalized as proposed, a MIPS eligible clinician could claim the second exclusion if all their requests are with payers that do not support all three FHIR IGs. If we do not finalize the Prior Authorization API requirements for payers as proposed in the 2026 CMS Interoperability Standards and Prior Authorization for Drugs proposed rule, we would still intend for this exclusion under the Electronic Prior Authorization measure to apply to Prior Authorization APIs that do not use all three IGs underlying the ONC health IT certification criteria at 45 CFR 170.315(g)(31), (32), and (33).

We refer readers to Tables C–G 2, C–G 5, C–G 6 and C–G 8 in sections IV.A.4.d.(4)(g)(i), IV.A.4.d.(4)(g)(ii)(D), and IV.A.4.d.(4)(g)(iv) of this proposed rule for information regarding the reporting requirements and scoring methodology of the MIPS Promoting Interoperability performance category beginning with the CY 2028 performance period/2030 MIPS payment year, which is contingent upon the finalization of the proposal to amend the Electronic Prior Authorization by modifying the measure to be a required measure.

We request public comment on this proposal.

(vii) Request for Information on Future Potential Performance-Based Measures of Electronic Prior Authorization

While the current measure requirement of achieving ''at least one'' electronic prior authorization is appropriate for the initial inclusion of the Electronic Prior Authorization measures for both medical items and services and for prescription drugs in the MIPS Promoting Interoperability performance category, we do not expect this minimal requirement to effectively increase electronic prior authorization usage over time. Therefore, we are seeking comments on potential future updates we could make to this measure to incentivize MIPS eligible clinicians to use CEHRT for electronic prior authorization for a more substantial set of the electronic prior authorization requests that they submit over the course of a performance period and corresponding MIPS payment year. Consistent with statutory requirements in section 1886(n)(3)(A)(ii) of the Act, we envision that expanding the scope of the measures in future rulemaking would lead to increased interoperable exchange of data that would not only decrease administrative burden, but could improve the quality of health by reducing the time needed for a patient to get access to necessary medical services and items as well as prescription drugs covered under the medical benefit. Reducing delays in the exchange of data and as a result providing patients care more efficiently, drives better care coordination which is a key objective of meaningful use. Additionally, because electronic prior authorization requires data sharing, this advances interoperability, which is a primary focus of meaningful use. We also intend to drive adoption of health IT capabilities supporting the complete electronic prior authorization workflow over time, by requiring MIPS eligible clinicians to address a wider array of prior authorization requests that require more complex interactions with payers. The public input we receive will contribute to future considerations for potentially updating the Electronic Prior Authorization measures in a manner that helps achieve HHS's goals of promoting meaningful use of certified EHR technology, electronic exchange of health information, and submission of clinical quality measures.

We seek public comment on potential future updates to this measure. We seek public comment on barriers and challenges that MIPS eligible clinicians in small, rural, or otherwise under-resourced practice settings might face when reporting performance-based electronic prior authorization measures. Also, we request comment on what alternative approaches should be considered to support use of electronic prior authorization. We seek public comment on how we can further strengthen the Electronic Prior Authorization measures in a manner that incentivizes progress while avoiding undue administrative complexity and implementation challenges for MIPS eligible clinicians.

(g) Proposal To Modify Requirements and Scoring Policies for the MIPS Promoting Interoperability Performance Category

(i) Proposal To Modify Objectives and Measures

In this proposed rule, we are proposing updates that would occur in different performance periods. For reference, Table C–G 2 sets forth the objectives and measures for the Promoting Interoperability performance category that would be required for the CY 2027 performance period/2029 MIPS payment year, the CY 2028 performance period/2030 MIPS payment year, and subsequent years if our proposals are finalized as proposed. Table C–G 2 reflects proposed modifications to previously established objectives and measures, including the proposals:

- For the CY 2026 performance period/2028 MIPS payment year: Remove the ONC Direct Review and ONC–ACB Surveillance attestations.
- For the CY 2027 performance period/2029 MIPS payment year: Remove the Security Risk Analysis measure and make the existing Electronic Prior Authorization measure an optional measure.
- For the CY 2028 performance period/2030 MIPS payment year: Make the existing Electronic Prior

Authorization measure required and unscored and create a new Electronic Prior Authorization for Prescription Drugs measure.

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TABLE C-G 2: PROPOSED OBJECTIVES AND MEASURES FOR THE MIPS PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR, CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR, THE CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR, AND SUBSEQUENT YEARS

Objective	Measure	Numerator	Denominator	Exclusion
Electronic Prescribing: Generate and transmit permissible prescriptions electronically	e-Prescribing – At least one permissible prescription written by the MIPS eligible clinician is transmitted electronically using CEHRT.	Number of prescriptions in the denominator generated and transmitted electronically using CEHRT.	Number of prescriptions written for drugs requiring a prescription to be dispensed other than controlled substances during the performance period; or number of prescriptions written for drugs requiring a prescription to be dispensed during the performance period.	Any MIPS eligible clinician who writes fewer than 100 permissible prescriptions during the performance period.
Electronic Prescribing	Query of PDMP – For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the performance period, the MIPS eligible clinician uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	Any MIPS eligible clinician who: 1. Is unable to electronically prescribe Schedule II opioids and Schedule III and IV drugs in accordance with applicable law during the performance period; OR 2. Does not electronically prescribe any Schedule II opioids or Schedule III or IV drugs during the performance period.
Health Information Exchange: The MIPS eligible clinician provides a summary of care record when transitioning care or referring their patient to another setting of care, receives or retrieves a summary of care record upon the receipt of a transition of care or referral or upon the first patient encounter with a new patient, and reconciles summary of care information from other healthcare providers into their EHR using the functions of CEHRT	Support Electronic Referral Loops by Sending Health Information – For at least one transition of care or referral, the MIPS eligible clinician that transitions care of a patient or refers their patient to another setting of care or healthcare provider: 1. Creates a summary of care using CEHRT; AND 2. Electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where the summary of care record was created using CEHRT and exchanged electronically.	Number of transitions of care and referrals during the performance period for which the MIPS eligible clinician was the transferring or referring clinician.	Any MIPS eligible clinician who transfers a patient to another setting or refers a patient fewer than 100 times during the performance period.
Health Information	Support Electronic	Number of	Number of electronic	Any MIPS eligible clinician

Objective	Measure	Numerator	Denominator	Exclusion
Exchange (HIE)	Referral Loops by Receiving and Reconciling Health Information – For at least one electronic summary of care record received for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, or for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient, the MIPS eligible clinician conducts clinical information reconciliation for medication, mediation allergy, and current problem list.	electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: 1. Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; 2. Medication allergy – Review of the patient's known medication allergies; and 3. Current Problem List – Review of the patient's current and active diagnoses.	summary of care records received using CEHRT for patient encounters during the performance period for which a MIPS eligible clinician was the receiving party of a transition of care or referral, and for patient encounters during the performance period in which the MIPS eligible clinician has never before encountered the patient.	who receives transitions of care or referrals or has patient encounters in which the MIPS eligible clinician has never before encountered the patient fewer than 100 times during the performance period.
Health Information Exchange (HIE)	Health Information Exchange Bi-Directional Exchange – Statement 1: I participate in an HIE to enable secure, bi-directional exchange to occur for every patient encounter, transition of care or referral and record stored or maintained in the EHR during the performance period in accordance with applicable law and policy. Statement 2: The HIE that I participate in is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs and not engaging in exclusionary behavior	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	when determining exchange partners. Statement 3: I use the functions of CEHRT to support bi-directional exchange with an HIE.			
Health Information Exchange	Enabling Exchange Under TEFCA – MIPS eligible clinicians attest to the following. Statement 1: I participate as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for every patient encounter, transition of care or referral, and record stored or maintained in the EHR during the performance period, in accordance with applicable law and policy. Statement 2: I use the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A
Health Information Exchange	Electronic Prior Authorization for Prescription Drugs (CY 2028 and subsequent performance periods) – For at least one prescription written by the MIPS eligible clinician during the	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	Any MIPS eligible clinician who: 1. Does not write a prescription that requires prior authorization during the applicable performance period; or 2. only writes prescriptions requiring prior authorization where the payer does not support the specified electronic prior

Objective	Measure	Numerator	Denominator	Exclusion
	performance period for which prior authorization is required, the prior authorization is requested electronically using CEHRT.*			authorization standard during the applicable performance period; or 3 writes fewer than 100 permissible prescriptions during the performance period.*
Health Information Exchange	Electronic Prior Authorization (CY 2027 performance period *only*) – For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the prior authorization is requested electronically through a Prior Authorization API using CEHRT.**	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None**
Health Information Exchange	Electronic Prior Authorization (CY 2028 and subsequent performance periods) – For at least one medical item or service (excluding drugs) ordered by the MIPS eligible clinician during the performance period, the MIPS eligible clinician uses CEHRT to electronically discover applicable coverage requirements, complete required documentation, submit the prior authorization request, and receive the payer response through a Prior Authorization API.*	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	Any MIPS eligible clinician who: 1. Does not order any medical items or services (excluding drugs) requiring prior authorization during the applicable performance period; OR 2. Only orders medical items or services (excluding drugs) requiring prior authorization from a payer that does not offer an API that meets CMS's specified Prior Authorization API requirements.*
Provider to Patient Exchange: The MIPS eligible clinician provides patients (or patient-authorized representative) with timely electronic access to their health information.	Provide Patients Electronic Access to Their Health Information – For at least one unique patient seen by the MIPS eligible clinician: 1. The patient (or the patient-authorized	Number of patients (or patient authorized representatives) in the denominator who are provided timely access to health information to view online, download, and	Number of unique patients seen by the MIPS eligible clinician during the performance period.	N/A

Objective	Measure	Numerator	Denominator	Exclusion
	representative) is provided timely access to view online, download, and transmit his or her health information; AND 2. The MIPS eligible clinician ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the Application Programming Interface (API) in the MIPS eligible clinician's CEHRT.	transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the MIPS eligible clinician's CEHRT.		
Public Health and Clinical Data Exchange: The MIPS eligible clinician is in active engagement with a public health agency or clinical data registry to submit electronic public health data in a meaningful way using CEHRT, except where prohibited, and in accordance with applicable law and practice.	Immunization Registry Reporting – The MIPS eligible clinician is in active engagement with a public health agency to submit immunization data and receive immunization forecasts and histories from the public health immunization registry/immunization information system (IIS).	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	The MIPS eligible clinician: 1. Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or immunization information system during the performance period; OR 2. Operates in a jurisdiction for which no immunization registry or immunization information system is capable of accepting the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. Operates in a jurisdiction where no immunization registry or immunization information system has declared readiness to receive immunization data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Electronic Case Reporting – The MIPS eligible clinician is in active engagement with a PHA to electronically submit	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	The MIPS eligible clinician: 1. Does not treat or diagnose any reportable diseases for which data is collected by their jurisdiction's reportable disease system

Objective	Measure	Numerator	Denominator	Exclusion
	case reporting of reportable conditions.			during the performance period; OR 2. Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the performance period; OR 3. Operates in a jurisdiction where no PHA has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the performance period.
Public Health and Clinical Data Exchange	Public Health Registry Reporting (Optional) – The MIPS eligible clinician is in active engagement with a PHA to submit data to public health registries.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting (Optional) – The MIPS eligible clinician is in active engagement to submit data to a clinical data registry.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting (Optional) – The MIPS eligible clinician is in active engagement with a PHA to submit syndromic surveillance data from an urgent care setting.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None
Public Health and Clinical Data Exchange	Public Health Reporting Using TEFCA (Optional)* – The MIPS eligible clinician: 1. Is participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website); 2.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None

Objective	Measure	Numerator	Denominator	Exclusion
	Is not suspended from participating in TEFCA exchange; 3. Submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; 4. Is in active engagement Option 2 (validated data production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; AND 5. Uses the functions of CEHRT to exchange with the PHA.			
Protect Patient Health Information: Protect electronic protected health information (ePHI) created or maintained by CEHRT through the implementation of appropriate technical, administrative, and physical safeguards. Protect Patient Health Information	High Priority Practices SAFER Guide – Beginning with the CY 2024 performance period/2026 MIPS payment year, submit an affirmative attestation regarding the MIPS eligible clinician's completion of the annual self-assessment under the High Priority Practices SAFER Guide measure using the 2025 High Priority Practices SAFER Guide during the year in which the performance period occurs.	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	N/A (measure is Yes/No and requires an affirmative attestation to meet requirement)	None

* Signifies a proposal in this proposed rule that would apply to the CY 2028 performance period and subsequent years.
** Signifies a proposal in this proposed rule that would apply to the CY 2027 performance period.

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(ii) Proposal To Modify Scoring Methodology

For reference, Tables C–G 3, C–G 4 and C–G 5 set forth the scoring methodology for the MIPS Promoting Interoperability performance category for CY 2026 performance period/2028 MIPS payment year, the CY 2027 performance period/2029 MIPS payment year, and the CY 2028 performance period/2030 MIPS payment year and subsequent years. In sections IV.A.4.d.(4)(c)(ii), IV.A.4.d.(4)(d)(ii), IV.A.4.d.(4)(e)(ii), IV.A.4.d.(4)(f)(ii), IV.A.4.d.(4)(f)(iii), IV.A.4.d.(4)(f)(iv), IV.A.4.d.(4)(f)(v), and IV.A.4.d.(4)(f)(vi) of this proposed rule, we discuss the proposed removal of certain measures, addition of certain measures, and modifications/updates to

certain measures for the MIPS Promoting Interoperability performance category. We refer readers to section IV.B.1.d. of this proposed rule for the discussion regarding the proposal that modifies the scoring methodology to account for the Electronic Prior Authorization measure being changed to an optional measure with an allocation of 10 bonus points for the CY 2027 performance period/2029 MIPS payment year. There are no implications to the scoring methodology for the proposal to update the definition of CEHRT in section IV.A.4.d.(4)(b)(ii) of this proposed rule. This section includes a discussion of scoring implications for the proposed changes in this proposed rule for the MIPS Promoting Interoperability performance category—

- Removal of the ONC Direct Review and ONC–ACB Surveillance attestations;
- Removal of the Security Risk Analysis measure;
- Addition of an Electronic Prior Authorization for Prescription Drugs measure; and
- Updates to the Electronic Prior Authorization measure.

(A) Proposal To Modify Scoring for the ONC Direct Review and ONC–ACB Surveillance Attestations

The proposal to remove the ONC Direct Review and ONC–ACB Surveillance attestations beginning with the CY 2026 performance period/2028 MIPS payment year as discussed in section IV.A.4.d.(4)(c)(ii) of this proposed rule will be reflected in the scoring of the MIPS Promoting Interoperability performance category in the following manner. Currently, to earn a score for the MIPS Promoting Interoperability performance category for inclusion in the MIPS final score, a MIPS eligible clinician must be a meaningful EHR user for MIPS and submit a ''Yes'' response attesting to engaging in activities supporting providers with performance of CEHRT, including acknowledging the requirement to cooperate in good faith with ONC Direct Review. The ONC–ACB Surveillance attestation is optional, and MIPS eligible clinicians can attest ''Yes'', ''No'' or not submit an attestation (81 FR 77019 to 77028).

Starting in the CY 2026 performance period/2028 MIPS payment year, we are proposing to remove scoring policies related to the ONC Direct Review attestation and the optional ONC–ACB Surveillance attestation since we are proposing in section IV.A.4.d.(4)(c)(ii) of this proposed rule to remove the attestations. The ONC Direct Review attestation will no longer be required to earn a score for the MIPS Promoting Interoperability performance category for inclusion in the final score. Since we did not provide measure points for either the attestation of ONC Direct Review and ONC–ACB Surveillance, removal of the attestation requirements and scoring policies starting with the CY 2026 performance period/2028 MIPS payment year will not result in a need to redistribute measure points in the MIPS Promoting Interoperability performance category.

We refer readers to Table C–G 3 in section IV.A.4.d.(4)(g)(ii)(D) of this proposed rule for more information on the scoring methodology for the MIPS Promoting Interoperability performance category for the CY 2026 performance period/2028 MIPS payment year.

We request public comment on this proposal.

(B) Proposal To Modify Scoring for the Security Risk Analysis Measure

We are proposing to remove the Security Risk Analysis measure beginning with the CY 2027 performance period/2029 MIPS payment year as discussed in section IV.A.4.d.(4)(d)(ii) of this proposed rule. Thus, we are proposing to remove the scoring policies corresponding to the Security Risk Analysis measure. The measure is not scored individually and the attestation of a ''Yes'' response does not contribute to the MIPS eligible clinician's MIPS Promoting Interoperability performance category score for the Protect Patient Health Information objective and measures. An attestation of a ''No'' demonstrates that the MIPS eligible clinician did not complete the actions included in the measure as required by § 414.1375(b)(2)(ii)(A) and did not satisfy the definition of a meaningful EHR user at § 414.1305. Therefore, if the MIPS eligible clinician submits a ''No'' response for this measure, they would not earn a score for the MIPS Promoting Interoperability performance category, resulting in a score of zero, in accordance with § 414.1375(b)(2) (90 FR 49870 and 49871). The proposed removal of the Security Risk Analysis measure, which does not contribute to the MIPS eligible clinician's MIPS Promoting Interoperability performance category score, will not result in the need to redistribute measure points in the MIPS Promoting Interoperability performance category. We refer readers to Table C–G 4 in section IV.A.4.d.(4)(g)(ii)(D) of this proposed rule for more information on the scoring methodology for the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year, which would no longer include the Security Risk Analysis measure, which is proposed for removal.

We request public comment on this proposal.

(C) Proposal To Modify Scoring for the New Electronic Prior Authorization for Prescription Drugs Measure

We are proposing to adopt a new attestation-based Electronic Prior Authorization for Prescription Drugs measure beginning with the CY 2028 performance period/2030 MIPS payment year as discussed in section IV.A.4.d.(4)(e)(ii) of this proposed rule. We are proposing that the Electronic Prior Authorization for Prescription Drugs measure would not be scored for the CY 2028 performance period/2030 MIPS payment year and subsequent years for MIPS eligible clinicians. A MIPS eligible clinician would be required to attest ''Yes'' to the measure or claim an exclusion, but the measure would not affect the total score for the MIPS Promoting Interoperability performance category. MIPS eligible clinicians that report a ''No'' attestation, fail to submit the measure, or fail to claim an applicable exclusion would receive a score of zero for the MIPS Promoting Interoperability performance category (currently weighted at 25 percent of the MIPS final score), and would not be considered a meaningful EHR user for MIPS for that performance year.

We request public comment on this proposal.

(D) Proposal To Modify Scoring for the Electronic Prior Authorization Measure

When we adopted the Electronic Prior Authorization measure in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we finalized that MIPS eligible clinicians would report the measure as an unscored attestation for the CY 2027 performance period specifically (89 FR 8910), but we did not specify its scoring methodology for subsequent years because we determined that it would be more appropriate to determine the measure's scoring structure closer in time to its effective date.

In sections IV.A.4.d.(4)(f)(v) and IV.B.1.d. of this proposed rule, we are proposing to modify the Electronic Prior Authorization measure by making the measure optional and eligible for 10 bonus points for MIPS eligible clinicians who submit a ''Yes'' response attesting to meeting the requirements of the measure for the CY 2027 performance period/2029 MIPS

payment year. We are proposing to make the measure eligible for 10 bonus points for MIPS eligible clinicians that submit a ''Yes'' response attesting to meeting the requirements of measure. Allocating 10 bonus points is an appropriate and effective incentive to promote the adoption and use of certified technology for requesting electronic prior authorizations among MIPS eligible clinicians. To account for the allocation of bonus points specific to the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year, we are proposing to amend § 414.1380(b)(4)(ii)(C) by adding a new provision at § 414.1380(b)(4)(ii)(C)(4). We refer readers to section IV.B.1. of this proposed rule for the proposal to establish the allocation of 10 bonus points in § 414.1380(b)(4)(ii)(C)(4), respectively, for MIPS eligible clinicians who affirmatively attested to meeting the requirements of the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year.

Also, as described in section IV.A.4.d.(4)(f)(v) of this proposed rule, we are proposing to require the measure for the CY 2028 performance period/2030 MIPS payment year and subsequent years. Similar to its original scoring methodology as adopted in the 2024 CMS Interoperability and Prior Authorization final rule (89 FR 8909 through 8927), we are proposing that the Electronic Prior Authorization measure would remain unscored for the CY 2028 performance period and subsequent years. This scoring methodology would allow time for MIPS eligible clinicians to adjust to the new electronic prior authorization workflow using Prior Authorization APIs without undue focus on scoring implications in the MIPS Promoting Interoperability performance category. We anticipate the Electronic Prior Authorization measure will retain its importance as an aspect of health information exchange.

We request public comment on these proposals.

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TABLE C-G 3: PROPOSED SCORING METHODOLOGY FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange Under TEFCA	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting • Public Health Reporting Using TEFCA	5 points (*bonus*)	Optional
Protect Patient Health Information	Security Risk Analysis	Not scored*	Required
	High Priority Practices SAFER Guide	Not scored*	Required
No Associated Objective: Attestation Requirements**	Actions to Limit or Restrict the Compatibility of CEHRT	Not scored*	Required

* Measures and attestations that are required but not scored do not have associated points, but failure to fulfill such requirements will result in a zero score for the MIPS Promoting Interoperability performance category.

**Attestation Requirements: The proposed removal of the ONC-Direct Review attestation and the ONC-ACB Surveillance attestation is applicable starting with the CY 2026 performance period/2028 MIPS payment year as discussed in section IV.A.4.d.(4)(c)(ii) of this proposed rule.

TABLE C-G 4: PROPOSED SCORING METHODOLOGY FOR THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange Under TEFCA	30 points	
	Electronic Prior Authorization*	10 points (*bonus*)	Optional
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting • Public Health Reporting Using TEFCA	5 points (*bonus*)	Optional
Protect Patient Health Information**	High Priority Practices SAFER Guide	Not scored***	Required
No Associated Objective: Attestation Requirements****	Actions to Limit or Restrict the Compatibility of CEHRT	Not scored***	Required

* In sections IV.A.4.d.(4)(f)(v) and IV.A.4.d(4)(f)(vi) of this proposed rule, we are proposing to make the Electronic Prior Authorization measure an optional measure for the CY 2027 performance period and required, but unscored, starting with the CY 2028 performance period.

** The proposed removal of the Security Risk Analysis measure is applicable starting with the CY 2027 performance period/2029 MIPS payment year as described in section IV.A.4.d.(4)(d)(ii) of this proposed rule.

*** Measures and attestations that are required, but not scored do not have associated points, but failure to fulfill such requirements will result in a zero score for the MIPS Promoting Interoperability performance category.

**** Attestation Requirements: The proposed removal of the ONC-Direct Review attestation and the ONC-ACB Surveillance attestation is applicable starting with the CY 2026 performance period/2028 MIPS payment year as discussed in section IV.A.4.d.(4)(c)(ii) of this proposed rule.

TABLE C-G 5: PROPOSED SCORING METHODOLOGY FOR THE CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR AND SUBSEQUENT YEARS

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of PDMP	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (MIPS eligible clinician's choice of one of the three reporting options)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange Under TEFCA	30 points	
	Electronic Prior Authorization*	Not scored**	Required
	Electronic Prior Authorization for Prescription Drugs***	Not scored**	Required
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting • Public Health Reporting Using TEFCA	5 points (*bonus*)	Optional
Protect Patient Health Information****	High Priority Practices SAFER Guide	Not scored**	Required
No Associated Objective: Attestation Requirements*****	Actions to Limit or Restrict the Compatibility of CEHRT	Not scored***	Required

* In section IV.A.4.d.(4)(f)(vi) of this proposed rule, we are proposing to make the Electronic Prior Authorization measure a required and unscored measure for the CY 2028 performance period. We note we are also proposing in section IV.A.4.d.(4)(f)(v) of this proposed rule to make the measure optional for the CY 2027 performance period.
** Measures and attestations that are required but not scored do not have associated points, but failure to fulfill such requirements will result in a zero score for the MIPS Promoting Interoperability performance category.
*** In section IV.A.4.d.(4)(e)(ii) of this proposed rule, we are proposing to adopt a new Electronic Prior Authorization for Prescription Drugs measure for the CY 2028 performance period, which is required and not scored.
**** The proposed removal of the Security Risk Analysis measure is applicable starting with the CY 2027 performance period/2029 MIPS payment year as discussed in section IV.A.4.d.(4)(d)(ii) of this proposed rule.
*****Attestation Requirements: The proposed removal of the ONC-Direct Review attestation and the ONC-ACB Surveillance attestation is applicable starting with the CY 2026 performance period/2028 MIPS payment year as discussed in section IV.A.4.d.(4)(c)(ii) of this proposed rule.

The proposals in this proposed rule include changes that would occur in the CY 2026 performance period/2028 MIPS payment year, CY 2027 performance period/2029 MIPS payment year, and CY 2028 performance period/2030 MIPs payment year. Table C–G 6 summarizes the required measures and attestations for each of these three performance periods.

TABLE C-G 6: SUMMARY OF PROPOSED REQUIREMENTS FOR THE PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY FOR THE CY 2026 PERFORMANCE PERIOD/2028 MIPS PAYMENT YEAR, CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR, CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR, AND SUBSEQUENT YEARS

Objective	Measure	2026 Performance Period	2027 Performance Period	2028 Performance Period and Subsequent Years
Electronic Prescribing	e-Prescribing	Required (10 points)	Required (10 points)	Required (10 points)
	Query of PDMP	Required (10 points)	Required (10 points)	Required (10 points)
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	Required (30 points for selected option)	Required (30 points for selected option)	Required (30 points for selected option)
	Support Electronic Referral Loops by Receiving and Reconciling Health Information			
	-OR-			
	Health Information Exchange Bi-Directional Exchange			
	-OR-			
	Enabling Exchange Under TEFCA			
	Electronic Prior Authorization	---	Optional (10 bonus points)	Required (not scored)*
	Electronic Prior Authorization for Prescription Drugs	---	---	Required (not scored)*
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	Required (25 points)	Required (25 points)	Required (25 points)
Public Health and Clinical Data Exchange	Report the following two measures: • Immunization Registry Reporting • Electronic Case Reporting	Required (25 points)	Required (25 points)	Required (25 points)
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting • Syndromic Surveillance Reporting • Public Health Reporting Using TEFCA	Optional (5 bonus points)	Optional (5 bonus points)	Optional (5 bonus points)
Protect Patient Health Information	Security Risk Analysis	Required (not scored)*	---	---
	High Priority Practices SAFER Guide	Required (not scored)*	Required (not scored)*	Required (not scored)*
No Associated Objective: Attestation Requirements	Actions to Limit or Restrict the Compatibility of CEHRT	Required (not scored)*	Required (not scored)*	Required (not scored)*

* Measures and attestations that are required but not scored do not have associated points, but failure to fulfill such requirements will result in a zero score for the MIPS Promoting Interoperability performance category.

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(iii) Exclusion Redistribution

Many required measures would have exclusions associated with them as set forth in Table C–G 7. If a MIPS eligible clinician determines an exclusion for a particular measure applies to them, they may claim it when they submit their data. The maximum available points, as shown in Table C–G 7, do not include the points that would be redistributed if a MIPS eligible clinician claims an exclusion for a specific measure. Table C–G 7 sets forth how points would be redistributed among the objectives and measures specified for the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year in the event a MIPS eligible clinician claims an exclusion for a given measure.

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TABLE C-G 7: PROPOSED EXCLUSION REDISTRIBUTION FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Objective	Measure	Redistribution if exclusion is claimed
Electronic Prescribing	e-Prescribing	10 points to HIE objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange (HIE)	Support Electronic Referral Loops by Sending Health Information	15 points to Provide Patients Electronic Access to Their Health Information measure
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points to the Support Electronic Referral Loops by Sending Health Information measure
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange Under TEFCA	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following two measures: • Electronic Case Reporting • Immunization Registry Reporting	If an exclusion is claimed for both measures, 25 points are redistributed to the Provide Patients Electronic Access to Their Health Information measure

(iv) ONC Health IT Certification Criteria

Table C–G 8 sets forth the objectives and measures for the MIPS Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year and the associated ONC health IT certification criteria set forth at 45 CFR 170.315, as is currently applicable. Table C–G 8 also summarizes any changes to the relevant ONC Health IT certification criteria if the HTI–5 proposals are finalized as proposed. We refer readers to section IV.A.4.d.(4)(b)(ii) of this proposed rule for discussion of and amendments to the definition of CEHRT at § 414.1305.

TABLE C-G 8: MIPS PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY OBJECTIVES AND MEASURES AND ONC HEALTH IT CERTIFICATION CRITERIA

Objective	Measure	Certification Criteria (CY 2027 Performance Period/2029 MIPS Payment Year) in Title 45 of the CFR	ONC Health IT Certification Criteria Changes if HTI-5 Proposals are Finalized as Proposed
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing	No change
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing	No change
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	§ 170.315(b)(1) Transitions of care	Revised
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	§ 170.315(b)(1) Transitions of care	Revised
		§ 170.315(b)(2) Clinical information reconciliation and incorporation	Removed
Health Information Exchange (alternative)	Health Information Exchange Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:	
		§ 170.315(b)(1) Transitions of care	Revised
		§ 170.315(b)(2) Clinical information reconciliation and incorporation	Removed
		§ 170.315(g)(7) Application access — patient selection	Removed
		§ 170.315(g)(9) Application access — all data request	Removed
		§ 170.315(g)(10) Standardized API for patient and population services	No change
Health Information Exchange (alternative)	Enabling Exchange Under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:	
		§ 170.315(b)(1) Transitions of care	Revised
		§ 170.315(b)(2) Clinical information reconciliation and incorporation	Removed
		§ 170.315(g)(7) Application access — patient selection	Removed
		§ 170.315(g)(9) Application access — all data request	Removed
		§ 170.315(g)(10) Standardized API for patient and population services	No change
Health Information Exchange	Electronic Prior Authorization*	Certified health IT capabilities that may support the actions of this measure	
		170.315(g)(31) Provider prior authorization API — coverage requirements discovery*	No change
		170.315(g)(32) Provider prior authorization API — documentation templates and rules*	No change
		170.315(g)(33) Provider prior authorization API —	No change

Objective	Measure	Certification Criteria (CY 2027 Performance Period/2029 MIPS Payment Year) in Title 45 of the CFR	ONC Health IT Certification Criteria Changes if HTI-5 Proposals are Finalized as Proposed
		prior authorization support*	
Health Information Exchange	Electronic Prior Authorization for Prescription Drugs**	170.315(b)(3) Electronic prescribing**	No change
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	§ 170.315(e)(1) View, download, and transmit to 3rd party	Revised
		§ 170.315(g)(7) Application access — patient selection	Removed
		§ 170.315(g)(9) Application access — all data request	Removed
		§ 170.315(g)(10) Standardized API for patient and population services	No change
Public Health and Clinical Data Exchange	Immunization Registry Reporting	§ 170.315(f)(1) Transmission to immunization registries	No change
	Syndromic Surveillance Reporting (Optional)	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance	No change
	Electronic Case Reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting	Revised
	Public Health Registry Reporting (Optional)	§ 170.315(f)(4) Transmission to cancer registries	Removed
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys	Removed
	Clinical Data Registry Reporting (Optional)	No ONC health IT certification criteria at this time.	No change
	Public Health Reporting Using TEFCA (Optional)	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:	
		§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting	Revised
Protect Patient Health Information	Security Risk Analysis	The requirements are a part of CEHRT specific to each certification criterion.	
	High Priority Practices SAFER Guide	No ONC health IT certification criteria at this time.	No change

* In sections IV.A.4.d.(4)(f)(v) and IV.A.4.d.(4)(f)(vi) of this proposed rule, we are proposing to make the Electronic Prior Authorization measure an optional bonus measure for the CY 2027 performance period and required, but unscored, starting with the CY 2028 performance period. ** In section IV.A.4.d.(4)(e)(ii) of this proposed rule, we are proposing to adopt a new Electronic Prior Authorization for Prescription Drugs measure for the CY 2028 performance period, which is unscored.

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B. MIPS Final Score Methodology

1. Performance Category Scores

a. Background

Sections 1848(q)(1)(A)(i) and (ii) and (5)(A) of the Act provide, in relevant part, that the Secretary shall develop a methodology for assessing the total performance of each MIPS eligible clinician according to certain specified performance standards and, using such methodology, provide for a final score for each MIPS eligible clinician. Section 1848(q)(2)(A)(i) of the Act requires us to use the quality performance category in determining each MIPS eligible clinician's final score, and section 1848(q)(2)(B)(i) of the Act describes the measures and activities that must be specified under the quality performance category. The statute does not specify the number of quality measures on which a MIPS eligible clinician must report, nor does it specify the amount or type of information that a MIPS eligible clinician must report on each quality measure.

In this section, we propose scoring policies that are consistent with the proposed MIPS core measure reporting requirement in section IV.A.4.d.(1)(c)(iii) of this proposed rule. Additionally, we propose policies building on the current scoring policies for topped out quality measures. Moreover, we propose policies to modify the benchmarks for Medicare

CQMs and apply flat benchmarks to Medicare eCQMs that are consistent with the proposed Medicare eCQM collection type in section III.G.3.d.(3) of this proposed rule. In this section, we also propose policy to update scoring for the Electronic Prior Authorization measure in the Promoting Interoperability performance category. Lastly, we also include a request for information (RFI) on the future direction of MVP scoring policies. Specifically, we propose to:

- Establish a policy for scoring MIPS core measures;
- Apply the defined topped out benchmark for certain topped out measures for clinicians impacted by limited measure choice;
- Apply the defined topped out benchmark for topped out MIPS core measures;
- Modify the publishing location of topped out measures impacted by limited measure choice and scored according to the defined topped out benchmark;
- Modify the flat benchmarking methodology for the Medicare CQMs collection type;
- Establish a flat benchmarking methodology for the Medicare eCQMs collection type; and
- Modify the Electronic Prior Authorization measure from a required measure to an optional measure under the Promoting Interoperability performance category for the CY 2027 performance period/2029 MIPS payment year.

Additionally, we discuss the impact of the proposed MIPS core measure scoring for small practices and explain that we would apply the historical benchmark if a measure is no longer topped out. We note that the proposed policies for scoring the quality performance category would apply to both traditional MIPS and MVP scoring.

b. Scoring the Quality Performance Category for the Following Collection Types: Medicare Part B Claims Measures, eCQMs, MIPS CQMs, QCDR Measures, the CAHPS for MIPS Survey Measures and Administrative Claims Measures

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules, the CY 2020, CY 2021, CY 2022, CY 2023, CY 2024, CY 2025, and CY 2026 PFS final rules (81 FR 77276 through 77308, 82 FR 53716 through 53748, 83 FR 59841 through 59855, 84 FR 63011 through 63018, 85 FR 84898 through 84913, 86 FR 65490 through 65509, 87 FR 70088 through 70091, 88 FR 79368 and 79369, 89 FR 98427 through 98439, and 90 FR 49903 through 49914), and § 414.1380(b)(1) for our current policies regarding, among other things, quality measure benchmarks, calculating total measure achievement points, calculating the quality performance category score, including achievement and improvement points, the small practice bonus, and scoring flexibilities. In the CY 2026 PFS final rule (90 FR 49903 through 49914), we finalized policies for scoring topped out measures impacted by limited measure choice and the scoring methodology for administrative claims-based quality measures at § 414.1380(b)(1)(i) and (b)(1)(ii)(D).

(1) Proposal for Scoring of MIPS Core Measures

Section 1848(q)(5)(B)(i) of the Act requires the Secretary to treat any MIPS eligible clinician who fails to report on a required measure or activity as achieving the lowest potential score applicable to the measure or activity. In the CY 2017 Quality Payment Program final rule (81 FR 77291), we finalized at § 414.1380(b)(1) that MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335, on which no data is submitted in accordance with § 414.1325. In the CY 2022 PFS final rule (86 FR 65421), we finalized that scoring the required quality measures in an MVP is consistent with traditional MIPS scoring policies described under § 414.1380(b)(1).

In section IV.A.4.d.(1)(c)(iii)(B) of this proposed rule, we propose that MIPS eligible clinicians would need to report a MIPS core measure, as one of their six required quality measures in traditional MIPS or one of their four required quality measures in MVP reporting. The proposed MIPS core measure requirement would replace the existing outcome or high priority measure requirement for clinicians participating in traditional MIPS and MVP reporting. In the same section, we propose an attestation requirement, during data submission, for clinicians who do not have an available and applicable MIPS core measure. Additionally, we propose in that section that the MIPS core measure reporting requirement would not apply to clinicians in small practices. We refer readers to section IV.A.4.d.(1)(c)(iii) of this proposed rule for details on the proposed MIPS core measure reporting requirement, the attestation process, and exemption of small practices from the MIPS core measure reporting requirement. We refer readers to Appendix 1: MIPS Quality Measures of this proposed rule for details on the MIPS core measures inventory for the CY 2027 performance period/2029 MIPS payment year.

Beginning in the CY 2027 performance period/2029 MIPS payment year, for scoring the quality performance category for clinicians that are not part of small practices, we would include the proposed MIPS core measure as one of the six required quality measures for clinicians participating in traditional MIPS or one of the four required quality measures for clinicians participating in MVP reporting. As discussed in section IV.A.4.d.(1)(c)(iii)(B) of this proposed rule, clinicians who attest to not having an applicable and available MIPS core measure would still need to report enough measures to meet the required number of six quality measures in traditional MIPS or four quality measures in MVP reporting. We would use the highest scoring six or four quality measures, respectively, to determine the quality performance category score. As discussed in section IV.A.4.d.(1)(c)(iii)(B), there may be instances in which a clinician attested to not having an applicable and available MIPS core measure, but new information or changing circumstances later made it so that the clinician does have an applicable and available MIPS core measure to report. To account for these cases, if an attestation is submitted during data submission and a MIPS core measure is also reported, we would score the MIPS core measure as one of the six required quality measures in traditional MIPS reporting or one of the four required quality measures in MVP reporting. If a MIPS eligible clinician submits data for more than one MIPS core measure, we would use the highest scoring MIPS core measure as one of the six or four quality measures, and the remaining scored measures will consist of either the five highest scoring quality measures or the three highest scoring measures, as applicable, in traditional MIPS and MVP reporting.

As discussed in section IV.A.4.d.(1)(c)(iii)(B) of this proposed rule, we propose to remove the current quality measure data submission requirement of one outcome measure (or, if an outcome measure is not available, one high priority measure) for traditional MIPS and MVP reporting and replace the requirement with a MIPS core measure data submission requirement. As discussed in section IV.A.4.d.(1)(c)(i) of this proposed rule, one of the factors considered for the proposed MIPS core measure selection includes an emphasis on whether the measure is an outcome-based measure. We refer readers to section IV.A.4.d.(1)(c)(i) of this proposed rule

for additional details on the proposal to designate MIPS core measures. Therefore, we propose to assign zero measure achievement points for one quality measure if clinicians reporting traditional MIPS or MVP do not submit a MIPS core measure and do not attest during data submission that they do not have an available and applicable MIPS core measure. This proposal is consistent with the existing rule under § 414.1380(b)(1)(i). Under the existing policy under § 414.1380(b)(1)(i), MIPS eligible clinicians who submit data in accordance with § 414.1325 on a greater number of measures than required under § 414.1335 are scored only on the measures with the greatest number of measure achievement points. Therefore, we are not proposing any changes to the regulatory text for this proposal.

We request public comment on this proposal.

(2) Small Practice Scoring Exemption Clarification for MIPS Core Measures

Historically, we have heard from clinicians in small practices that they face unique challenges to successfully participate in MIPS. To further support clinicians in small practices, who often have limited resources to successfully participate in MIPS, we implemented policies to provide them with more flexibilities. For example, as described under § 414.1380(b)(1)(v)(C), beginning with the CY 2019 performance period/2021 MIPS payment year, MIPS eligible clinicians in small practices receive 6 measure bonus points if they submit data to MIPS on at least 1 quality measure. To continue the existing flexibilities and further support clinicians in small practices, we propose in section IV.A.4.d.(1)(c)(iii)(C) of this proposed rule that small practice clinicians participating in both traditional MIPS and MVP reporting would be exempt from the MIPS core measure reporting requirement. Under this proposal, clinicians in small practices are not required to submit MIPS core measures and would not need to attest during data submission if they do not have an available and applicable MIPS core measure. The existing regulation text under § 414.1380(b)(1)(i) states that MIPS eligible clinicians receive zero measure achievement points for each measure required under § 414.1335 for which no data is submitted in accordance with § 414.1325. Consistent with the existing regulation at § 414.1380(b)(1)(i) and given the proposal to exempt small practices from the MIPS core measure requirement in section IV.A.4.d.(1)(c)(iii)(C) of this proposed rule, we would not assign zero measure achievement points for one MIPS core measure if clinicians in small practices do not submit data for such measure in traditional MIPS and MVP reporting. If a small practice chooses to submit data on a MIPS core measure, we would include the core measure in the quality performance category score only if the MIPS core measure is one of the six highest scoring measures in traditional MIPS or one of the four highest scoring measures in MVP reporting, in accordance with the existing regulation under § 414.1380(b)(1)(i). We refer readers to Appendix 1: MIPS Quality Measures of this proposed rule for details on the proposed MIPS core measures inventory for the CY 2027 performance period/2029 MIPS payment year.

(3) Scoring Topped Out Measures

(a) Background on Scoring Topped Out Measures

We refer readers to the CY 2017, CY 2018, and CY 2019 Quality Payment Program final rules (81 FR 77282 through 77287, 82 FR 53721 through 53727), the CY 2023, CY 2025, and CY 2026 PFS final rules (83 FR 59761 through 59765, 88 FR 70090 and 70091, 89 FR 98428 through 98435, and 90 FR 49902 through 49908), and § 414.1380(b)(1)(iv) for established topped out measure scoring policies.

Topped out measures are measures for which measure performance is considered so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (81 FR 77136). Section 1848(q)(3)(B) of the Act requires that in establishing performance standards with respect to measures and activities, we consider, among other things, the opportunity for continued improvement. Topped out measures do not provide an opportunity for continued improvement, nor do payment adjustments based on topped out measures incentivize clinicians to improve their care. As a result, we finalized policies in the CY 2018 Quality Payment Program final rule (82 FR 53723 through 53727) to identify and cap the scoring potential of topped out measures. Additionally, we established policies for the removal of topped out measures, such as establishing the topped out measure lifecycle, to continue to drive quality improvement in areas where such improvement is possible and necessary. The topped out measure lifecycle is described in the CY 2018 Quality Payment Program final rule (82 FR 53721 through 53727). We established at § 414.1380(b)(1)(iv)(B) that we will cap scoring for topped out measures at seven measure achievement points in the second consecutive year that the measure benchmark is identified as topped out. If a measure has been identified as topped out for three consecutive years after being originally identified through the benchmarks, such measure may then be proposed for removal through notice-and-comment rulemaking (83 FR 59761). This timeline, however, is not fixed. We noted our concern that removal of topped out measures may leave clinicians with fewer than six applicable measures to report and that such removal in those instances will impact some specialties more than others (82 FR 53721). We stated that consideration for ensuring available applicable measures would be made when considering measure removals (83 FR 59763).

In the CY 2018 Quality Payment Program final rule (82 FR 53727), we established the topped out scoring cap to encourage MIPS eligible clinicians to submit measures that are not topped out. However, we created an exemption to this policy in the CY 2025 PFS final rule (89 FR 98428 through 98435) for certain topped out measures that are frequently used by certain specialties impacted by limited measure choice (89 FR 98428 through 98435). To address scoring scenarios in which limited measure choice compels clinicians to report topped out measures with scoring caps, we finalized in the CY 2025 PFS final rule (89 FR 98428 through 98435) at § 414.1380(b)(1)(iv)(C) that beginning with the CY 2025 performance period/2027 MIPS payment year, topped out measures frequently used by certain specialties reporting specialty measure sets that are impacted by limited measure choice, as specified in accordance with § 414.1380(b)(1)(ii)(E), are not subject to the 7-point scoring cap. In the CY 2025 PFS final rule, we finalized at § 414.1380(b)(1)(ii)(E) that beginning with the CY 2025 performance period/2027 MIPS payment year, we will annually publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice. Measures included in the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period, in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

In the CY 2026 PFS final rule (90 FR 49904 through 49908), we modified our approach for identifying the list of measures impacted by limited measure

choice and subject to defined topped out measure benchmarks. We finalized that each specialty measure set and MVP is reviewed by collection type to identify if the prevalence of topped out measures within such a set of measures hinders a clinician's ability to successfully participate in the MIPS quality performance category. To make such a determination, we finalized a policy stating that we will analyze the ability of clinicians reporting the specialty measure sets and MVPs to reasonably achieve 75 percent of available quality achievement points based upon the measures available to them and program requirements. Specifically, at the collection type level, each measure is assigned points based upon the current benchmarking data: new measures receive 7 or 5 points based on year in the program, measures with benchmarks are given points based upon the highest decile achievable with a less than perfect score (less than 100 percent or greater than 0 percent for inverse measures), and measures with no available historic benchmark are given 0 points. All measure set points are added together to get an output of scoring potential; the Medicare Part B claims collection type measure sets have an additional 6 points added to the output to account for the small practice bonus. The sum of quality achievement points for each specialty measure set and MVP are then compared to the analysis threshold of 75 percent of available quality achievement points, based on the number of available measures. Any specialty measure sets or MVPs that are unable to meet or exceed the analysis threshold are flagged as ''at-risk.''

Additional factors that we take into consideration include whether the topped out measure is considered a cross-cutting measure or is a broadly applicable measure, which we consider to be a measure included in three or more specialty sets or MVPs. We also consider whether the specialty measure set or MVP contains more than ten measures, by collection type (90 FR 49904 through 49908).

(b) Proposal of Measures Impacted by Limited Measure Choice To Be Subject to Defined Topped Out Benchmark for the CY 2027 Performance Period/2029 MIPS Payment Year

Table C–H1 of this proposed rule contains the list of measures that meet the criteria for topped out measures impacted by limited measure choice in specialty measure sets and MVPs as finalized in the CY 2026 PFS final rule (90 FR 49904 through 49908), and for which we are proposing to apply the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year.

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TABLE C-H1: PROPOSED TOPPED OUT MEASURES IMPACTED BY LIMITED MEASURE CHOICE AND SUBJECT TO DEFINED TOPPED OUT MEASURE BENCHMARKS FOR THE CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Measure ID	Collection Type	Measure Title
127	MIPS CQM	Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention - Evaluation of Footwear
144	MIPS CQM	Oncology: Medical and Radiation - Plan of Care for Pain
145	Medicare Part B Claims, MIPS CQM	Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy
249	Medicare Part B Claims, MIPS CQM	Barrett's Esophagus
250	Medicare Part B Claims, MIPS CQM	Radical Prostatectomy Pathology Reporting
351	MIPS CQM	Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation
360	MIPS CQM	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies
364	MIPS CQM	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines
395	Medicare Part B Claims, MIPS CQM	Lung Cancer Reporting (Biopsy/Cytology Specimens)
396	MIPS CQM	Lung Cancer Reporting (Resection Specimens)
397	Medicare Part B Claims, MIPS CQM	Melanoma Reporting
405	MIPS CQM	Appropriate Follow-up Imaging for Incidental Abdominal Lesions
406	Medicare Part B Claims, MIPS CQM	Appropriate Follow-up Imaging for Incidental Thyroid Nodules in Patients
430	MIPS CQM	Prevention of Post-Operative Nausea and Vomiting (PONV) - Combination Therapy
440	MIPS CQM	Skin Cancer: Biopsy Reporting Time - Pathologist to Clinician
463	MIPS CQM	Prevention of Post-Operative Vomiting (POV) - Combination Therapy (Pediatrics)
477	MIPS CQM	Multimodal Pain Management

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We had considered proposing measures 143: Oncology: Medical and Radiation—Pain Intensity Quantified (eCQM and MIPS CQM), 320: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patient (Medicare Part B Claims and MIPS CQM), and 350: Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy (MIPS CQM) to be subject to the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year since the measures meet the criteria for topped out measures in specialty measure sets or MVPs impacted by limited measure choice according to the methodology finalized in the CY 2026 PFS final rule (90 FR 49904 through 49908). However, we are not proposing these measures for the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year because we are proposing to remove these measures from the

quality performance category measure inventory for the CY 2027 performance period/2029 MIPS payment year in section IV.A.4.d.(1)(e)(ii) of this proposed rule. We propose that if we do not finalize the removal of these measures from the MIPS quality performance category inventory for the CY 2027 performance period/2029 MIPS payment year, we would score these measures with the defined topped out measure benchmark for the CY 2027 performance period/2029 MIPS payment year.

We request public comment on this proposal.

(c) Proposal to Score Topped Out MIPS Core Measures According to Defined Topped Out Benchmark

In section IV.A.4.d.(1)(c)(iii)(B) of this proposed rule, we are proposing that MIPS eligible clinicians would need to report a MIPS core measure as one of their six required quality measures in traditional MIPS or one of their four required quality measures in MVP reporting, beginning in the CY 2027 performance period/2029 MIPS payment year. We refer readers to Appendix 1: MIPS Quality Measures of this proposed rule for the proposed MIPS core measure inventory. There are 19 proposed MIPS core measures that are topped out and subject to the 7-point topped out measure scoring cap for the CY 2026 performance period/2028 MIPS payment year. As described in section IV.B.1.b.(3)(a) of this proposed rule, to address scoring scenarios in which limited measure choice compels clinicians to report topped out measures with scoring caps, we finalized the defined topped out benchmark in the CY 2025 PFS final rule (89 FR 98428 through 98435). The defined topped out benchmark removes the 7-point scoring cap for topped out measures and scores them from 1 to 10 measure achievement points according to a benchmark calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

The prevalence of topped out MIPS core measures, combined with the limited measure choice associated with MIPS core measures, could result in a clinician being compelled to report a topped out MIPS core measure as one of their six required quality measures in traditional MIPS or one of their four required quality measures in MVP reporting. Given the combination of limited measure choice and the 7-point scoring cap for topped out measures, we are concerned that the application of the 7-point scoring cap to topped out MIPS core measures would penalize clinicians for complying with the proposed reporting requirement. Therefore, we are proposing that MIPS core measures in their second or more consecutive year of being topped out would not be subject to the 7-point topped out measure scoring cap, and instead the measures would be scored from 1 to 10 measure achievement points according to the defined topped out benchmark.

Subsequently, we are proposing to create the scoring methodology for MIPS core measures that are topped out. Thus, we are proposing to amend and codify at § 414.1380(b)(1)(ii) by establishing a new provision at § 414.1380(b)(1)(ii)(H), which would establish the scoring (1 to 10 measure achievement points) for MIPS core measures that have benchmarks identified as topped out for 2 or more consecutive years. Specifically, we are proposing to establish and codify at § 414.1380(b)(1)(ii)(H), which would determine the following: Beginning in the CY 2027 performance period/2029 MIPS payment year, MIPS core measures, which are required under § 414.1335(a)(1)(i) and (ii), for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years, are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year. Also, we are proposing for MIPS core measures not to be subject to the 7-point topped out measure scoring cap. Specifically, we are proposing to amend and codify at § 414.1380(b)(1)(iv) by establishing a new provision at § 414.1380(b)(1)(iv)(D), which would determine the following: Beginning with the CY 2027 performance period/2029 MIPS payment year, MIPS core measures, which are required under § 414.1335(a)(1)(i) and (ii), are not subject to the 7 measure achievement point cap specified at § 414.1380(b)(1)(iv)(B).

We request public comment on this proposal.

(d) Clarification Regarding Scoring Non-Topped Out Measures According to Historical Benchmark

In the CY 2025 PFS final rule (89 FR 98428 through 98435), we finalized at § 414.1380(b)(1)(ii)(E) that beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice on an annual basis. Measures included in the list will be scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year. The measures are identified using a methodology finalized in the CY 2026 PFS final rule (90 FR 49904 through 49908), which analyzes whether the prevalence of topped out measures within a specialty measure set or an MVP hinders a clinician's ability to successfully participate in the MIPS quality performance category. Using current benchmarking data, the analysis evaluates the ability of clinicians to reasonably achieve 75 percent of available quality achievement points given the measures available to them and program requirements.

At the time of the internal analysis to inform the list of measures impacted by limited measure choice, the most current benchmarking data is for the performance period prior to that which the defined topped out measure benchmark would be applied. For example, we analyzed CY 2026 benchmarks to inform the list of measures impacted by limited measure choice for the CY 2027 performance period/2029 MIPS payment year. Therefore, there are instances in which a measure is finalized to be scored according to the defined topped out benchmark for a given performance period, but it is later determined that the historic baseline period benchmark for that measure is not topped out for that performance period. This was the case for Medicare Part B Claims Measure 141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care for the CY 2026 performance period/2028 MIPS payment year. In the CY 2026 PFS final rule (90 FR 49906 through 49908), we finalized Medicare Part B Claims Measure 141 to be scored according to the defined topped out measure benchmark for the CY 2026 performance period/2028 MIPS payment year based on an analysis of the CY 2025 performance period/2027 MIPS payment year benchmarks, the most recently available benchmarks at the time of the analysis. However, the subsequently released benchmarks for the CY 2026 performance period/2028 MIPS payment year indicated that the baseline period benchmark for Medicare

Part B Claims Measure 141 was not topped out. Given the topped out measure lifecycle, as finalized in the CY 2018 Quality Payment Program final rule (82 FR 53721 through 53727), Medicare Part B Claims Measure 141 would not be capped at 7 measure achievement points for the CY 2026 performance period/2028 MIPS payment year since it was not topped out.

If a measure is not topped out, it no longer meets the criteria for the removal of the 7 measure achievement point cap. We clarify that if a measure previously finalized for removing the 7-point cap is no longer topped out, it would be scored using its historical benchmark instead of the topped-out measure benchmark.

(e) Proposal To Modify Location for Publishing List of Measures Subject to Defined Topped Out Benchmark

In the CY 2025 PFS final rule (89 FR 98428 through 98435), we finalized at § 414.1380(b)(1)(ii)(E) to state that beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list in the **Federal Register** of topped out measures determined to be impacted by limited measure choice on a yearly basis. Measures included in the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year. In the CY 2026 PFS final rule (90 FR 49904 through 49908), we finalized the methodology to identify topped out measures impacted by limited measure choice. We analyze whether the prevalence of topped out measures with a 7-point cap within a specialty measure set or an MVP hinders a clinician's ability to successfully participate in the MIPS quality performance category. This analysis is based on the most current benchmarking data available at that time. We finalized in the CY 2018 Quality Payment Program final rule that MIPS eligible clinicians will know the quality performance category measure benchmarks in advance of the performance period, when possible (81 FR 77271 and 77272), and that the benchmarks will be posted on the Quality Payment Program website (81 FR 77139).

Given the benchmark availability timeline, the list of topped out measures scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark published in the **Federal Register** for a performance period may not accurately indicate whether a measure is topped out for that performance period. For example, as discussed in section IV.B.1.b.(3)(d) of this proposed rule, a measure previously determined to be topped out and scored from 1 to 10 points for the CY 2026 performance period/2028 MIPS payment year based on data using the CY 2025 performance period benchmarks was later found not to be topped out based on the updated CY 2026 benchmarks. This occurs because, during the time of the analysis to identify measures impacted by limited measure choice, only the most recent benchmarks s from the prior performance period are available. For example, we analyzed CY 2026 performance period benchmarks to inform topped out measures impacted by limited measure choice for the CY 2027 performance period/2029 MIPS payment year.

We are concerned that publishing the list of topped out measures impacted by limited measure choice and scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark in the **Federal Register**, prior to the benchmark information for that performance period being available, can lead to confusion. To avoid confusion for clinicians, we are proposing that, beginning in the CY 2027 performance period/2029 MIPS payment year, we would publish the list of topped out measures impacted by limited measure choice and scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark annually on the Quality Payment Program website at *https://qpp.cms.gov.* Specifically, we are proposing to remove the phrase ''in the **Federal Register**'' under § 414.1380(b)(1)(ii)(E).

Further, we note that the measures included in this list would still be identified using the previously finalized methodology for determining topped out measures impacted by limited measure choice in specialty measure sets and MVPs, as finalized in the CY 2026 PFS final rule (90 FR 49904 through 49908). By publishing the list of topped out measures impacted by limited measure choice on the Quality Payment Program website, we would be able to update the list, once the benchmark information for that performance period becomes available, to remove measures that are not topped out for that performance period, consistent with the topped out measure lifecycle, finalized in the CY 2018 Quality Payment Program final rule (82 FR 53721 through 53727). We refer readers to section IV.B.1.b.(3)(d) of this proposed rule for our discussion that measures previously finalized to be scored using the defined topped out benchmark would instead be scored using the baseline period benchmark if updated benchmark data show the measure is not topped out for that performance period.

We would publish the list of topped out measures impacted by limited measure choice and scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark on the Quality Payment Program website no later than the publication of the proposed rule for that CY performance period/MIPS payment year. This timeline would provide interested parties with sufficient opportunity to review and provide comments on the list of measures during the public comment period for that proposed rule. Once the list of topped out measures impacted by limited measure choice and scored from 1 to 10 measure achievement points according to the defined topped out measure benchmark is finalized during rulemaking, the only changes to the list would be the removal of a measure because it is no longer topped out based on most current benchmarks published in the performance period.

Thus, we are proposing to amend § 414.1380(b)(1)(ii)(E) by removing the phrase ''in the **Federal Register**''. Also, we are proposing a technical amendment in § 414.1380(b)(1)(ii)(E) for grammar purposes, which would modify the beginning of the second sentence in § 414.1380(b)(1)(ii)(E) from ''. . . measure included in the list . . .'' to ''measure included on the list . . .''. The revised § 414.1380(b)(1)(ii)(E) would state: Beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list of topped out measures determined to be impacted by limited measure choice on a yearly basis. Measures included on the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

We request public comment on these proposals.

c. Scoring the Quality Performance Category for Medicare Shared Savings Program ACOs

(1) Proposal To Use Flat Benchmarks To Score Medicare Shared Savings Program ACOs Reporting Medicare CQMs

In the CY 2025 PFS final rule (89 FR 98117), we finalized our proposal to establish new benchmarks for scoring Medicare Shared Savings Program ACOs on the Medicare CQMs under MIPS in alignment with MIPS benchmarking policies. As historical Medicare CQM data would not be available, we finalized that for performance years 2024 and 2025, we will score Medicare CQMs using performance period benchmarks. We also finalized that, for performance year 2026 and subsequent performance years, when baseline period data are available to establish historical benchmarks in a manner that is consistent with the MIPS benchmarking policies at § 414.1380(b)(1)(ii), we would score Medicare CQMs using historical benchmarks. In the CY 2025 PFS final rule, we also finalized our proposal to add § 414.1380(b)(1)(ii)(F) to state that beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQM collection type would be scored using flat benchmarks for their first two performance periods in MIPS (89 FR 98120).

As described in section III.G.3.c. of this proposed rule, we are proposing to modify § 414.1380(b)(1)(ii)(F) by removing the applicability of the first two performance periods to the use of flat benchmarks and extending the use of flat benchmarks to score all Medicare CQMs for performance year 2025 and subsequent performance years. Also, we are proposing to retroactively apply flat benchmarks to Quality IDs 001 (Diabetes: Glycemic Status Assessment Greater Than 9%), 134 (Preventive Care and Screening: Screening for Depression and Follow-up Plan), and 236 (Controlling High Blood Pressure), if reported via the Medicare CQMs collection type for performance year 2026.

Specifically, we are proposing to amend and codify at § 414.1380(b)(1)(ii)(F), by converting such section to a title section entitled ''Medicare CQMs collection type benchmarks'' and establishing § 414.1380(b)(1)(ii)(F)(*1*) and (*2*). In § 414.1380(b)(1)(ii)(F)(*1*), we are proposing that for the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQMs collection type would utilize flat benchmarks for their first two performance periods in MIPS. In § 414.1380(b)(1)(ii)(F)(*2*), we are proposing to retroactively apply the utilization of flat benchmarks for the Medicare CQMs collection type beginning with the CY 2026 performance period/2028 MIPS payment year. Specifically, we are proposing that beginning with the CY 2026 performance period/2028 MIPS payment year, measures of the Medicare CQMs collection type would utilize flat benchmarks. We refer readers to section III.G.3.c. of this proposed rule for further discussion regarding the extension of applying the utilization of flat benchmarks for the Medicare CQMs collection type, including discussion about the retroactive use of flat benchmarks for the Medicare CQMs collection type in the CY 2026 performance period/2028 MIPS payment year.

We request public comment on these proposals.

(2) Proposal To Use Flat Benchmarks To Score Medicare Shared Savings Program ACOs Reporting Medicare eCQMs

As described in section III.G.3.d.(3) of this proposed rule, we are proposing to develop a policy that establishes the utilization of flat benchmarks for measures of the newly proposed Medicare eCQMs collection type reported by Medicare Shared Savings Program ACOs. As a result, Medicare eCQMs would be scored using flat benchmarks beginning with the 2027 performance period. To effectuate such proposal under MIPS for purposes of assessing and scoring performance for the quality performance category, we are proposing to add § 414.1380(b)(1)(ii)(G) to establish a new provision specific to benchmarks for measures of the Medicare eCQMs collection type, entitled ''Medicare eCQMs collection type benchmarks.'' Subsequently, we are proposing to add § 414.1380(b)(1)(ii)(G)(1), which establishes the utilization of flat benchmarks under the Medicare eCQMs collection benchmarks provision established at § 414.1380(b)(1)(ii)(G). Specifically, we are proposing in § 414.1380(b)(1)(ii)(G)(1) to establish that beginning with the CY 2027 performance period/2029 MIPS payment year, measures of the Medicare eCQMs collection type would utilize flat benchmarks.

We request public comment on this proposal.

d. Scoring the Promoting Interoperability Performance Category

Proposal To Modify the Scoring of the Electronic Prior Authorization Measure for CY 2027 Performance Period/2029 MIPS Payment Year

In section IV.A.4.d.(4)(f)(ii) of this proposed rule, we are proposing to modify the Electronic Prior Authorization measure by changing the measure from a required measure to an optional measure and eligible for 10 bonus points when MIPS eligible clinicians affirmatively attest (''Yes'' response) to meeting the requirements of the measure for the CY 2027 performance period/2029 MIPS payment year. We believe that the allocation of 10 bonus points is an appropriate and effective incentive to promote the adoption and use of certified technology for requesting electronic prior authorizations among MIPS eligible clinicians. To account for the allocation of bonus points specific to the Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year, the scoring methodology for optional measures available for bonus points needs to be amended.

In § 414.1380(b)(4)(ii)(C)(3), the optional measures available for reporting are not identified or categorized by objective; however, the applicable optional measures available in the MIPS Promoting Interoperability performance category as of the CY 2026 performance period (Syndromic Surveillance Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Public Health Reporting Using TEFCA) are all under the Public Health and Clinical Data Exchange objective. When reporting one, more than one, or all such optional measures, the total number of bonus points that could be earned is five bonus points. To distinguish between such optional measures that are available under the Public Health and Clinical Data Exchange objective and the Electronic Prior Authorization measure as an optional measure for the CY 2027 performance period/2029 MIPS payment year that is under the Health Information Exchange objective and has an allocation of 10 bonus points, we are proposing to modify the scoring methodology to account for the optional measures available under each applicable objective within the MIPS Promoting Interoperability performance category.

We are proposing to modify the scoring methodology for optional measures to reflect an allocation of a total of five bonus points when

reporting one, more than one, or all optional measures (Syndromic Surveillance Reporting, Public Health Registry Reporting, Clinical Data Registry Reporting, and Public Health Reporting Using TEFCA) available under the Public Health and Clinical Data Exchange objective bonus and an allocation of a total of 10 bonus points when reporting the optional Electronic Prior Authorization measure for the CY 2027 performance period/2029 MIPS payment year available under the Health Information Exchange objective.

Thus, we are proposing to amend § 414.1380(b)(4)(ii)(C)(*3*) by modifying the provision to identify the MIPS Promoting Interoperability performance category objective, specifically the Public Health and Clinical Data Exchange objective, in which the applicable optional measures are available to earn a total of five bonus points when reporting one, more than one, or all optional measures. Specifically, we are proposing to amend § 414.1380(b)(4)(ii)(C)(*3*) by modifying the provision to indicate that the total number of bonus points available to be earned when reporting one optional measure, more than one optional measure, or all optional measures under the Public Health and Clinical Data Exchange objective is a total of five bonus points beginning with the CY 2026 performance period/2028 MIPS payment year. Additionally, we are proposing to establish a new provision at § 414.1380(b)(4)(ii)(C)(*4*) to account for the Electronic Prior Authorization measure being an optional measure under the Health Information Exchange objective and having an allocation of a total of 10 bonus points for the CY 2027 performance period/2029 MIPS payment year. Specifically, we are proposing to establish § 414.1380(b)(4)(ii)(C)(*4*), which would determine that the total number of bonus points available to be earned when reporting the Electronic Prior Authorization optional measure is a total of 10 bonus points for the CY 2027 performance period/2029 MIPS payment year. The establishment of such provision (only applicable to the CY 2027 performance period/2029 MIPS payment year) would enable a MIPS eligible clinician to earn 10 bonus points for affirmatively attesting that they requested a prior authorization electronically using CEHRT to send a request through a payer's Prior Authorization API for at least one medical item or service (excluding drugs) ordered within the CY 2027 performance period/2029 MIPS payment year.

We request public comment on this proposal.

e. MVP Scoring Request for Information

As discussed in section IV.A.3.c. of this proposed rule, we are proposing to move to full implementation of MVP reporting beginning in the CY 2029 performance year/2031 MIPS payment year. As a part of the transition to full MVP implementation, we intend to examine current MVP scoring policies to align with full MVP reporting. For example, we could consider scoring approaches that allow us to more fairly compare performance of clinicians within the same MVP. MVPs focus on measures that are relevant to a given specialty and offer clinicians with meaningful groupings of measures and activities that relate to a specialty or medical condition. Reporting from these smaller, more aligned sets of quality and cost measures, improvement activities, and foundational layer of Promoting Interoperability measures and population health measures allows for performance measurement that more closely compares clinicians within the same specialty and provides connected assessment of quality of care.

In the CY 2022 PFS final rule (86 FR 65419 through 65427), we finalized policies for MVP scoring at § 414.1365(d). We noted that unless there was a compelling reason to adopt a different scoring policy to further the goals of the MVP framework, we generally applied the traditional MIPS scoring policies to MVPs to reduce complexity as clinicians transition to reporting MVPs.

In the CY 2025 PFS proposed rule, we issued an RFI on how we can achieve full MVP implementation as we move toward the sunsetting of traditional MIPS (89 FR 62011 through 62016). In response to that RFI, we received feedback from interested parties regarding the scoring of MVPs. Commenters discussed scoring fairness within MVP reporting and across MVPs. Specifically, commenters shared concerns about the availability of measures in an MVP, having topped out measures with a 7-point cap, and reporting Class 2 measures that cannot be scored based on performance due to the lack of a benchmark or failure to meet the case minimum.

We recognize that MVP performance data is currently limited as we have data from only the CY 2023 through 2025 performance periods/2025 through 2027 MIPS payment years and MVP participation remains nascent in the early years. Hence, a small number of MIPS eligible clinicians voluntarily reported MVPs during those three performance periods. While additional data will be needed to confirm any findings, we are assessing whether an MVP score normalization is needed within an MVP to ensure scoring fairness across MVPs. We are also considering the timing for implementing a new MVP scoring methodology: beginning with the CY 2029 performance period/2031 MIPS payment year, consistent with the proposed timeline for full MVP implementation described in section IV.A.3.c. of this proposed rule, or whether an earlier pilot rollout would be appropriate to give clinicians experience with the new scoring approach while traditional MIPS reporting is available. We request feedback on when a potential change to MVP scoring should be implemented.

As we move toward the full implementation of MVPs in the CY 2029 performance period/2031 MIPS payment year, we are exploring scoring policies that consider commenter feedback and align with the intended goals of MVPs. Specifically, we are exploring an MVP scoring methodology and policies to fairly evaluate and reward MVP participants for delivering high-quality and low-cost care by comparing clinician performance to others reporting the same MVP. As we consider policy options for MVP scoring, we are seeking comments on the following questions to further discussion and considerations for the future of MVP scoring.

- We are seeking feedback on a scoring methodology that would help us ensure appropriate comparisons between clinicians participating in different MVPs, with each MVP focusing on measures and activities that are relevant to a given specialty or medical condition.

++ Prior to MIPS payment adjustment determination, should we consider normalizing scores, such that MIPS eligible clinicians reporting a given MVP would have their scores compared to other MIPS eligible clinicians reporting the same MVP? If so, should normalization occur at the final score level or at a performance category level? If at a performance category level, which performance category(ies) should be normalized?

++ For example, should we consider normalizing performance category or final scores using a methodology similar to the current standard-deviation based benchmark methodology used to score cost and administrative claims-based quality measures. Current cost and administrative claims-based quality measures use performance period standard deviation, median, and an

anchored point value that is derived from the performance threshold.

++ How would a new scoring approach of normalizing final scores influence provider behaviors?

++ How would a new scoring approach of normalizing performance category scores influence provider behaviors?

++ Should we normalize scores within each MVP to result in similar distributions of scores across MVPs? We anticipate doing so would change scores based on a clinician's relative performance within their MVP. Would this approach justify the interest of scoring fairness across MVPs while impacting final scores and payment adjustments?

• We are also soliciting feedback on any additional scoring methodologies or approaches we should consider to ensure fairness within and across MVPs.

• While we are considering scoring fairness within and across specialty-based MVPs as a primary goal for the future of MVP scoring, we are also interested in other goals to consider.

++ For example, should we consider whether MVP scoring policies provide more meaningful rewards for the high performing clinicians via larger positive payment adjustments?

++ Given that MIPS is a budget-neutral program, would an increase in rewards for high performers warrant the trade-off of having more clinicians receiving negative payment adjustments?

++ Some scoring approaches may increase scoring fairness within and across MVPs while it may also reduce a clinician's ability to predict their performance category or final score. However, clinicians and practices still have access to the benchmarks used for normalization in the prior year. How could we better support scoring transparency and predictability as a key consideration for the future of MVP scoring?

• If we move forward with proposing a scoring normalization for MVPs in future rulemaking, what resource materials would be most helpful to understand and navigate new MVP scoring policies?

Please note, this is an RFI only. In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), this general solicitation is exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

f. Proposed Improvement Activities Scoring for APMs

In the CY 2017 Quality Payment Program final rule (81 FR 77008 through 77012), we established policies for scoring the improvement activities performance category, including criteria for weighting and attestation. In that same rule, we also established special scoring provisions for MIPS eligible clinicians participating in Alternative Payment Models (APMs), recognizing that such clinicians are often already engaged in activities aligned with MIPS improvement activities through their APM participation. Specifically, we finalized a policy under § 414.1380(b)(3)(i) to assign a minimum score for the improvement activities performance category for MIPS eligible clinicians participating in APMs (81 FR 77096). We explained that this approach was intended to reduce reporting burden while acknowledging that APM participants are typically undertaking practice improvement efforts consistent with the goals of the improvement activities performance category.

We have maintained this policy in subsequent rulemaking, specifically the CY 2021 PFS final rule (85 FR 84472), we attempted to ensure that scoring this category did not inadvertently harm participants. However, in doing so we introduced scenarios where IA scores for some APM participants would not be awarded credit as established in section 1848(q) of the Act.

We are proposing to revise § 414.1380(b)(3)(i) to clarify and maintain that, for MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent. This revision is consistent with the policy we established in the CY 2017 Quality Payment Program.

We request public comment on this proposal.

H. Third Party Intermediaries General Requirements

1. Background

We refer readers to 42 CFR 414.1305,414.1400, the CY 2017 Quality Payment Program final rule (81 FR 77362 through 77390), the CY 2018 Quality Payment Program final rule (82 FR 53806 through 53819), the CY 2019 PFS final rule (83 FR 59894 through 59910), the CY 2020 PFS final rule (84 FR 63049 through 63080), the May 8th COVID–19 IFC (85 FR 27594 and 27595), the CY 2021 PFS final rule (85 FR 84926 through 84947), the CY 2022 PFS final rule (86 FR 65538 through 65550), CY 2023 PFS final rule (87 70102 FR through 70109), the CY 2024 PFS final rule (88 FR 79381 through 79394), the CY 2025 PFS final rule (89 FR 98459), and the CY 2026 PFS final rule (90 FR 49920) for our previously established policies regarding third party intermediaries.

In this section of the proposed rule, we propose to update our requirements for third party intermediaries related to conditions for approval for Qualified Clinical Data Registries (QCDRs) and qualified registries, remove the additional requirements for health IT vendors, and update our remedial action/termination policies. Specifically, we propose the following:

• Additional Requirements for Health IT Vendors:

++ Clarifying that additional requirements for health IT vendors do not apply beginning with the CY 2025 performance period/2027 MIPS payment year, because beginning in the CY 2025 performance period/2027 MIPS payment year health IT vendors are no longer allowed to submit MIPS data as a third-party intermediary,

• Conditions for Approval:

++ Clarifying that performance feedback reports would be provided based on participation level (for example, individual, group, subgroup, virtual group, or APM entity).

++ Updating the existing two policies in which (1) a third party intermediary with fewer than 10 Quality Payment Program participants submitting MIPS data must audit all Quality Payment Program participants and (2) a third party intermediary submitting data for Quality Payment Program participants with fewer than 5 patient records must audit all patient records.

++ Updating the policy in which third party intermediaries that do not submit data for one year are required to submit a self-nomination participation plan.

++ Modifying the qualified postings' policy in which changes to the information submitted should not be done after the qualified posting is publicly posted on the Quality Payment Program's Resource Library page.

++ Revising existing policies to specify a QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one MIPS core measure to align with the proposed removal of high priority designation from MIPS quality

measures and the MIPS core measure reporting requirements in section IV.A.4.d.(1)(c) of this proposed rule.

- Remedial Action and Termination of Third Party Intermediaries:

++ Clarifying that if a third party intermediary does not submit data for one year, they would be required to provide documentation and would be terminated if documentation cannot be provided and/or the documentation shows that they would not be submitting data for the given MIPS performance period.

2. Proposal To Further Clarify in Regulation Text That Health IT Vendors Can Not Submit Data Beginning With the CY 2025 Performance Period/2027 MIPS Payment Year and That Preexisting Requirements for Health IT Vendors No Longer Apply

In the CY 2017 Quality Payment Program final rule (81 FR 77377 through 77382), we established the category of health IT vendors as a type of third party intermediary in the Quality Payment Program. In the CY 2019 PFS final rule, we codified the definition of a health IT vendor as an entity that supports the health IT requirements on behalf of a MIPS eligible clinician (including obtaining data from a MIPS eligible clinician's Certified Electronic Health Record Technology (CEHRT) (83 FR 59907). In the CY 2022 PFS final rule (86 FR 65541), we finalized a reorganization of the regulatory text governing third party intermediaries to improve clarity and readability. In that revised text, we established general requirements at § 414.1400(a), additional requirements for QCDRs and qualified registries at § 414.1400(b), and additional requirements for health IT vendors at § 414.1400(c).

The CY 2024 PFS final rule eliminated health IT vendors from the category of third party intermediaries in the Quality Payment Program beginning in the CY 2025 performance period/2027 MIPS payment year at § 414.1400(a)(1)(iii) (88 FR 79390 and 79391). We noted that the removal of health IT vendors from the definition of third party intermediary would not preclude the vendors from assisting MIPS eligible clinicians with reporting under the program by providing their technology for clinicians to directly report under MIPS. We also noted that eliminating the category of health IT vendor as a distinct type of third party intermediary created a clearer distinction between (1) vendors that are submitting data to CMS for the purposes of MIPS and must meet the requirements of a qualified registry or QCDR, and (2) vendors that work with clinicians through the sale and support of health IT permitting the clinician or group to submit the data.

We recognize that § 414.1400(c)(1) outlines additional requirements for health IT vendors submitting data for the MIPS performance category beginning with the CY 2021 performance period/2023 MIPS payment year even though we removed the category of health IT vendors for the Quality Payment Program beginning in the CY 2025 performance period/2027 MIPS payment year at § 414.1400(a)(1)(iii). These requirements being left in the regulation text caused confusion for some organizations interested in serving as third party intermediaries because it was not clear that these additional requirements for health IT vendors were no longer in place. If an organization that was previously under the health IT vendor category as a third party intermediary would like to continue serving as a third party intermediary for the Quality Payment Program, they must meet the requirements to become a qualified registry or QCDR.

Therefore, to reduce confusion and further clarify our existing policies, we propose to add at § 414.1400(c)(2) that beginning with the CY 2025 performance period/CY 2027 MIPS payment year, health IT vendors cannot submit MIPS data unless they meet the requirements for a qualified registry or QCDR. We also propose to modify § 414.1400(c)(1) to clarify that the additional requirements for health IT vendors only apply for the CY 2021 performance period/CY 2023 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year, when health IT vendors were still a separate type of third party intermediaries.

We request public comment on these proposals.

3. Conditions for Approval

a. Proposal To Provide Performance Feedback Reports at the Level of Data Submitted

In the CY 2017 Quality Payment Program final rule, we established requirements for performance feedback for QCDRs (81 FR 77367 through 77374) and qualified registries (81 FR 77383 through 77387) to provide timely feedback, at least four times a year, on all MIPS performance categories that the QCDR or qualified registry would report. We also finalized that the feedback should be given to the individual MIPS eligible clinician or group (if participating as a group) at the individual participant level or group level, as applicable, for which the QCDR or qualified registry reports. In the CY 2020 PFS final rule, we codified the requirement for QCDRs (84 FR 63057 and 63058) and qualified registries (84 FR 63076 and 63077) to provide timely feedback at least four times per year along with a new requirement to provide specific feedback to their clinicians and groups on how they compare to other clinicians who have submitted data on a given measure. In the CY 2022 PFS final rule (86 FR 65538 through 65550), we reorganized and consolidated the regulatory text governing third party intermediaries for clarity and simplicity and specifically to consolidate regulations that applied identically to both QCDRs and qualified registries. In that reorganization, the previously established policy for QCDRs and qualified registries to provide feedback which had been established at § 414.1400(b)(1) and (c)(1) was consolidated and redesignated at § 414.1400(b)(3)(iii) without a change in requirements. In the initial codification of the requirements for performance feedback in the CY 2020 PFS final rule for QCDRs (84 FR 63057 and 63058) and qualified registries (84 FR 63076 and 63077), we did not codify but also did not propose to remove the requirements previously established in the CY 2017 Quality Payment Program final rule for QCDRs (81 FR 77367 through 77374) and qualified registries (81 FR 77383 through 77387) that the feedback should be given to the individual MIPS eligible clinician or group (if participating as a group) at the individual participant level or group level, as applicable, for which the QCDR or qualified registry reports. We also did not refer to this requirement in the CY 2022 PFS final rule reorganization and redesignation of the regulatory text.

We have identified situations in which QCDRs or qualified registries provide the required performance feedback, but the feedback may reflect the performance of the individual when the clinician is reporting within a group. Alternatively, the feedback report reflects the performance of a group, but it was the individual that is reporting. We believe that this undermines the improvement opportunity that is inherent in these feedback reports and the value of these QCDRs and qualified registries. For this reason, we propose to add at § 414.1400(b)(3)(iii) that QCDRs and qualified registries must provide the performance feedback at the level at which the data was or will be submitted (for example, individual, group, virtual group, subgroup, APM entity). This proposal would codify the requirements

that were previously established but not codified in the CY 2017 Quality Payment Program final rule for QCDRs (81 FR 77367 through 77374) and qualified registries (81 FR 77383 through 77387) to provide feedback at the level at which data is submitted. We also propose to remove the term ''clinicians and groups'' in both places in this portion of the regulation. We believe that this requirement aligns with the requirement originally established in the CY 2017 Quality Payment Program Rule (81 FR 77363) but reflects the increased types of reporting entities available to MIPS eligible clinicians to include individuals, groups, virtual groups, subgroups, and APM entities.

We request public comment on these proposals.

b. Data Validation Requirements

(1) Background

Section 414.1400(b)(3)(v) outlines the requirements for a third party intermediary's annual data validation audit. As finalized in the CY 2024 PFS final rule (88 FR 79388), specified at § 414.1400(b)(3)(v)(E), the QCDR or qualified registry must conduct each data validation audit using a sampling methodology that meets the following requirements: (1) Uses a sample size of at least 3 percent of a combination of individual clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups and APM entities, and no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities; and (2) Uses a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

(2) Proposal To Update Sampling Methodology for Data Validation Purposes

We noticed that recently certain third party intermediaries are using less than the minimum sample size as required by § 414.1400(b)(3)(v)(E), which raises concern as to whether the data sample that is being submitted is adequate. Hence, to ensure that our data remains true, accurate, and complete, we propose the following updates:

- If the third party intermediary submits MIPS data to CMS for fewer than 10 Quality Payment Program participants, the data validation audit sample must include all Quality Payment Program participants. Hence, we propose to modify the existing requirements at § 414.1400(b)(2)(v)(E)(1) and (2) that govern a QCDR or qualified registry's data validation audit sampling methodology. Specifically, we propose at § 414.1400(b)(2)(v)(E)(1) that if the intermediary submits MIPS data to CMS for fewer than 10 Quality Payment Program participants, the data validation audit sample must include all Quality Payment Program participants. If the intermediary submits data for 10 or more Quality Payment Program participants, it must use a sample size of at least 3 percent of a combination of the individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups, or APM entities, and no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities.
- If there are fewer than 5 patient records from a Quality Payment Program participant, the patient record audit sample must include all patient records. Hence, we propose at § 414.1400(b)(2)(v)(E)(2) that if there are fewer than 5 patient records, the patient record audit sample must include all patient records. If there are 5 or more patient records, the intermediary must use a sample that includes at least 25 percent of the patient records of the individual clinician, group, virtual group, subgroup, or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

These updates would help third party intermediaries submit data that is true, accurate, and complete while meeting their submission requirements for data validation purposes.

We request public comment on these proposals.

c. Proposal To Require a Submission of a Self-Nomination Plan for Third Party Intermediaries That Do Not Submit Data for One Year

In the CY 2022 PFS final rule, we noted that we had identified several QCDRs and qualified registries that continued to self-nominate to become a third party intermediary for the MIPS program but had not submitted clinician, group, or virtual group data to CMS (86 FR 65545). We further noted as the MIPS program continues to mature, we wished to reduce the number of third party intermediaries that self-nominate to become a CMS-approved third party intermediary but do not actively participate in the MIPS program. Maintaining these vendors who do not actively participate does not provide a benefit to the MIPS program, rather it creates interested parties confusion by including these vendors in our qualified postings. We also noted that our goal was to decrease the operational burden on CMS and those third party intermediaries that do not submit MIPS data to CMS (86 FR 65546).

Accordingly, we finalized requirements for approved QCDRs and qualified registries that have not submitted performance data to submit a participation plan as part of their self-nomination process. We finalized an incremental approach to addressing this issue. First, at § 414.1400(b)(3)(vii), we finalized a participation plan requirement, which requires a QCDR or qualified registry that was approved but did not submit data for any of the CY 2017 through 2020 performance periods/2019 through 2022 MIPS payment years to submit a participation plan in order to be approved for the CY 2023 performance period/2025 MIPS payment year (86 FR 65545 and 65546). Second, at § 414.1400(b)(3)(viii), we finalized that a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan in order for it to be approved for the CY 2024 performance period/2026 MIPS payment year or a future performance period/payment year (86 FR 65546).

While this policy has reduced the number of QCDRs and Qualified Registries that do not submit data, some QCDRs and Qualified Registries are still being listed on the qualified posting for as long as three years without submitting data. Maintaining these third party intermediaries that do not actively participate does not provide a benefit to the MIPS program, rather it creates confusion for interested parties by including these third party intermediaries in our qualified postings. We continue to emphasize that our goal is to continue decreasing the operational burden on CMS and interested parties. CMS would decrease its operational burden by eliminating the need to screen these third party intermediaries.

In an effort to avoid further confusion, reduce administrative burden for both

CMS and interested parties, and ensure compliance, we propose to reduce the timeframe available for a QCDR or qualified registry that was approved but did not submit any MIPS data to submit a participation plan. Currently, a QCDR or qualified registry must submit a participation plan if they do not submit data for either of the 2 years preceding the applicable self-nomination period. We propose to require a QCDR or qualified registry to submit a participation plan if they do not submit data for the year preceding the applicable self-nomination period. We propose to redesignate and amend § 414.1400(b)(3)(viii) and add § 414.1400(b)(3)(viii)(A) and (B). Additionally, we also note that we encourage QCDRs and qualified registries to implement the participation plan at the beginning of the calendar year instead of waiting until the self-nomination period, which generally opens on July 1 and closes on September 1 of the year prior to the applicable MIPS performance period.

In summary, we specifically propose to redesignate the existing text at § 414.1400(b)(3)(viii) to § 414.1400(b)(3)(vii)(B) and amend the text to reflect that this requirement applies from the CY 2024 performance period/2026 MIPS payment year through the CY 2026 performance period/2028 MIPS payment year. Additionally, we also propose to add at § 414.1400(b)(3)(vii)(C) that beginning with the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for the year preceding the applicable self-nomination period must submit a participation plan for CMS' approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry. We also propose to redesignate the existing text at § 414.1400(b)(3)(vii) to at § 414.1400(b)(3)(vii)(A) and add the heading participation plan for third party intermediary not submitting data at § 414.1400(b)(3)(vii).

We request public comment on these proposals.

d. Proposal To Update Qualified Posting

Every year, CMS publishes a qualified posting on the CMS website containing a list of all CMS-approved third party intermediaries that have self-nominated to submit data on behalf of MIPS eligible clinicians for the MIPS performance period. This list is updated to account for withdrawals, remedial action, or termination of third party intermediaries. The qualified posting contains information about approved third party intermediaries such as organization details, information about remedial action or termination, supported performance categories, specialty focus, a description of services they provide and associated costs, reporting options (MVP versus traditional MIPS) and participation options (individual clinician, group, subgroup, virtual group, APM entity) supported, and measures they are approved to support. MIPS eligible clinicians can refer to information in the qualified posting to identify and select a third party intermediary.

In the CY 2017 Quality Payment Program final rule (81 FR 77367 through 77369 and 77384 through 77385), we established that QCDRs and qualified registries must sign a document that verifies their name, contact information, cost for MIPS eligible clinicians or groups to use the qualified registry, services provided, and the specialty-specific measure sets the qualified registry intends to report. As technology progressed, we no longer needed third party intermediaries to sign a document and instead required an attestation. We became aware that this requirement was no longer consistent with our established policy in describing the manner in which the QCDR or qualified registry documents this information. To align with current processes, we finalized in the CY 2024 PFS final rule to add § 414.1400(b)(3)(xiv), which required that QCDRs and qualified registries attest that the information listed on the qualified posting is accurate (88 FR 79385). Additionally, we also finalized in the CY 2024 final rule, at § 414.1305, to define qualified posting as the document made available by CMS that lists QCDRs or qualified registries available for use by MIPS eligible clinicians, groups, subgroups, virtual groups, and APM Entities (88 FR 79385). We noted that we had used the term qualified posting since the inception of the Quality Payment Program but had not previously defined the term.

We have recently been made aware that certain third party intermediaries are making changes to the information that was provided for their qualified posting after receiving CMS approval of the qualified posting. Examples of changes include updates to costs, services that are included in the initial cost, and other administrative changes. This creates an increased administrative burden for CMS, who must identify and rectify such changes, and it creates confusion amongst clinicians who contract with the third party intermediary as to what they will pay for the cost of the third party intermediary's services. Subsequently, we must make additional updates to the qualified posting, which increases the administrative burden on us. Hence, in efforts to reduce administrative burden for both clinicians and CMS, we propose to update § 414.1400(b)(3)(xiv) by adding a requirement that changes to information (for example, cost, services included) on the qualified posting must be included and finalized during the qualified posting review period. We propose specifying in regulatory text that third party intermediaries will not be permitted to make changes after the qualified posting is publicly posted on the Quality Payment Program Resource Library page.

We request public comments on these proposals.

e. Proposal To Update CMS Data Submission Requirements for Third Party Intermediaries

In the CY 2017 Quality Payment Program final rule, we finalized at § 414.1400(b)(3)(x) and (b)(3)(x)(A) that a QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one outcome measure and if no outcome measure is available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure (81 FR 77368).

However, in section IV.A.4.d.(1)(c) of this proposed rule, we are proposing to remove the high priority designation from MIPS quality measures beginning in the CY 2027 performance period/CY 2029 MIPS payment year. Additionally, we are also proposing to remove the requirement to report an outcome measure and require reporting a MIPS core measure. Hence, under the new proposal, MIPS eligible clinicians participating through traditional MIPS must submit data on at least six measures, including at least one MIPS core measure.

To align third party intermediaries' requirements with the MIPS core measure set and high priority designation for MIPS quality measures proposals, we propose to revise § 414.1400(b)(3)(x)(B) to state that beginning in the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry must be able to submit to CMS, data for at least six quality measures including at least one MIPS core measure. We also propose to revise § 414.1400(b)(3)(x) and (b)(3)(x)(A) so that the requirement for a QCDR or qualified registry to be able to submit an outcome measure and if

the outcome measure is not available, then a high priority measure can be submitted, concludes with the CY 2026 performance period/CY 2028 MIPS payment year.

We request public comment on these proposals.

4. Remedial Action and Termination of Third Party Intermediaries

a. Background

We refer readers to § 414.1400(e), the CY 2017 Quality Payment Program final rule (81 FR 77548) the CY 2019 PFS final rule (83 FR 59908 through 59910), the CY 2020 PFS final rule (84 FR 63077 through 63080), the CY 2021 PFS final rule (85 FR 84947), the CY 2022 PFS final rule (86 FR 65542 and 65550), and the CY 2023 PFS final rule (87 FR 70106 through 70108) for previously finalized policies for remedial action and termination of third party intermediaries.

b. Proposed Termination of a Third Party Intermediary That Does Not Submit Data for 1 Year

In the CY 2023 PFS final rule, we established that we will terminate QCDRs and qualified registries that are required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period, and continue to not submit MIPS data to CMS for the applicable performance period (87 FR 70107 through 70108). We believe that timely termination of third party intermediaries that are not submitting data is important to minimize unnecessary operational and administrative tasks for both CMS and third party intermediaries. Maintaining third party intermediaries that do not actively participate does not provide a benefit to the MIPS program, rather it creates confusion for interested parties by including these third party intermediaries in our qualified postings (86 FR 65545).

We note that the policy for termination of third party intermediaries not submitting data would be impacted by the proposed requirement to submit a participation plan for third party intermediaries that do not submit data for one year in section IV.C.3.c. of this proposed rule. This proposed policy means that we would terminate QCDRs and qualified registries that were required to submit participation plans during the applicable self-nomination period under § 414.1400(b)(3)(viii) because they did not submit any MIPS data for 1 year (rather than 2 years) preceding the applicable self-nomination period, and continue to not submit MIPS data to CMS for the applicable performance period. However, because the data submission period lasts for one year following the performance period, there is a delay in CMS being made aware of whether a third party intermediary submitted data for a given year. Therefore, currently, CMS does not have a mechanism to acquire the necessary knowledge to appropriately terminate a third party intermediary until the year after the applicable performance period.

Currently, if a third party intermediary does not submit data for the performance period for which they submitted a self-nomination participation plan, they will be terminated. However, CMS does not become aware of the third party intermediary's failure to submit data for a given MIPS performance period until the year following the performance period. For example, under the current policy, if a third party intermediary self-nominated for the 2024 performance period and was required to submit a self-nomination participation plan but does not submit data for the 2024 performance period, CMS would not know the third party intermediary did not submit MIPS data for the 2024 performance period until the end of the submission period in March 2025. Therefore, the third party intermediary can continue to participate for the 2025 MIPS performance period as if they were already approved and posted as a 2025 CMS-approved third party intermediary. Hence, to shorten the timeline of when CMS is aware that the third party intermediary does not submit any data and when CMS appropriately terminates the third party intermediary, we propose to update our policy such that CMS would request documentation that the third party intermediary has contracted with Quality Payment Program's participants who will submit MIPS data for the given MIPS performance period. CMS's query for documentation would occur before the end of the calendar year for the given MIPS performance period. If the appropriate documentation cannot be provided by the date specified by CMS, the third party intermediary would be terminated. This proposal would provide the information needed to be able to terminate a third party intermediary during the applicable performance period year instead of having to wait until the following year to terminate them.

Specifically, we propose to add a new requirement for third party intermediaries to submit documentation about intent to submit MIPS data and to terminate a third party intermediary if they do not submit the appropriate documentation by the date specified by CMS. We also propose to add at § 414.1400(e)(5)(ii) that beginning with the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under § 414.1400(b)(3)(viii), but does not submit MIPS data for the applicable performance period for which they self-nominated under § 414.1400(b)(3)(viii), will be queried by CMS before the end of the calendar year of the given MIPS performance period for documentation that they have contracted with Quality Payment Program participants who will submit data for the given MIPS performance period. If the appropriate documentation cannot be provided, the third party intermediary would be terminated. We also propose to redesignate the existing text at § 414.1400(e)(5) to § 414.1400(e)(5)(i). We also propose to add the heading ''Termination for Third Party Intermediary not submitting data.'' at § 414.1400(e)(5).

We request public comment on this proposal.

D. Calculating Final Score

1. Background

For a description of the statutory basis of and our previously finalized policies for calculating the final score for each MIPS eligible clinician, including performance category weights and reweighting the performance categories, we refer readers to § 414.1380(c) and the discussion in the CY 2017 and CY 2018 Quality Payment Program final rules, and the CY 2019, CY 2020, CY 2021, CY 2022, CY 2023, and 2025 PFS final rules (81 FR 77319 through 77329, 82 FR 53769 through 53785 and 53895 through 53900, 83 FR 59868 through 59878, 84 FR 63020 through 63031, 85 FR 84908 through 84917, 86 FR 65509 through 65527, 87 FR 70093 through 70096, 89 FR 98455 through 98459 respectively).

As described in more detail in the following sections, we propose to change the data source that CMS uses to determine eligibility for reweighting under the automatic extreme and uncontrollable circumstances (EUC) policy beginning with the CY 2027 performance period/2029 MIPS payment year. We also propose to change the deadline by which clinicians must request reweighting where data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the

MIPS eligible clinician delegated submission of the data to their third party intermediary.

Section 1848(q)(5)(A) of the Act requires the Secretary to develop a methodology for assessing the total performance of each MIPS eligible clinician according to the performance standards for the applicable measures and activities for each performance category applicable to such clinician for a performance period and, using the methodology, provide for a final score (using a scoring scale of 0 to 100) for each MIPS eligible clinician for the performance period.

Additionally, section 1848(q)(5)(E) of the Act specifies how we must weigh the scores for each performance category in our calculation of the MIPS eligible clinician's final score. We have codified these weights at § 414.1380(c)(1). Meanwhile, section 1848(q)(5)(F) of the Act provides that, if there are not sufficient measures and activities applicable and available to each type of MIPS eligible clinician involved, the Secretary shall assign different scoring weights (including a weight of 0). We also have finalized at § 414.1380(c)(2) several policies addressing the basis for reweighting one or more performance categories, and how those weights will be redistributed to the remaining performance categories.

2. Proposal To Use Alternative Data Sources to Determine Clinician Eligibility for the Automatic EUC

For the quality, cost, and improvement activities performance categories, under the current reweighting policies at § 414.1380(c)(2)(i)(A)(6) through (8), and for the Promoting Interoperability performance category, under the reweighting policies at § 414.1380(c)(2)(i)(C)(*2*) and (3), performance category weights may be redistributed to another performance category or categories in circumstances where MIPS eligible clinicians are subject to, or located in an area affected by, an EUC. This includes MIPS eligible clinicians with an approved application-based EUC reweighting request (83 FR 59871 through 59874 and 82 FR 53680 through 53687) or an automatic reweighting for a clinician identified as located in a CMS designated region affected by an EUC such as a Federal Emergency Management Agency (FEMA)-designated major disaster or a public health emergency (as determined by the Secretary of Health and Human Services) (82 FR 53895 through 53900). The automatic EUC policy for quality, cost, and improvement activities performance categories is described at § 414.1380(c)(2)(i)(A)(8) and the automatic EUC policy for the Promoting Interoperability performance category is described at § 414.1380(c)(2)(i)(C)(3). Additionally, we previously finalized at § 414.1380(c) that MIPS eligible clinicians scored on fewer than two performance category scores will receive a final score equal to the performance threshold, which will result in a neutral payment adjustment (81 FR 77326 through 77328 and 82 FR 53778 through 53779). We noted in the CY 2018 Quality Payment Program final rule that we anticipate the types of events that could trigger the automatic EUC policy would be events designated as a FEMA major disaster or a public health emergency declared by the Secretary, although we will review each situation on a case-by-case basis (82 FR 53897).

In the CY 2018 Quality Payment Program final rule, we specified that CMS will determine if an individual MIPS eligible clinician is located in an area affected by an EUC as identified by CMS based on the practice location address listed in the Provider Enrollment, Chain and Ownership System (PECOS) (82 FR 53898). Since adopting a policy to use PECOS data, recent clinician reweighting requests have increasingly identified clinicians who were incorrectly excluded from the automatic EUC policy because PECOS address data may be inaccurate or outdated in some cases. For example, individual MIPS eligible clinicians impacted by an EUC may not be identified by CMS in circumstances where a clinician has not updated their PECOS data or in circumstances where a clinician begins providing services in an additional geographic location or zip code. In order to ensure the accurate identification of impacted clinicians for subsequent performance periods, we propose that beginning with the CY 2027 performance period/2029 MIPS payment year CMS will use the most current and reliable data available to determine if an individual MIPS eligible clinician is located in an area that has been identified as being affected by an EUC. For example, we may use the zip codes on billed claims, that identify the location of service, to make this determination. This data source may be used in addition to or in lieu of the zip codes included in PECOS address data to achieve our goal of accurately identifying all impacted clinicians. This proposal will ensure that all individual MIPS eligible clinicians affected by natural disasters and public health emergencies are accurately identified by CMS.

We request public comment on this proposal.

3. Proposal To Update the Deadline for Clinicians To Inform CMS That Third Party Intermediary Did Not Submit Data Due to Reasons Outside the MIPS Eligible Clinician's Control

We previously finalized at § 414.1380(c)(2)(i)(A)(10) and (c)(2)(i)(C)(12) that beginning with the CY 2024 performance period/2026 MIPS payment year, we may reweight one or more of the quality, improvement activities, and Promoting Interoperability performance categories where we determine, based on documentation submitted to us through a reweighting request on or before November 1st of the year preceding the relevant MIPS payment year, that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of their data to a third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and the third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines (89 FR 62096). We previously finalized that this reweighting policy is available only for the quality, improvement activities, and Promoting Interoperability performance categories because a MIPS eligible clinician may delegate data submission to a third party intermediary for these three performance categories, and not the cost performance category. MIPS eligible clinicians do not submit data separately for measures for the cost performance category; we score cost measures based solely on administrative claims data (89 FR 98455 through 98455).

As specified in the CY 2025 PFS final rule, we would only approve reweighting requests with evidence of a written agreement between the MIPS eligible clinician and a third party intermediary. Such written agreement must provide that the MIPS eligible clinician delegated submission of their data to the third party intermediary, and that the third party intermediary agreed to submit data on their behalf in accordance with applicable deadlines, for the performance category or performance categories in question. We review requests and make determinations to reweight based on our assessment that data were not submitted due to reasons outside the control of the MIPS eligible clinician (89 FR 62096).

Under this reweighting policy, the MIPS eligible clinician must submit reweighting requests beginning with the close of a relevant performance period's data submission period, only after it is confirmed that no data has been submitted in accordance with applicable deadlines. MIPS eligible clinicians must then submit reweighting requests on or before November 1st of the year preceding the associated MIPS payment year in order to allow time for CMS to re-calculate their final score and MIPS payment adjustment factor (89 FR 62096).

We propose to adjust the deadline by which clinicians would be able to submit reweighting requests for the quality, improvement activities, and Promoting Interoperability performance categories due to scenarios where a third party intermediary did not submit data on their behalf in accordance with the applicable data submission deadlines. Specifically, we propose that beginning with the CY 2025 performance period/2027 MIPS payment year, MIPS eligible clinicians would be able to submit reweighting requests on or before December 31st of the year preceding the relevant MIPS payment year. We also propose to codify this updated deadline at § 414.1380(c)(2)(i)(A)(10) for the quality and improvement activities performance categories and at § 414.1380(c)(2)(i)(C)(12) for the Promoting Interoperability performance category. Under this proposed reweighting policy, the MIPS eligible clinician must submit reweighting requests beginning with the close of a relevant performance period's data submission period, only after it is confirmed that no data has been submitted in accordance with applicable deadlines. Under this proposed deadline, MIPS eligible clinicians would still be able to submit reweighting requests before the beginning of the associated MIPS payment year.

The deadline for MIPS eligible clinicians to submit reweighting requests before the beginning of the associated MIPS payment year is aligned with the requirements finalized in the CY 2020 PFS final rule for clinicians to request reweighting in circumstances where data are inaccurate, unusable, or otherwise compromised. Under this policy, we apply reweighting only in cases when we learn of the compromised data before the beginning of the associated MIPS payment year (84 FR 63023 through 63026). We intend for this policy to offer increased flexibility to impacted clinicians and note that this timeline will encourage MIPS eligible clinicians and their third party intermediaries to inform us of these concerns in a timely manner so we can update our data sets while minimizing the impacts to other interested parties who utilize MIPS data. The proposed deadlines will still allow CMS to re-calculate final scores and MIPS payment adjustments factor in a timely manner.

We request public comment on these proposals.

E. Public Reporting

1. Background

Public reporting of Merit-based Incentive Payment System (MIPS) eligible clinician performance information on the Compare Tool on medicare.gov (here after referred to as the ''Compare Tool'') is authorized under section 10331(a)(1) and (2) of the Affordable Care Act (ACA). Section 10331(a)(1) of the ACA established a physician compare website for the public reporting of clinician performance information.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) amended the Social Security Act by adding Section 1848(q)(9), which requires the Secretary to continue to make publicly available, on the Compare Tool and in an easily understandable format, information regarding the performance of individual MIPS eligible clinicians and groups (81 FR 77391).

For previous discussions and established policies regarding public reporting on the Compare Tool, we refer readers to § 414.1395 as well as, the CY 2016 PFS final rule (80 FR 71116 through 71123), the CY 2017 Quality Payment Program final rule (81 FR 77390 through 77399), the CY 2018 Quality Payment Program final rule (82 FR 53819 through 53832), the CY 2019 PFS final rule (83 FR 59910 through 59915), the CY 2020 PFS final rule (84 FR 63080 through 63083), the CY 2021 PFS final rule (85 FR 84947 through 84948), the CY 2022 PFS final rule (86 FR 65550 through 65554), the CY 2023 PFS final rule (87 FR 70109 through 70104), the CY 2024 PFS final rule (88 FR 79394 through 79401), and the CY 2026 PFS final rule (90 FR 49862). The Compare Tool is available at *https://www.medicare.gov/care-compare/* and in the Medicare Provider Data Catalog available at *https://data.cms.gov/provider-data/topics/doctors-clinicians.*

In this section of the proposed rule, we propose to remove the requirement preventing the public reporting of any performance data reported through a MIPS Value Pathway (MVP) on new improvement activities and Promoting Interoperability (PI) measures on the Compare Tools for the first year the new measures and activities are included in such MVP. We also include a request for information (RFI) to obtain feedback on potential improvements to the current star rating assignment methodology for quality measure scores reported under the administrative claims collection type.

2. Proposal To Remove the Public Reporting Requirements for the MIPS Value Pathway (MVP) Requirement at § 414.1395(c)(2)

In the CY 2022 PFS final rule (86 FR 65550 through 65552), we finalized a policy under which we would not publicly report any MVP data, or MIPS performance data reported through an MVP, on a new improvement activity or PI measure, objective, or activity for the first year the new activity or measure is included in an MVP. For example, if a new improvement activity is finalized for inclusion in MIPS and an MVP for the CY 2027 performance period/CY 2029 MIPS payment year, under the current regulatory framework, we would not publicly report the first year of its data for MIPS eligible clinicians who report the new improvement activity through the MVP reporting framework. The purpose of this requirement was to encourage participation in the new MVP reporting framework and to provide participants with additional time to transition to MVPs before their performance on new measures or activities is publicly reported. However, we have determined that this requirement has not served as an effective incentive for MVP participation because most improvement activities and PI measures included in MVPs are not considered new and would be publicly reported, as they have been included in MIPS for over a year.

Consistent with section 1848(q)(9)(A)(i)(II) of the Act, we finalized in the CY 2017 Quality Payment Program final rule a decision to make all measures, objectives, or activities under the MIPS quality, cost, improvement activities, and PI performance categories available for public reporting on the Compare tools (81 FR 77391 through 77396), using a phased approach for new performance information facilitated by Section 1848(q)(9)(A) and (D). In the CY 2018 PFS final rule (82 FR 53825 through 53827), we further finalized that the first year of data for new improvement activities and PI measures would be publicly reported for MIPS eligible clinicians on the Compare tools if all

other public reporting criteria established under § 414.1395(b) are met. Since we established § 414.1395(c)(2), the annual consumer testing conducted consistent with the requirements of § 414.1395(b) demonstrates that most patients and caregivers find the new improvement activities and PI information understandable and useful for their decision-making. Therefore, this information should be publicly reported. The purpose of the Compare Tools is to provide patients with the most timely, clear, and credible information on provider performance that is available for public reporting.

Since the adoption of the requirement to not publicly report the first year of new improvement activity or PI information for participants who report through the MVP reporting framework, we have observed that the policy does not apply to a sufficient number of MIPS eligible clinicians to encourage meaningful participation in MVPs. For example, during 2025, only four individual providers' performance information would not have been publicly reported for new improvement activities included in MVPs, and there were no new PI measures included in MVPs for 2025. This represented less than 1 percent of clinicians reporting the new improvement activities for that performance period. Similarly, we observed that this requirement applied to less than 1 percent of MIPS eligible clinicians reporting new improvement activities and PI information overall since MVPs became available as a reporting framework beginning with the CY 2023 performance period. There have not been a sufficient number of new PI measures or improvement activities included in MVPs, and there is not enough data to continue supporting this requirement.

We propose to remove the requirement at § 414.1395(c)(2) that we would not publicly report any MVP data on new improvement activity or PI measure, objective, or activity during the first year in which it is included in an MVP. Upon the removal of this requirement, we would revert to the original policy, finalized in the CY 2018 PFS final rule (82 FR 53825 through 53827), and would include all eligible performance information for new improvement activities and new PI measures in public reporting on the Compare Tools during the first year in which the measures and activities are included in the program.

We request public comments on this proposal.

3. Request for Information: Star Rating Assignment Methodology for Administrative Claims Quality Measures

a. Background

MACRA requires the continuous public display of individual MIPS eligible clinician and groups performance information, in an easily understandable format, on the CMS Compare tool on Medicare.gov (81 FR 77391). Our process for the assignment of star ratings is set forth in § 422.166(b), which establishes the public reporting parameters of star ratings.

As finalized in the CY 2015 and CY 2016 PFS final rules (79 FR 67547 and 80 FR 70885, respectively), CMS continued to expand public reporting on the Compare Tool. This expansion included publicly reporting both individual eligible clinicians and groups starting with 2016 data available for public reporting in late 2017, as well as the inclusion of a 5-star rating based on a benchmark in late 2017 based on 2016 data (80 FR 71125 and 71129), among other additions.

b. Adjustments to the Star Rating Assignment Methodology for Administrative Claims Quality Measures

The goal of publicly reporting clinician performance information is to ensure that patients can easily understand how quality measure scores reflect each provider's performance. While the current system of benchmarking for public reporting has been in place for several years, we are currently seeking feedback on alternative options for distributing scores. We are investigating improvements to the star rating assignment methodology for quality measure scores collected under the administrative claims collection type (42 CFR 414.1305). Our intent is to provide a more easily understood distribution of the administrative claims quality measure scores on clinician profile pages for patients via the Compare Tool on *https://www.medicare.gov/care-compare/.*

Administrative claims quality measures differ from other MIPS quality measure collection types as they are automatically calculated and risk-adjusted for groups and clinicians who meet measure requirements. The administrative claims quality measure scores have been found to form a more normal distribution. However, the existing quality measure score conversion calculations and supporting code for the current star rating assignment methodology may not optimally align with the standard deviation-based methodology employed by CMS to score administrative claims quality measures (42 CFR 414.1380(b)(2)(i)(B)). With more information, we can determine whether an alternative methodology for star rating assignments is more appropriate for administrative claims quality measures prior to the public reporting of these scores on clinicians' profile pages on the *Medicare.gov* Compare Tool. We have been investigating how to adjust these calculations so that measure-level scores are more representative of clinician performance and better understood by patients.

Currently, we calculate star rating cutoffs for the Achievable Benchmark of Care (ABC) 5-star methodology through the equal ranges method for a subset of Merit-based Incentive Payment System (MIPS) quality and promoting interoperability measures that meet the established public reporting standards and resonate with users (§ 414.1395(b)). The equal ranges method is based on the difference between an established ABC methodology benchmark and the lowest performance score for a given measure. This range is then used to assign star ratings of one to four stars. Clinicians who meet or exceed the ABC benchmark for the applicable measure receive 5 stars.[387]

We seek to investigate a new option that would assign star ratings using a standard-deviation-based approach for the administrative claims quality measure scores. The MIPS benchmarking process employed by CMS for measures of this collection type applies a standard deviation-based approach for a 10-point scoring scale,[388] which differs from the ABC methodology. We expect that using a similar standard deviation-based methodology for assigning star ratings, as is currently used in the MIPS benchmarking process, would be more straightforward and easier to understand. We also anticipate that this shift to using standard deviations for assigning star ratings to the administrative claims measures would avoid the clustering-around-the-mean issues observed under the ABC methodology, where virtually all scores result in 2, 3, or 4 stars.

In addition, the adoption of a standard-deviation-based methodology

[387] For more information about the equal ranges method and the ABC methodology, visit *https://www.cms.gov/files/document/2023-doctors-clinicians-star-ratings-fact-sheet-546-kb.pdf.*

[388] For a more detailed explanation of the standard deviation approach to the MIPS 10-point scale, please visit *MIPS Cost scores are coming—what to know for 2024 and prepping for 2025.*

may be extended to the public reporting of cost measures on clinician profile pages. Given that cost measure scores are automatically calculated and risk-adjusted using administrative claims data, star rating cutoffs may also require a similar standard deviation-based framework. We also seek feedback on developing a similar standard deviation-based approach for cost measures. We plan to investigate more ways to publicly report cost measures in a manner that better reflects provider performance and is more readily understood by patients. We are considering proposing to adopt a standard deviation-based methodology in the CY 2028 PFS rule to improve the clarity and interpretability of the distribution of the administrative claims quality measure scores displayed on the clinician profile pages of the *Medicare.gov* Compare Tool. We request public comments on the following topics regarding adjustments to a star rating assignment methodology:

- The public reporting methodology used for star rating assignments on clinician profile pages has used the equal ranges method based off an established ABC benchmark for calculating star rating cutoffs for several years. We request feedback on the current star rating assignment methodology and whether we must adjust this process for administrative claims quality measures.
- We request feedback on the statistical framework for transitioning the current star rating assignment methodology to a standard deviation-based methodology for administrative claims quality measures.
- We also request feedback on expanding the standard deviation-based adjustments for the administrative claims star rating assignment methodology to the public reporting of cost measures on clinician profile pages of the *Medicare.gov* Compare Tool in future program years. We seek to ensure that the display of cost measure performance more accurately reflects provider performance and can be understood by patients.
- We also request feedback on whether there are any unintended consequences or impacts to providers or patients that we must acknowledge before proposing any adjustments to the star rating assignment methodology for the administrative claims collection type.

5. Advanced APMs

a. Overview

The Quality Payment Program provides incentives for eligible clinicians to engage in value-based, patient-centered care under Medicare Part B via MIPS and Advanced APMs. The structure of the Quality Payment Program enables us to advance accountability and encourage improvements in care. Our vision for increased clinician participation in Advanced APMs is aimed at integrating individuals' clinical needs across a spectrum of providers and settings to improve patient care and population health. As we continue to make improvements to the Quality Payment Program, we seek to develop, propose, and implement policies that encourage broad and meaningful clinician participation in Advanced APMs.

In the CY 2026 PFS final rule (90 FR 50012), we finalized an update to our methodology to add an individual-level calculation to Qualifying APM Participant (QP) determinations, as set forth in §§ 414.1425(b)(3) and (c)(3), for all eligible clinicians participating in an Advanced APM, such that each eligible clinician would receive both APM Entity-level calculation and an individual-level calculation. Second, we finalized a policy at §§ 414.1435 and 414.1305 to perform QP determinations using both an E/M services approach and a Covered Professional Services approach.

Together with the addition of individual calculations and the use of specific services in our calculation, our methodology provides flexibility to ensure that participants receive incentives across model design and clinical specialty. However, we continue to identify misalignment between Advanced APM participation and the incentive structure of QPP, specifically in the application or the QP status to all of an eligible clinician's Tax Identification Number (TIN) reassignments irrespective of whether the TIN in question is participating in an Advanced APM. We also recognize the need for improvements and updates for technical or legislative reasons. The following policy proposals aim to address this misalignment and to make various improvements.

b. QP Determination

(1) General

In the CY 2017 Quality Payment Program final rule (81 FR 77439 through 77445), we finalized our policy for QP determinations at § 414.1425. We perform QP determinations for eligible clinicians three times during the QP Performance Period using claims data for services furnished from January 1 through each of the respective QP determination snapshot dates. An eligible clinician can be determined to be a QP only if the eligible clinician appears on the Participation List on a snapshot date that we use to determine the APM Entity group and to make QP determinations as described at § 414.1425.

In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77440) we established a process to calculate Partial QP status at § 414.1425(d). While to date our Partial QP policies have impacted only a small number of eligible clinicians, and thus we have not focused our discussion on this specific policy, we note that any changes to QP determinations at § 414.1425 also would likely require conforming changes to the policies for Partial QPs for consistency across the program.

(2) Applying QP Determinations at the TIN/NPI Level

When we initially established our policy in the CY 2017 Quality Payment Program final rule to make most QP determinations at the APM Entity level, we also specified that we would apply QP status at the NPI level (81 FR 77440). In other words, for a given eligible clinician (NPI), were one of their TIN/NPI relationships to be determined a QP, that QP status has applied all of their TIN/NPI relationships, both for purposes of being excluded from MIPS as well as for the application of QP financial incentives. Given the complexity of the program, we believed it was the best approach at the time to create one QP status result for a clinician at all of their billing organizations. However, we did not intend for the policy to create conflicting incentives to participation in Advanced APMs. We realized that an NPI being a QP at all of their TINs also meant that they would receive the financial incentives of QP status, at the time the APM Incentive Payment, across all of those TINs, irrespective of whether those TINs were participating with Advanced APMs. However, we believed that the significance of that incentive would serve to increase clinician participation in Advanced APMs, and that the application of the QP thresholds would ensure that the clinician was appropriately incented to try to increase their individual Advanced APM participation. Further, we also had finalized at § 414.1450(c)(1) that we would pay the entire APM Incentive Payment amount to the TIN associated with the QP's participation in the Advanced APM Entity through which QP status had been attained (81 FR 77555), and we believed that by directing the lump sum entirely to the

TIN participating with the Advanced APM Entity, we would reward the clinician without also rewarding non-participating TINs.

Upon gaining early experience implementing the APM Incentive Payments, we learned that for a variety of reasons (clinician movement, changes to a practice's TINs), we were not always able to send payment to the TIN associated with the APM Entity. We revised § 414.1450(c) in the CY 2021 PFS (88 FR 85035) to establish a hierarchy we would apply when determining where to send the APM Incentive Payments, which still prioritized TINs participating in Advanced APMs but allowed for payment to be sent to other, non-participating TINs if that was the only place we could find the clinician active at the time of payment. Still, we were satisfied that our prioritization of the lump-sum APM Incentive Payment to TINs that had Advanced APM participation remained a protection against providing non-participating TINs significant windfalls.

However, section 1848(d)(1)(A) of the Act establishes that, beginning with payment year 2026, QPs will receive a higher qualifying conversion factor update than non-QPs on their covered professional services claims. While the APM Incentive Payment has been extended multiple times as described in section XXX of this proposed rule, the implementation of the QP conversion factor means that a QP financial incentive goes directly to TINs in the form of claims payment. Particularly as the QP conversion factor grows and constitutes a larger proportion of the QP incentive structure over time, we are concerned that a significant proportion of incentives paid for QP status will be paid to TINs that are not part of an Advanced APM, creating a disincentive for these TINs to join an Advanced APM and meaningfully engage in risk-bearing value-based care.

As such, we propose adding new provisions at §§ 414.1425(c)(8) and (d)(5) to apply QP status and Partial QP status, respectively, strictly to an eligible clinician as such term is defined at § 414.1305, specifically as a TIN/NPI combination, and that meets the definition at § 414.1305 of Qualifying APM participant (QP) or Partial QP, respectively, by participating in an Advanced APM during the QP performance period. Under the proposal, QP status and Partial QP status would therefore only apply to the clinician at the TIN that is participating with the APM Entity in the Advanced APM. Therefore, the financial incentives in the form of both the APM Incentive Payment and the QP conversion factor would apply to the NPI's claims only with those TINs, as would the ability of a Partial QP to opt into or out of MIPS.

For an eligible clinician who is participating in multiple APM Entities, the proposal's effects would be based on how the clinician becomes a QP or Partial QP. Section 414.1435(h)(2) specifies that CMS assigns to the eligible clinician the score that results in the greater QP status. In accordance with this provision, if an eligible clinician attains QP status at the individual level from participation in multiple APM Entities, under the proposal we would assign the QP status at each of the clinician's TINs participating across those APM Entities. If, however, the eligible clinician did not attain QP status at the individual level and did attain QP status as part of a specific APM Entity-level determination, we would assign QP status to the clinician at only the TIN(s) that are associated with the APM Entity or Entities that collectively attained QP status. If the eligible clinician did not attain any QP status through any determination but did attain Partial QP status, this same preference for the highest status would apply for Partial QP status. This approach maintains the longstanding policy within QPP to give the clinician the highest possible outcome available to them.

This proposal would mean that QP status would no longer apply to a clinician as a whole and we recognize the possibility of this being perceived as introducing complexity into an eligible clinician's QPP experience, for example because under the proposal some eligible clinicians would be a QP with one TIN and participating in MIPS with another. We want to emphasize that for the majority of clinicians in Advanced APMs, this policy will not change their participation in QPP, because they are already participating with an APM Entity in an Advanced APM with all of their TIN reassignments. In these cases, the eligible clinician's QP status would apply at each of their TINs under the proposal. For the clinicians who are not already participating in an Advanced APM across all of their TIN reassignments, we believe that this policy would provide a meaningful incentive to increase their participation in an Advanced APM. Participation in Advanced APMs across Original Medicare continues to grow and we expect this policy to support our progress.

We note further that our proposal aligns with MIPS, which already operates on a TIN/NPI basis, meaning that QPP internal operations and communications would be the same for all clinicians. Under our current policy, we receive a significant number of inquiries from billing organizations where clinicians have been excluded from MIPS as a result of QP status with another billing organization where that organization is participating in an Advanced APM. In these cases, organizations have made a significant investment to report MIPS but do not receive a MIPS final score and MIPS payment adjustment for these clinicians. Our proposed policy would ensure that these billing organizations are in control of how MIPS eligibility criteria apply to clinicians that have been reassigned to their organizations.

In addition to programmatic alignment, our operational experience tells us that, when a TIN has any clinicians who are subject to MIPS, it most often simply reports on all of its clinicians, as including everybody is easier than removing clinicians before reporting. As such, we believe that in the relatively few situations where the proposal would result in an eligible clinician with QP status at one TIN being subject to MIPS at one or more other TINs, reporting is in many cases is already being done for that clinician, meaning that neither the clinician nor their MIPS-participating TIN(s) would bear any new burden as a consequence of the proposed policy. Further, as it was established at the outset operational experience indicates that MIPS eligible clinicians' experience has not been significantly impaired by the TIN/NPI operation of that portion of the program.

Finally, we recognize that this proposal would decrease the dollar value of the financial incentives available for affected QPs. However, we believe that assigning QP status at the TIN/NPI level will serve to prevent an increasing windfall for TINs that do not participate in Advanced APMs, particularly given that the higher qualifying conversion factor update that is now part of the physician fee schedule is baked in to the amount Medicare pays on claims and therefore always is paid to the TIN through which the service was furnished without regard to whether that TIN is part of the Advanced APM that conferred QP status to the clinician. We believe that this proposal would prevent waste and potential for abuse, and that these matters outweigh concerns around complexity or reduced incentives. Notably, under current law the QP conversion factor will compound to a greater degree each year relative to the non-QP conversion factor. In addition, because payment of the claims is made directly to the TINs through which the

services were billed means that CMS has no mechanism of directing these incentives to Advanced APM participating TINs in the way we have done with the APM Incentive Payment. As such, while relatively few QPs would be affected by this proposal, CMS anticipates the amount of the resulting windfall flowing directly to non-participating TINs under the current framework will increase over time, with little benefit to the clinician and no benefit to the practices that are doing the work of Advanced APM participation.

With respect to Partial QP status, the proposal would maintain programmatic alignment within QPP and would provide for the application of the ability to opt out of MIPS at the TIN/NPI level. While there are not financial incentives for these eligible clinicians in the same manner that there are for QPs, we believe that applying the opt-out flexibility at the TIN/NPI level similarly confers the burden reduction of Partial QP status only to those TINs that are affiliated with the APM Entity participating in the Advanced APM.

We propose amending § 414.1425(c) to add new subparagraph (8) to apply QP status strictly to the eligible clinician as such term is defined at § 414.1305, specifically as a TIN/NPI combination, and that meets the definition of Qualifying APM participant (QP) as defined at § 414.1305 by participating in an Advanced APM during the QP performance period. We also propose amending § 414.1425(d) to add new paragraph (5) to establish the same policy with respect to the application of Partial QP status.

We seek public comments on this proposal.

6. APM Entity Terminations

a. Overview

In the CY 2017 Quality Payment Program final rule (81 FR 77446 through 77447), we finalized for the timing of QP determinations that a QP Performance Period runs from January 1 through August 31 of the calendar year that is 2 years prior to the payment year. We finalized that during the QP Performance Period, we will make QP determinations at three separate snapshot dates (March 31, June 30, and August 31), each of which will be a final determination for the eligible clinicians who are determined to be QPs. The QP Performance Period and the three separate QP determinations apply similarly for both the group of eligible clinicians on a Participation List and the individual eligible clinicians on an Affiliated Practitioner List.

In the CY 2017 Quality Payment Program final rule, we finalized at §§ 414.1425(c)(5) and 414.1425(d)(3) that an eligible clinician is not a QP or Partial QP for a year, respectively, if the APM Entity group voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period (81 FR 77446 through 77447). We also finalized at §§ 414.1425(c)(6) and 414.1425(d)(4) that an eligible clinician is not a QP or Partial QP for a year if one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP or Partial QP payment amount threshold or QP or Partial QP patient count threshold based on participation in the remaining non-terminating APM Entities (81 FR 77446 through 77447).

b. APM Entity Terminations Before Financial Risk Was Borne

In the CY 2020 PFS final rule (84 FR 63087 through 63089), we finalized revisions to § 414.1425(c)(5) to add § 414.1425(c)(5)(i) and (ii) to state, beginning with the 2020 QP Performance Period, that an eligible clinician is not a QP for a year if: (1) The APM Entity voluntarily or involuntarily terminates from an Advanced APM before the end of the QP Performance Period; (2) or the APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs. We also finalized conforming revisions in § 414.1425(d)(3) with respect to Partial QP status. In addition, we finalized revisions to our regulation at § 414.1425(c)(6) and add §§ 414.1425(c)(6)(i) and (ii) to state, beginning with the 2020 QP Performance Period, that an eligible clinician is not a QP for a year if: (1) One or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM before the end of the QP Performance Period, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities; or (2) one or more of the APM Entities in which the eligible clinician participates voluntarily or involuntarily terminates from the Advanced APM at a date on which the APM Entity would not bear financial risk under the terms of the Advanced APM for the year in which the QP Performance Period occurs, and the eligible clinician does not achieve a Threshold Score that meets or exceeds the QP payment amount threshold or QP patient count threshold based on participation in the remaining non-terminating APM Entities. We also finalized conforming revisions in § 414.1425(4)(3) with respect to Partial QP status.

When we finalized the revisions in the CY 2020 PFS, due to a clerical error we inadvertently included language in the text of § 414.1425(c)(5)(ii) that we believe is unnecessary and has potential to cause confusion. Specifically, § 414.1425(c)(5)(ii) states that an eligible clinician is not an QP for a year when an APM Entity termination occurs ''at a date on which the APM Entity would not bear financial risk for that QP performance period under the terms of the Advanced APM, *even if such termination date occurs within such QP Performance Period*'' (emphasis added). The inclusion of the emphasized language was a clerical error. This language did not appear in the CY 2020 PFS proposed rule regulation text for § 414.1425(c)(5)(ii) (84 FR 40929) nor does it appear in the companion finalized regulation for Partial QP status at § 414.1425(d)(3)(ii). What's more, in the CY 2020 PFS final rule, we indicated that we were finalizing these policies ''without modification'' (84 FR 63089), but the addition of this clause would have constituted a modification that we would have discussed if intentionally made. Further, we believe the language is unnecessary because § 414.1425(c)(5)(i) already addresses terminations within the QP performance period. Therefore, we believe that the clause not only serves no meaningful purpose, but also that it could result in confusion because it could appear to be filling a regulatory gap that in fact does not exist. However, we do not believe any clarifying language is necessary. The principal reasons that cause us to change proposed regulatory text in final are to address public comments or fix an error or address an issue that we recognized only after the proposal was made. We had not received any comments that indicated any confusion regarding the applicable timeframe for the proposed version of § 414.1425(c)(5)(ii) (that again, did not include the relevant clause), and we had not independently identified any problems with the proposed text, so we did not have any reason to believe we needed to clarify the applicable timing.

Furthermore, we have not experienced any problems in the implementation of the companion regulation with respect to Partial QP status, which also does not contain this additional clause.

Therefore, to align the QP regulation text at § 414.1425(c)(5)(ii) with the Partial QP regulation text at § 414.1425(d)(3)(ii), and to remove any potential for confusion with respect to the intended timeframe for APM Entity terminations before financial risk is borne in the Advanced APM, we now propose to amend the text of § 414.1425(c)(5)(ii) to remove ''**,** even if such termination date occurs within such QP Performance Period.'' Under this proposal, the text of § 414.1425(c)(5)(ii) will read ''The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that performance period under the terms of the Advanced APM.'' This proposed change will make the text of § 414.1425(c)(5)(ii) read as we always intended and will remove both the misalignment with the text of the Partial QP regulation and any confusion that the unnecessary clause might cause.

c. Clarification for APMs Without a Participation List

The definition of ''Participation List'' was first established in the CY 2017 QPP final rule, (81 FR 77008). In that rule, we codified the definition of ''Participation List'' at § 414.1305 as the mechanism by which CMS identifies the eligible clinicians associated with a given APM Entity for purposes of QP determinations and related QPP functions (81 FR 77246 through 77257). The definition has remained substantively unchanged since its initial adoption in the CY 2017 QPP final rule, though the regulatory provisions that rely upon it—including those governing QP determination methodology under § 414.1425, APM Entity group composition under § 414.1317, and APM Performance Pathway eligibility under § 414.1367—have been refined through subsequent annual rulemaking. The existing regulatory definition of ''Participation List'' does not expressly address the circumstance in which an APM does not require or generate a Participation List for its APM Entities. This gap has the potential to create interpretive ambiguity—particularly as CMS considers the design of future episode-based, mandatory, and other APMs under which Participation Lists may not be a structural feature of APM participation. To enhance regulatory clarity and ensure that the framework governing QP determinations and MIPS APM scoring can accommodate the full range of APM designs CMS may implement, we are proposing a clarification to ensure that in cases where a participation list is not operationally practicable, we would not include these APMs for MIPS scoring or QP determinations.

We seek public comments on this proposal.

d. APM Incentive Payment

(1) Overview

Section 1833(z)(1) of the Act establishes an incentive payment for participation in eligible alternative payment models, which originally ran from payment years 2019–2024. As such, when we established the definition of ''APM Incentive Payment'' at § 414.1305 in the CY 2017 Quality Payment Program final rule (81 FR 77008) we included in the definition that the payment would be made from payment year 2019 through payment year 2024. We also established at § 414.1450(b)(1) that the amount of the APM Incentive Payment was ''equal to 5 percent of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year'' (81 FR 77554).

(2) APM Incentive Payment Extension

The incentive payment originally was extended as part of the Consolidated Appropriations Act, 2023, which provided for a 3.5 percent payment in payment year 2025. In the CY 2023 PFS final rule (88 FR 79539), we finalized revisions to § 414.1450(a)(1)(i) to make reference payment years 2019 through 2025 and to § 414.1450(b)(1) to codify the legislative extension. The Consolidated Appropriations Act, 2024 provided an additional payment of 1.88 percent in payment year 2026, and in the CY 2024 PFS final rule (89 FR 98564) we again made conforming updates to §§ 414.1450(a)(1)(i) and (b)(1) to incorporate that extension. As such, currently, in §§ 414.1450(a)(i) and (b)(1), the lump sum APM Incentive Payment is available for payment years 2019 through 2026, with the applicable percentage varying by year in accordance with the statute: 5 percent for payment years 2019 through 2024, 3.5 percent for payment year 2025, 1.88 percent for payment year 2026.

The Consolidated Appropriations Act, 2026, now has provided for a 3.1 percent APM Incentive Payment in payment year 2028. Accordingly, we are proposing to codify this extension for 2028 into §§ 414.1450(a)(1)(i) and (b)(1). We also recognize that with several extensions of this payment now having occurred, and each extension having a new and unique applicable percentage, the current single-paragraph structure of the regulation at § 414.1450(b)(1) is beginning to get unwieldy and becoming harder to follow. Specifically, the relevant percentages and years have been listed within a single sentence at § 414.1450(b)(1) that describes the amount of the incentive payment. With each extension, this set of clauses has grown longer, creating greater distance between the concept of a percentage applying and the description of what the percentage in question applies to. Adding the most recent extension will make this sentence longer still.

Therefore, we are proposing a technical restructuring of § 414.1450(b)(1), which would not change the policies of this paragraph but, we believe, simply make it easier to read in light of now having three years of extensions at different percentages. Under the proposal, we would pull out the references to percentages and years from the first sentence of (b)(1) into a new list of subparagraphs, mirroring the way that the QP and Partial QP thresholds are listed in § 414.1430. Specifically, we propose to amend § 414.1450(b)(1) by: (1) remove all of the language in the first sentence that references percentages and payment years and begin the sentence ''The amount of the APM Incentive Payment is''; (2) insert after ''is'' the phrase ''the applicable percentage established for the payment year''; (3) add at the end of the subparagraph ''The applicable percentage is the following value for the indicated payment years:''; and (4) create new subparagraphs (i) through (iv) to list the specific applicable percentages, including the extension for 2028. The proposed revised paragraph would read:

''(1) The amount of the APM incentive payment is the applicable percentage established for the payment year of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment. The applicable percentage is the following value for the indicated payment years below.

- 2019 through 2024: 5 percent.
- 2025: 3.5 percent.
- 2026: 1.88 percent.

• 2028: 3.1 percent.''

We believe that this proposed revised structure is cleaner than the current single paragraph with its increasingly long detailing of years and percentages, and therefore will provide an easier-to-follow explanation of the APM Incentive Payment amount. These proposed technical structural changes would not modify the substantive policies of this provision. The only substantive change we are proposing is the codifying in new subparagraph § 414.1450(b)(1)(iv) of the 3.1 percent legislated for 2028.

(3) APM Incentive Payment Definition

As described in the overview, we established the definition of ''APM Incentive Payment'' at § 414.1305 in the CY 2017 Quality Payment Program final rule (81 FR 77008), we included language that specifically referenced payment years 2019 through 2024. However, when we revised § 414.1450 in the CY 2023 and CY 2024 PFS final rules to codify the legislative extensions of the APM Incentive Payment, we neglected to make conforming changes to the definition of ''APM Incentive Payment'' at § 414.1305 to reflect those subsequent legislative actions. As such, the current definition at § 414.1305 references only the original statutory payment years of 2019 through 2024, making it out-of-date. To address this, we are proposing to update the definition to remove the references to specific years and instead refer to § 414.1450(b)(1). The revised definition would read: ''*APM Incentive Payment* means the lump sum incentive payment for a year as described in section 414.1450(b)(1) and that is paid for an eligible clinician who is a QP for the applicable year.'' This proposal would allow for the APM Incentive Payment definition to automatically be inclusive of any year that may be added through future legislation and codified at § 414.1450(b)(1) without the need for a conforming change to the definition at § 414.1305 itself.

We seek public comment on this proposal.

(4) Summary

We are proposing to codify the most recent legislative extension of the APM Incentive Payment by: (1) revising § 414.1450(a)(1)(i) to include the payment amounts for 2019 through 2028; and (2) revising § 414.1450(b)(1) to make structural changes that include the applicable percentages for 2019 through 2024, 2025, 2026, and 2028, respectively at §§§§ 414.1450(b)(1)(i), (ii), (iii) and (iv). We note that the only substantive change involved in these modifications would be the addition of the 2028 extension. The proposed structural changes would not affect the policies of this provision but simply improve the readability of this paragraph.

We also are proposing to revise the definition of ''APM Incentive Payment'' at § 414.1305 to remove the current references to specific payment years and replace them with a reference to the years described in § 414.1450(b)(1).

We seek public comment on these proposals.

e. QP and Partial QP Thresholds

Section 1833(z)(2) of the Act specifies the thresholds for the level of participation in Advanced APMs required for an eligible clinician to become a QP for a year. The Medicare Option, based on Part B payments for covered professional services or counts of patients furnished covered professional services under Part B, has been applicable since payment year 2019 (performance period 2017). The All-Payer Combination Option, through which QP status is calculated using the Medicare Option in addition to an eligible clinician's participation in Other Payer Advanced APMs, has been applicable since payment year 2021 (performance period 2019). In the CY 2017 Quality Payment Program final rule (81 FR 77433 through 77439), we finalized our policy for QP and Partial QP Thresholds for the Medicare Option as codified at § 414.1430(a) and for the All-Payer Combination Option at § 414.1430(b). Section 304(a)(2) of Division G, Title I, Subtitle C, of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42, March 9, 2024) amended section 1833(z)(2) of the Act by extending for payment years 2025 and 2026 (performance periods 2023 and 2024) the applicable payment amount and patient count thresholds for an eligible clinician to achieve QP status. Specifically, section 304(a)(2) of the CAA, 2024, amended section 1833(z)(2) of the Act to continue the QP payment amount thresholds that applied in payment year 2025 (performance period 2023) to payment year 2026 (performance period 2024). Additionally, section 304(a)(2) of the CAA, 2024, amended section 1833(z)(2) of the Act to require that, for payment year 2026, the Secretary use the same percentage criteria for the QP patient count threshold that applied in payment year 2022. Section 304(b) of the CAA, 2024, also amended section 1848(q)(1)(C)(iii) of the Act to extend through payment year 2026 the Partial QP thresholds that were established beginning for payment year 2021 under the Medicare Option. Under the All-Payer Combination Option, the QP thresholds for payment year 2026 (performance period 2025) will remain at 50 percent for the payment amount method and 35 percent for the patient count method. The Partial QP thresholds for payment year 2026 (performance period 2024) will continue at 40 percent for the payment amount method and 25 percent for the patient count method. To become a QP through the All-Payer Combination Option, eligible clinicians must first meet certain minimum threshold percentages under the Medicare Option. For payment year 2026 (performance period 2024), the minimum Medicare Option threshold an eligible clinician must meet to be eligible for the All-Payer Combination Option is 25 percent for the payment amount method or 20 percent for the patient count method. For Partial QP status, the minimum Medicare Option threshold an eligible clinician must meet to be eligible for the All-Payer Combination Option is 20 percent for the payment amount method or 10 percent for the patient count method.

To conform our regulation with the amendments made by the CAA, 2024, we propose to amend § 414.1430 by revising paragraphs (a) and (b) to reflect the statutory QP and Partial QP threshold percentages for both the payment amount and patient count under the Medicare Option and the All-Payer Option with respect to payment year 2026 (performance period 2024). Over the years, as legislative changes have been enacted, we have added new regulatory subsections. Additionally, we note that these thresholds all increased for payment year 2027 (performance period 2025), and were legislatively restored to lower levels for payment year 2028 (performance period 2026). To maintain relative structural simplicity in the regulation, we are proposing to condense the lists of applicable years and thresholds. The proposed structure would limit duplication in our description of the applicable thresholds.

We propose the following revisions to § 414.1430(a) and (b) for the Medicare Option and All-Payer Combination Option QP and Partial QP thresholds as follows:

• Paragraph (a)(1)(vi) to state that for 2027 the amount is 75 percent, and a new paragraph (a)(1)(vii) to state that for 2028, the amount is 50 percent, and a new paragraph (a)(1)(viii) to state that for 2029 and later, the amount is 75 percent.

• Paragraph (a)(2)(vi) to state that for 2027 the amount is 50 percent, and a

new paragraph (a)(2)(vi) to state that for 2028 the amount is 40 percent, and a new paragraph that for 2028 and later, the amount is 50 percent.

- Paragraph (a)(3)(vi) to state that for 2027 the amount is 50 percent, and a new paragraph (a)(3)(vii) to state that for 2028, the amount is 35 percent, and a new paragraph (a)(3)(viii) to state that for 2029 and later, the amount is 50 percent.
- Paragraph (a)(4)(vi) to state that for 2027 the amount is 35 percent, and a new paragraph (a)(4)(vii) to state that for 2028, the amount is 25 percent, and a new paragraph (a)(3)(viii) to state that for 2029 and later, the amount is 35 percent.
- Paragraph (b)(1)(i)(B) to state that for 2027 the amount is 75 percent, and a new paragraph (b)(1)(i)(C) to state that for 2028, the amount is 50 percent, and a new paragraph (b)(1)(i)(D) to state that for 2029 and later, the amount is 75 percent.
- Paragraph (b)(2)(i)(B) to state that for 2027 the amount is 75 percent and a new paragraph (b)(2)(i)(C) to state that for 2027, the amount is 50 percent, and a new paragraph (b)(2)(i)(D) to state that for 2028 and later, the amount is 75 percent.
- Paragraph (b)(3)(i)(B) to state that for 2027 the amount is 50 percent, and a new paragraph (b)(3)(i)(C) to state that for 2028, the amount is 35 percent, and a new paragraph (b)(3)(i)(D) to state that for 2029 and later, the amount is 50 percent.
- Paragraph (b)(4)(i)(B) to state that for 2027 the amount is 35 percent, and a new paragraph (b)(4)(i)(C) to state that for 2028, the amount is 25 percent, and a new paragraph (b)(4)(i)(D) to state that for 2029 and later, the amount is 35 percent.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520, we are required to provide notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. Collection of information is defined under 5 CFR 1320.3(c) of the PRA''s implementing regulations. To fairly evaluate whether an information collection should be approved by OMB, 44 U.S.C. 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment (see section V.D. of this proposed rule) on each of the aforementioned issues for the following sections of this document that contain confirmed or potential information collection requirements (ICRs). Comments, if received, will be responded to within the subsequent final rule (CMS–1848–F, OMB 0938–1485).

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' (BLS) May 2025 National Occupational Employment and Wage Estimates for all salary estimates (*https://www.bls.gov/oes/tables.htm*). In this regard, Tables D–A1 and D–A2 present BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage. There are many sources of variance in the average cost estimates, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Therefore, we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

We note that the BLS data does not include median hourly wage rates for multiple physician occupation types listed in Table D–A2; in these cases, the BLS identifies that the median wage rate is equal to or greater than $115.00/hr or $239,200 per year. BLS data for prior years, such as the May 2022 and May 2023 data, provide similar notes for median wage rates for occupations that are above the same threshold ($115.00/hr or $239,200 per year for the May 2022 BLS data (*https://www.bls.gov/oes/2022/may/oes_nat.htm*) and May 2023 BLS data (*https://www.bls.gov/oes/2023/may/oes_nat.htm*)). Therefore, for consistency with previous years for estimating physician wage rates, we have continued to use mean hourly wage rates across our wage estimates.

TABLE D-A1: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES (EXCLUDING PHYSICIANS)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Billing and Posting Clerks	43-3020	24.55	24.55	49.10
Business Operations Specialists	13-1000	44.63	44.63	89.26
Computer System Analysts	15-1211	55.10	55.10	110.20
General and Operations Managers	11-1021	64.87	64.87	129.74
Licensed Practical and Licensed Vocational Nurses	29-2061	32.24	32.24	64.48
Medical and Health Services Managers	11-9110	67.77	67.77	135.54
Software Quality Assurance Analysts and Testers	15-1253	53.60	53.60	107.20
Training and Development Managers	11-3131	71.33	71.33	142.66

For our purposes, BLS' May 2025 National Occupational Employment and Wage Estimates does not provide an occupation that we could use for ''Physician'' wage data. To estimate a Physician's costs, we used an average conglomerate wage of $307.74/hr as demonstrated in Table D–A2.

TABLE D-A2: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES (PHYSICIANS)

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Anesthesiologists	29-1211	173.35	173.35	346.70
Family Medicine Physicians	29-1215	122.99	122.99	245.98
General Internal Medicine Physicians	29-1216	128.46	128.46	256.92
Obstetricians and Gynecologists	29-1218	134.16	134.16	268.32
Orthopedic Surgeons, Except Pediatric	29-1242	179.60	179.60	359.20
Pediatric Surgeons	29-1243	241.37	241.37	482.74
Pediatricians, General	29-1221	101.98	101.98	203.96
Physicians, All Other	29-1229	125.98	125.98	251.96
Psychiatrists	29-1223	129.78	129.78	259.56
Surgeons	29-1240	175.17	175.17	350.34
Surgeons, All Other	29-1249	179.78	179.78	359.56
Total				3,385.24
Average Physician Wage (3,385.24/11)				307.74

Private Sector

To derive average costs, we used the most recently available data from the US Bureau of Labor Statistics (BLS), the May 2025 National Occupational Employment and Wage Statistics, for all salary estimates (*https://www.bls.gov/oes/tables.htm*). In this regard, Table D–A3 presents BLS' mean hourly wage, our estimated cost of fringe benefits and other indirect costs (calculated at 100 percent of salary), and our adjusted hourly wage.

TABLE D-A3: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Other Indirect Costs ($/hr)	Adjusted Hourly Wage ($/hr)
Billing and Posting Clerks	43-3021	24.55	24.55	49.10
Computer System Analysts	15-1211	55.10	55.10	110.20
General and Operations Managers	11-1021	64.87	64.87	129.74
Licensed Practical and Licensed Vocational Nurses	29-2061	32.24	32.24	64.48
Medical and Health Services Managers	11-9110	67.77	67.77	135.54
Physicians	29-1210	133.30	133.30	266.60
Software Quality Assurance Analysts and Testers	15-1253	53.60	53.60	107.20

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and other indirect costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, we believe that doubling the hourly wage to estimate the total cost is a reasonably accurate estimation method.

Wages for Individuals

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $24.05/hr.

The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices [389] identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, we used a measurement of the usual weekly earnings of wage and salary workers of $1,159 [390] for 2024 and then divided by 40 hours to calculate an hourly pre-tax wage rate of $28.98/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent or $4.93/hr ($28.98/hr × 0.17), resulting in the post-tax hourly wage rate of $24.05/hr ($28.98/hr − $4.93/hr). Unlike our

[389] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//176806/VOT.pdf.*

[390] *https://fred.stlouisfed.org/series/LEU0252881500A.*

private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment.

B. Proposed Information Collection Requirements (ICRs)

1. ICR Regarding Rebate Reduction Requests Under Sections 11101 and 11102 (§§ 427.402, 428.302, and 428.303)

This ICR collects information from manufacturers of Part B rebatable biosimilar biological products and generic Part D rebatable drugs and biosimilars that are requesting rebate reductions to inform CMS' determinations regarding such rebate reduction requests pursuant to the policies adopted in the CY 2025 PFS final rule (89 FR 97710). The information collection requirements for the Rebate Reduction Requests under sections 11101 and 11102 of the IRA ICR currently approved under OMB Control Number 0938–1474 are scheduled to expire on July 31, 2027. We intend to seek renewal of this collection from OMB prior to its expiration. The renewal will continue the currently approved requirements with technical updates to the forms, such as the email address to submit rebate reduction requests and references to relevant sections of the CY 2025 PFS final rule. No policy changes related to this collection are proposed in this rule. Consequently, we are not setting out any proposed burden estimates under this section of this proposed rule.

2. ICRs Regarding Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-In of Payment Reductions (§ 414.504)

As stated in section 1834A(h)(2) of the Act, chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, does not apply to information collected under section 1834A of the Act. Consequently, we are not setting out any proposed burden estimates under this section of the proposed rule. Please refer to section VII.F.4. of this proposed rule for a discussion of the impacts associated with the proposed changes described in section III.C. of this proposed rule.

3. Ambulatory Specialty Model

In this proposed rule, we make several proposals related to the Ambulatory Specialty Model (ASM), which is tested under the authority of section 1115A of the Act. As stated in the CY 2026 PFS final rule (90 FR 49973), under section 1115A(d)(3) of the Act, Chapter 35 of title 44, United States Code, does not apply to the testing, evaluation, and expansion of models under section 1115A of the Act and, therefore, the information collection requirements associated with the ASM proposals in this rule are not subject to the PRA. Nevertheless, for transparency, we briefly describe the anticipated administrative effects of these proposals.

The proposed ASM revisions in this proposed rule would have limited impact on the collection of information overall. For example, within the quality ASM performance category, we propose to replace the Functional Status Change for Patients with Low Back Impairments (MIPS Q220) with the Functional Outcome Assessment (MIPS Q182) measure, which should not impact burden given we are removing one measure and replacing with another. The proposed addition of the administrative claims-based quality measure would not entail additional data collection or submission requirements given there is no data submission for such measures. Similarly, remaining proposals should not impact the collection of information significantly.

4. ICRs Regarding Limiting Medicare Coverage of Certain Individuals

In accordance with section 1899C of the Act and in this proposed rule, we intend to update the Medicare initial enrollment forms to expand the response options to include specific types of citizenship and alien status data elements to support Medicare Part A enrollment eligibility determinations. This is a small change that will not increase the burden already accounted for in OMB control numbers 0938–0251 (CMS 18–F–5), 0938–0245 (CMS 4040), 0938–0251 (CMS–10797) and 0938–0080 (CMS 43).

Our estimate is that the addition of the citizenship section to the CMS–10797, the form used to apply for Medicare using a Special Enrollment Period for Exceptional Conditions, does not change the currently approved burden estimates accounted for in OMB Control Number 0938–0251. The majority of respondents are expected to be U.S. citizens or nationals who will spend no more than one minute on the citizenship section, which is considered negligible. The currently approved burden for this collection reflects 34,612 respondents generating 34,612 total annual responses at 0.25 hours per response, for a total of 8,653 burden hours (34,612 responses × 0.25 hr/response) at a cost of $208,105 (8,653 hours × $24.05/hr), or $6.01 per respondent ($208,105/34,612 respondents). We request comment on the burden assumptions for the CMS–10797.

The addition of the new SEP category to the CMS–10797 creates additional burden for individuals who utilize the SEP to apply for re-enrollment in Medicare following a change in their citizenship, nationality, or immigration status. We do not have historical data on which to base a precise estimate of SEP utilization, as this is a newly proposed enrollment pathway with no prior utilization experience. OACT estimates that approximately 32,000 individuals will lose Medicare coverage beginning in 2027. For purposes of this burden estimate, we assume that approximately 10 percent of individuals projected to lose Medicare coverage, approximately 3,200 (32,000 × 0.10) individuals annually, may utilize the SEP to re-enroll in Medicare following a change in their citizenship, nationality, or immigration status. This is a placeholder assumption, as there is no historical precedent on which to base the estimate. We estimate 3,200 total respondents annually at 0.25 hours per response, for a total additional burden of 800 hours (3,200 responses × 0.25 hr/response) at a total estimated additional cost of $19,240 (800 × $24.05/hr), or $6.01 per respondent ($19,240/3,200 respondents), beginning in CY 2027. We assume that the 0.25 hours per response applies to this proposed SEP, as the burden associated with reestablishing immigration status and updating documentation is outside the Medicare enrollment process and therefore this burden estimate only accounts for time to enroll in Medicare.

The updated total burden for OMB control number 0938–1426, inclusive of both the currently approved burden and the additional SEP burden, is 37,812 total respondents (34,612 + 3,200) and 9,453 total burden hours (8,653 + 800) at a total cost of $227,345 ($208,105 + $19,240).

All information impacts related to the procedural steps that MA and Part D plans must take to receive and process disenrollment transactions have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) and 0938–0964 (CMS–10141) and no additional burden is attributed to this provision for those activities as this change is small relative to the number of disenrollment transactions processed by MA and Part D plans annually.

We are seeking public comments on all aspects of the proposed changes to entitlement and eligibility rules for Parts A and B, the underlying burden

assumptions, and the changes to limit coverage under Medicare cost plans, MA plans, and Part D plans.

5. ICR Regarding Medicare Prescription Drug Inflation Rebate (§ 428.203(c))

The following proposed changes will be submitted to OMB for review under control number 0938–1485 (CMS–10930).

In section III.G.3.c.2.c. of this proposed rule, we are proposing to require all providers and suppliers that are covered entities as defined under § 10.3 (hereinafter collectively ''340B providers'' unless otherwise noted) to submit data elements from their Part D 340B claims to the 340B repository for all covered Part D drugs billed to Medicare Part D by such covered entity or its contractor(s) beginning in 2027 for Part D claims with dates of service on or after January 1, 2027. To allow sufficient time for 340B providers to gather, validate, and submit the specified data to the 340B repository, we propose to require that 340B providers would be expected to report data on a quarterly basis (though they may choose to submit more frequently) to the 340B repository within one calendar quarter following the close of the relevant calendar quarter. For example, for claims with dates of service between October 1, 2027, through December 31, 2027, 340B providers would submit the data elements from Part D 340B claims to the 340B repository no later than March 31, 2028. 340B providers would submit this data directly to CMS to be included in the 340B repository. We propose that we would rely upon the completeness and accuracy of the data submitted by 340B providers to the 340B repository, consistent with the 340B provider requirement to certify the accuracy of such submissions, to consider all data elements received by the 340B repository to be associated with Part D 340B claims. We also propose, as part of every submission to require 340B providers (or an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification) to certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, its submissions include all Part D 340B claims for the 340B provider at the time of submission for the relevant period. 340B providers or their authorized representative would be required to certify the completeness and accuracy of the data submitted and to certify that the submitter is authorized to submit on behalf of the 340B provider. We would match the stored data elements in the 340B repository to PDE transactions for each Part D rebatable drug dispensed during the applicable period and would evaluate 340B repository data for: (1) data integrity, and (2) submission frequency and completeness across covered entity types and geographies.

The information collected by CMS from 340B providers would provide CMS with information to assess the usability of the data received and feasibility of CMS removing 340B units from the total number of units used to calculate the total rebate amount in the future based on the data submitted. This data and information is necessary to implement statutory requirements of the Medicare Part D Drug Inflation Rebate Program at section 1860D–14B(b)(1)(B) of the Act, which requires that beginning with plan year 2026, we shall exclude from the total number of units for a Part D rebatable drug, with respect to an applicable period, those units for which a manufacturer provides a discount under the 340B Program. As stated earlier, we are proposing to require all 340B providers to submit data elements from their Part D 340B claims to the 340B repository for all covered Part D drugs billed to Medicare Part D beginning in 2027 for Part D claims with dates of service on or after January 1, 2027.

Based on internal CMS analyses of the unique 340B ID numbers in the OPAIS database that are active (that is, not terminated) with at least one contract pharmacy association listed, we estimate that approximately 14,000 340B providers would respond by submitting data 4 times per year (quarterly) to the 340B repository in the format and manner specified by CMS.

For a 340B provider or its third-party administrator (TPA), we estimate it would take 6 hours at $107.20/hr for a Software Quality Assurance Analyst and Tester sampling for each submission and 2 hours at $129.74/hr for a General and Operations Manager to review each submission. In addition to the recurring submissions, we estimate it would take a General and Operations Manager one hour at $129.74/hr to complete the one-time registration for the 340B repository.

In aggregate, we estimate an annual burden of 462,000 hours ([56,000 responses × 8 hr/response] + [14,000 340B providers × 1 hr/registration]) at a cost of $52,366,440 [(2 hr × $129.74/hr × 56,000 responses) + (6 hr × $107.20/hr × 56,000 responses) + (1 hr × $129.74/hr × 14,000 registrations)]) (see Table D–A4).

TABLE D-A4: SUMMARY OF TOTAL ANNUAL BURDEN FOR ALL 340B PROVIDERS OR TPAS TO COMPLETE 340B REPOSITORY DATA ELEMENTS FORM IN 2026

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Regarding the Medicare Prescription Drug Inflation Rebate Program under Sections 11101 and 11102 of the Inflation Reduction Act	0938-1485 (CMS-10930)	14,000 340B Providers or TPAs	70,000 (14,000 registrations/year + 56,000 responses/year	Varies	462,000	Varies	52,366,440

6. ICRs Regarding the Medicare Shared Savings Program

Section 1899(e) of the Act provides that chapter 35 of title 44 U.S.C., which includes such provisions as the PRA, shall not apply to the Shared Savings Program. Accordingly, we are not setting out Shared Savings Program burden estimates under this section of the rule. Please refer to the Regulatory Impact Analysis (section VII. of this proposed rule) for a discussion of the impacts associated with the proposed changes to the Shared Savings Program as described in section III.G. of this proposed rule.

7. ICRs Regarding the Quality Payment Program

a. Background

The following identifies proposed changes will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

However, independent of this proposed rulemaking's changes, we also intend to merge the information collection requests in the Virtual Groups PRA package (OMB control number 0938–1343, CMS–10652) into OMB control number 0938–1314 (CMS–10621) in order to consolidate QPP-related ICRs into a single collection of information request to avoid duplication. For more detailed information on our proposed policies, we refer readers to section IV. of this proposed rule.

We apply the updated BLS wage rate data identified in section V.A. of this proposed rule. We refer readers to section VII.F.11.e. of this proposed rule for the Regulatory Impact Analysis for discussion of impacts to final scores and payment adjustments.

All changes to burden and information collections for Quality Payment Program ICRs due to changes associated with proposed policies will be submitted to OMB for review under control number 0938–1314 (CMS–10621). Non-rulemaking revisions, resulting from updated data and assumptions, will also be submitted to OMB. It is intended to focus our PRA score on the impact of this rule's proposed policy changes.

(1) Framework for Understanding the Burden of MIPS Data Submission

Across organizations permitted or required to submit data on behalf of clinicians, there can be variation across the types of data provided, and whether a clinician is a MIPS eligible clinician or other eligible clinician voluntarily submitting data, a MIPS Alternative Payment Model (APM) participant, or an Advanced APM participant. MIPS eligible clinicians and other clinicians voluntarily submitting data to MIPS for the quality, Promoting Interoperability, and improvement activities performance categories may submit data as the following participation types: individual; group; virtual groups (available only for traditional MIPS); subgroups (available only for MIPS Value Pathways (MVPs)); and APM Entities. Eligible clinicians who attain Partial Qualifying APM Participant (QP) status may be subject to data collection burden if they elect to participate in MIPS. MIPS eligible clinicians are not required to submit any data for the cost performance category, as CMS calculates performance on measures specified for this performance category based on claims-data. Virtual groups are subject to the same data submission requirements per performance category as groups, and therefore, we will refer only to groups for the remainder of this section, unless otherwise noted.

For the aforementioned participation types, we assessed the same burden per reporting option and assumed from our available data that all non-Medicare Shared Savings Program (Shared Savings Program) APM Entity submissions are assessed based on a single Taxpayer Identification Number (TIN). Per section 1899(e) of the Act, the PRA does not apply to the Shared Savings Program, thus excluded submissions by Shared Savings Program APM Entities from our MIPS reporting estimates. The regulatory impact analysis in section VII.F.11.b. of this proposed rule discusses impacts to the Shared Savings Program from provisions associated with this proposed rule.

There are three MIPS reporting options: traditional MIPS, MVPs, and the APM Performance Pathway (APP). In section V.B.7.c.(1) of this proposed rule, we provide distinct estimates for the traditional MIPS and MVP reporting options for the quality performance category, focusing on changes to our currently approved burden estimates. As with the CY 2026 PFS final rule (90 FR 49942 through 49943), we have not separately estimated burden for traditional MIPS and MVPs for the Promoting Interoperability and improvement activity performance categories. Traditional MIPS and MVPs require reporting on all Promoting Interoperability performance category objectives and measures. Traditional MIPS reporting for the improvement activities performance category typically requires attestation to two improvement activities; however, clinicians, groups, and virtual groups with a special status designation are only required to attest to one improvement activity. All MVP participants are only required to attest to one improvement activity. For additional details on historic burden assumptions for the improvement activities performance category, we refer readers to the CY 2025 PFS final rule (89 FR 98492). In the related collection of information request (OMB control number 0938–1314, CMS–10621), we aggregate submissions across all reporting options. For additional burden historic frameworks, we refer readers to the CY 2024 PFS final rule (88 FR 79422 through 79424) and the CY 2025 PFS proposed rule (89 FR 62111 through 62114).

(2) Additional Data Considerations

The accuracy of our estimates of the total burden for data submission for MIPS performance categories may be impacted by several factors. First, we are unable to predict with certainty the number of participants who will obtain a QP status, thus exempt from MIPS reporting, for the CY 2027 performance period/2029 MIPS payment year and later years. Eligible clinicians who do not achieve QP status for a given performance period may be required to participate in the Merit-Based Incentive Payment System (MIPS). Second, it is difficult to predict whether Partial QPs, who can elect to report to MIPS, will choose to participate in the CY 2027 performance period/2029 MIPS payment year or later years. Therefore, the actual number of Partial QP participants and whether they elect to submit MIPS data may differ from our estimates. However, we believe our methodology for assessing burden, as described in the preceding Framework for Understanding the Burden of MIPS Data Submission section, is most appropriate given all the limitations. We refer readers to section VII.F.11.e.(2) (b) of this proposed rule for a discussion of the potential but unquantifiable burden implications on MIPS-related burden of the proposal to modify the application of the QP and partial QP status, presented in section IV.F.2. of this proposed rule.

b. ICRs Regarding Third Party Intermediaries (§ 414.1400)

We refer readers to § 414.1400(d) for our previously established requirements for CMS-approved third party intermediaries that may submit data on behalf of MIPS eligible clinicians, groups, virtual groups, subgroups, and APM Entities. The following sections detail proposals that impact existing ICRs relevant to Third Party Intermediaries. Additionally, in section

IV.C. of this proposed rule, we are proposing to (1) add a requirement that CMS-approved third-party intermediaries may be terminated after failure to submit data for 1 year ; and (2) add a new requirement for third party intermediaries to submit documentation about intent to submit MIPS data and to terminate a third party intermediary if they do not submit documentation by the date specified by CMS. We refer readers to section VII.F.11.e.(2)(c) of this proposed rule for additional discussion on the impact of these proposals for which burden is not quantifiable.

(1) Full and Simplified Self-Nomination for Qualified Clinical Data Registries (QCDRs) and Qualified Registries

As described in section IV.C. of this rule, we are proposing to: (1) further clarify that additional requirements for health IT vendors do not apply beginning with the CY 2025 performance period/2027 MIPS payment year because health IT vendors are no longer allowed to submit MIPS data as third party intermediaries starting in that year; (2) clarify the level at which performance feedback reports are provided; (3) update the existing sampling methodologies for data auditing purposes; and (4) update the policy so that third party intermediaries will not be permitted to make changes to the qualified posting after it is publicly posted on the Quality Payment Program resource library. We assume that there will be no impact on the time required to complete either the full or simplified self-nomination process due to these proposals. Additionally, related to our proposal to implement core measures in traditional MIPS and MVPs in section IV.A.4.d.(1)(c) of this proposed rule, we are proposing to revise the data submission requirement in which a QCDR or a qualified registry must be able to submit at least six qualified measures including at least one MIPS core measure, beginning with the CY 2027 performance period/2029 MIPS payment year. This proposal does not alter the minimum number of measures a qualified registry or QCDR is required to support; therefore, we assume no impact to the overall time estimated for qualified registries or QCDRs to submit their information at the time of self-nomination. We are not proposing revisions to our estimated responses and time per response for both the Full and Simplified Self-Nominations for Qualified Registries and QCDRs under OMB control number 0938–1314 (CMS–10621).

(2) Third Party Intermediary Plan Audits

We are proposing updates related to Third Intermediary Plan Audits, which include targeted audit requirements, participation plan submissions, and corrective action and termination processes for third party intermediaries.

(a) Participation Plans

In section IV.C.3.c. of this proposed rule, we are proposing to update the conditions for approval related to participation plans such that third party intermediaries that do not submit data for 1 year would be required to submit a participation plan during self-nomination. Currently, third party intermediaries are required to submit a participation plan only after not submitting data for 2 consecutive years. We do not expect this proposal to affect the number of participation plans submitted during the self-nomination process and therefore do not anticipate an impact on burden; therefore, we are not proposing to modify our burden estimates under OMB control number 0938–1314 (CMS–10621).

c. ICRs Regarding Quality Data Submission

(1) Proposed Changes to Quality Performance Category Submissions

In section IV.A.4.a. of this proposed rule, we are proposing to add three new MVPs beginning with the CY 2027 performance period/2029 MIPS payment year. In section IV.A.3. of this proposed rule, we are also proposing that beginning in the CY 2029 performance period/2031 MIPS payment year, eligible clinicians participating in MIPS, and not reporting the APM Performance Pathway (APP/APP+), would be required to report the measures and activities in a selected MVP. Related to this proposal, we are proposing to include virtual groups in MVP reporting beginning in the CY 2029 performance period/2031 MIPS payment year. We refer readers to sections V.B.7.c.(1)(a) of this proposed rule for additional details regarding the quality data reporting estimates for both MIPS and MVPs due to these updated proposals.

The following proposed policies would not have impact on burden as they do not affect the minimum reporting requirements for the respective quality performance category submission:

In section IV.A.4.a.(2) of this proposed rule, we are proposing MVP maintenance updates to our MVP inventory that are aligned with the MVP development criteria (85 FR 84849 through 84854), in section IV.A.4.d.(1)(c)(iii) of this proposed rule, we are also proposing MIPS core measures in traditional MIPS and MVPs with an attestation process. In section IV.A.4.d(1)(e) of this proposed rule, we are also proposing MIPS quality measure inventory updates.

In section IV.A.4.d.(1)(c)(iii) of this proposed rule, we are proposing to establish a MIPS core measure attestation process whereby the clinician would be required to attest during the data submission period that there was not an available and applicable MIPS core measure for them to report. We are not proposing revisions due to this proposal as we believe the currently approved burden for traditional MIPS and MVP quality measure submissions is sufficient to absorb the negligible effort of the attestation in lieu of reporting a quality measure.

In the following sections, we estimate the number of submissions for each collection type that require active reporting by individual clinicians, groups, subgroups (as applicable for MVP reporting), or non-Shared Savings Program APM Entities for the CY 2027 performance period/2029 MIPS payment year through CY 2029 performance period/2031 MIPS payment year per the policy proposals previously discussed. Available collection types include Medicare Part B claims measures (small practices only), MIPS Clinical Quality Measures (CQM), QCDR measures, and electronic Clinical Quality Measures (eCQMs). We do not assess burden for the administrative claims-based quality measures, as CMS automatically calculates scores for individual clinicians, groups, subgroups (as applicable for MVP reporting), or non-Shared Savings Program APM Entities that meet requirements to be scored. As there are no policy proposals related to the non-Shared Savings Program related APM Performance pathway, we assume no change to our currently approved burden estimates.

(a) CY 2027 Performance Period/2029 MIPS Payment Year and CY 2028 Performance Period/2030 MIPS Payment Year

The following section details the burden estimate for the proposal to add 3 new MVPs starting with the CY 2027 performance period/2029 MIPS payment year consistent with the proposals outlined in section V.B.7.c.(1)(a)(ii) of this rule. These burden estimates will also apply to the CY 2028 performance period/2030 MIPS payment year.

(i) Updated Data Assumptions for Quality Submissions

For the traditional MIPS and MVP Quality Performance Category ICRs, our currently approved estimates used submission data from the CY 2023 performance period/2025 MIPS payment year and estimated that: (1) 14 percent of quality submissions will submit as an MVP based on the MVP inventory available in the CY 2026 performance period/2028 MIPS payment year; and (2) 20 subgroups (90 FR 49948 through 49949). At the time of this rulemaking, we have updated historic submission data for the CY 2024 performance period/2026 MIPS performance year, inclusive of individual, group, and non-Shared Savings Program APM Entities.

In Tables D–A5 and D–A6, we identify the updated response estimates by reporting option due to the availability of this updated data and add our estimate of 20 subgroup submissions currently approved under OMB control number 0938–1314 (CMS–10621). The response estimates for these ICRs apply our existing approach for estimating the impact of MVPs as a percentage of historic submissions, the currently approved estimate of 14 percent as established in the CY 2026 PFS Final Rule (90 FR 49949).

The impact on burden for each proposal discussed in the following sections use these updated active response estimates when calculating change in total time and cost. The updated estimates will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

TABLE D-A5: RESPONDENT COUNTS FOR QUALITY PERFORMANCE CATEGORY AND MVP REGISTRATION ICRs

Reporting Option	Performance Category	Requirement	Currently Approved Responses*	Revised Responses **	Change Due to Updated Data
Traditional MIPS	Quality	Medicare Part B Claims Measure Collection Type Submission	8,350	7,307	(1,043)
Traditional MIPS	Quality	MIPS CQM and QCDR Measure Collection Type Submission	17,407	18,820	1,413
Traditional MIPS	Quality	eCQM Collection Type Submission	23,936	22,830	(1,106)
MVPs	N/A	MVP Registration	8,110	7,989	(121)
MVPs	Quality	Medicare Part B Claims Measure Collection Type Submission	1,359	1,189	(170)
MVPs	Quality	MIPS CQM and QCDR Measure Collection Type Submission	2,844	3,074	230
MVPs	Quality	eCQM Collection Type Submission	3,907	3,726	(181)

*Under OMB control number 0938-1314 (CMS-10621).

**Traditional MIPS updates calculated as updated submission data for CY 2024 performance period/2026 MIPS payment year submissions minus 14 percent (existing MVP submission rate). MVPs calculated as 14 percent of historic submissions plus estimated subgroup submissions (split evenly across the eCQM and MIPS CQM/QCDR measure collection types).

(ii) MVP Participation Estimate

We estimate the number of MVP submissions for the CY 2027 performance period/2029 MIPS payment year as a percent of the total traditional MIPS and MVP submissions from the CY 2024 performance period/2026 MIPS payment year (see Table D–A5). We assessed measure-level submission trends from the CY 2024 performance period/2026 MIPS payment year data for the new MVPs as proposed in section IV.A.4.a. of this proposed rule. The total average of quality measure submissions for the proposed new MVPs was equivalent to approximately 6 percent of the total quality performance category submissions in the CY 2024 performance period/2026 MIPS payment year. With the existing 14 percent estimate previously finalized in the CY 2026 PFS final rule (90 FR 32789) plus the incremental change of an additional 6 percent due to the proposed new MVPs, we estimate that 20 percent of quality performance category submissions may report via MVPs for the CY 2027 performance period/2029 MIPS payment year (row b). While this approach to estimate MVP submissions as a function of historic traditional MIPS and MVP submissions, and not just MVP submissions from a given year, is used to estimate future reporting behaviors with an expect increased adoption due to the annual expansion of the MVP inventory, as summarized in section IV.A.4.a. of this proposed rule, there are limitations, such as lack of longitudinal data to appropriately assess behavior changes related to future adoptions or submissions in both new and existing MVPs. For example, the most recent submission data available is from the CY 2024 performance period/2026 MIPS payment year when the MVP inventory was composed of 16 MVPs, whereas for CY 2027 performance period/2029 MIPS payment year we are proposing an MVP inventory of 30 MVPs. Consistent with the past approach, we project any increase to our expected MVP participation rate reduces the number of estimated submissions for each quality performance category collection type via traditional MIPS.

Table D–A6 of this proposed rule identifies our methods to estimate the number of individual clinicians, groups, and non-Shared Savings Program APM Entities that may submit data via each collection type in the CY 2027 performance period/2029 MIPS payment year, separating traditional MIPS and MVP estimates. We identify estimated submissions per collection type from CY 2024 performance period/2026 MIPS payment year data (row a). Consistent with the policy finalized in the CY 2018 Quality Payment Program final rule that for MIPS eligible clinicians who collect measures via Medicare Part B claims, MIPS CQM/QCDR, or eCQM collection types and submit more than the required number of measures (82 FR 53735 through 54736), we will score the clinician on the required measures with the highest assigned measure achievement points and thus, the same clinician may be counted as a respondent for more than one collection type. Therefore, our columns in Table D–A6 are not mutually exclusive. We assume that each response or submission per collection type for traditional MIPS includes six quality measures, and that each response or submission per collection type for MVPs includes four quality measures.

TABLE D-A6: ESTIMATED NUMBER OF SUBMISSIONS FOR QUALITY PERFORMANCE CATEGORY BY COLLECTION TYPE

	Medicare Part B Claims Measure	MIPS CQM/QCDR Measure	eCQM
Total 2027 Performance Period Quality Performance Category Submissions (Excludes QPs) (a)	8,496	21,894	26,556
2026 Performance Period Approved MVPs (14 percent) (b) = (a) × 0.14	1,189	3,065	3,718
2027 Performance Period Proposed MVPs (20 percent) (c) = (a) × 0.20	1,699	4,379	5,311
2027 Traditional MIPS Performance Period (Excludes QPs and Estimated MVP Submissions) (d) = (a) - (c)	6,797	17,515	21,245
Number of Submissions Moving to MVPs due to New MVPs (e) = (c) - (b)	510	1,313	1,593

* Estimates in the table are rounded to the nearest whole number, therefore the Number of Submissions Moving to MVPs due to New MVPs row may deviate from the provided formula due to rounding.

(iii) Traditional MIPS Quality Data Submission

The following estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians, groups, and non-Shared Savings Program APM Entities. For our most recent discussions of related burden, we refer readers to the CY 2024 PFS final rule (88 FR 70149 through 70151) and the CY 2025 PFS final rule (89 FR 98479 through 98483), and CY 2026 PFS final rule (90 FR 49946 through 49949). All estimates encompass time to review measure specifications unless otherwise noted.

(A) Medicare Part B Claims Measure Collection Type

The following estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians from a small practice with less than 15 clinicians. We acknowledge a range of times for computer system analysts to submit quality measure data (minimum, mean, and maximum burden estimates) for this collection type. We continue to apply the maximum burden in our total burden estimates.

For the CY 2027 performance period/2029 MIPS payment year, we estimate a decrease of 510 submissions due to proposing three new MVPs in this proposed rule. When considering a range of Computer System Analyst response times (from 1.15 to 8.2 hr/response) we estimate a maximum total decrease of 7,242 hours and $883,105 as demonstrated in Tables D–A7 through D–A9.

TABLE D-A7: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR TRADITIONAL MIPS MEDICARE PART B CLAIMS MEASURE COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR AND CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Range: Time/Cost	Time (hr) - Computer System Analyst	Time (hr) - Other Occupations	Total Time (hr)	Cost ($) - Computer System Analyst	Cost ($) - Other Occupations	Total Cost ($)
Minimum	(587)	(3,060)	(3,647)	(64,632)	(422,249)	(486,881)
Mean	(1,046)	(3,060)	(4,106)	(115,214)	(422,249)	(537,463)
Maximum	(4,182)	(3,060)	(7,242)	(460,856)	(422,249)	(883,105)

TABLE D-A8: ESTIMATED INFORMATION COLLECTION BURDEN RANGE FOR COMPUTER SYSTEM ANALYSTS IN TRADITIONAL MIPS MEDICARE PART B CLAIMS MEASURE COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR AND CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Computer System Analyst	Wage ($/hr)		Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Minimum	110.20	(510)	1.15	(587)	(64,632)
Mean	110.20	(510)	2.05	(1,046)	(115,214)
Maximum	110.20	(510)	8.2	(4,182)	(460,856)

TABLE D-A9: ESTIMATED INFORMATION COLLECTION BURDEN RANGE FOR OTHER OCCUPATIONS IN TRADITIONAL MIPS MEDICARE PART B CLAIMS MEASURE COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR AND CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Other Occupations	Wage ($/hr)		Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Billing Clerks	49.10	(510)	1	(510)	(25,041)
Licensed Practical Nurses (LPNs)	64.48	(510)	1	(510)	(32,885)
Medical and Health Service Managers	135.54	(510)	3	(1,530)	(207,376)
Physicians	307.74	(510)	1	(510)	(156,947)
Total	n/a	(510)	varies	(3,060)	(422,249)

(B) MIPS CQM and QCDR Measure Collection Types

For the CY 2027 performance period/2029 MIPS payment year, we estimate a decrease of 1,313 submissions due to proposing three new MVPs in this proposed rule. Multiplying the estimated change in submissions (1,313) by the time per submission by labor category, we estimate a decrease of 11,926 hours and $1,499,903 as demonstrated in Table D–A10.

TABLE D-A10: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR TRADITIONAL MIPS CQM AND QCDR MEASURE COLLECTION TYPES FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR AND CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Other Occupations	Wage ($/hr)		Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	(1,313)	4.083	(5,361)	(590,782)
Billing Clerks	49.10	(1,313)	1	(1,313)	(64,468)
Licensed Practical Nurses (LPNs)	64.48	(1,313)	1	(1,313)	(84,662)
Medical and Health Service Managers	135.54	(1,313)	2	(2,626)	(355,928)
Physicians	307.74	(1,313)	1	(1,313)	(404,063)
Total	N/A	(1,313)	Varies	(11,926)	(1,499,903)

(C) MIPS eCQM Collection Type

For the CY 2027 performance period/2029 MIPS payment year, we estimate a decrease of 1,593 submissions due to proposing three new MVPs in this proposed rule. Multiplying the estimated change in submissions by the time per submission by labor category, we estimate a decrease of 12,744 hours and $1,629,639 as demonstrated in Table D–A11.

TABLE D-A11: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR TRADITIONAL MIPS eCQM COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR AND CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Other Occupations	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	(1,593)	3	(4,779)	(526,646)
Billing Clerks	49.10	(1,593)	1	(1,593)	(78,216)
Licensed Practical Nurses (LPNs)	64.48	(1,593)	1	(1,593)	(102,717)
Medical and Health Service Managers	135.54	(1,593)	2	(3,186)	(431,830)
Physicians	307.74	(1,593)	1	(1,593)	(490,230)
Total	N/A	(1,593)	Varies	(12,744)	(1,629,639)

(iv) MVP Registration: Individuals, Groups, Subgroups, and APM Entities

We estimate that the proposed addition of three new MVPs would result in an increase of 3,416 MVP registrations. Using the currently approved estimate of 0.25/hr per registration, we estimate an annual burden increase of 854 hours (+3,416 registrations × 0.25 hr/registration) at a cost of +$94,111 (+854 hr × $110.20/hr for a computer system analyst or equivalent).

(v) MVP Quality Performance Category Submission

We estimate a change to the number of annual MVP quality performance category submissions per collection type from our currently approved burden estimates, beginning with the CY 2027 performance period/2029 MIPS payment year. These estimates include the figures detailed in section V.B.7.c.(1)(a) of this proposed rule. These estimates aggregate individual clinician, group, subgroup, and non-Shared Savings Program APM Entity submissions. All estimates presume maximum submission time and encompass time to review measure specifications unless otherwise noted.

(A) Medicare Part B Claims Measure Collection Type

We estimate an increase of 510 submissions due to the proposed addition of three new MVPs. Multiplying the estimated change in submissions (+510) by the time per submission by labor category, we estimate a total increase of 4,816 hours at a cost of $587,143 as demonstrated in Table D–A12.

TABLE D-A12: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR MVP MEDICARE PART B CLAIMS MEASURE COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR AND CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	510	5.46	2,785	306,907
Medical and Health Service Managers	135.54	510	2	1,020	138,251
Licensed Practical Nurses (LPNs)	64.48	510	0.66	337	21,730
Billing Clerks	49.10	510	0.66	337	16,547
Physicians	307.74	510	0.66	337	103,708
Total	n/a	510	varies	4,816	587,143

(B) MIPS CQM and QCDR Measure Collection Type

We estimate an increase of 1,313 submissions due to the proposed addition of three new MVPs. Multiplying the estimated change in submissions (+1,313) by the time per submission by labor category, we estimate a total increase of 7,840 hours at a cost of $986,867 as demonstrated in Table D–A13.

TABLE D-A13: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR MVP CQM AND QCDR MEASURE COLLECTION TYPES FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR AND CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	1,313	2.66	3,493	384,929
Medical and Health Service Managers	135.54	1,313	1.33	1,746	236,653
Licensed Practical Nurses (LPNs)	64.48	1,313	0.66	867	55,904
Billing Clerks	49.10	1,313	0.66	867	42,570
Physicians	307.74	1,313	0.66	867	266,811
Total	N/A	1,313	Varies	7,840	986,867

(C) eCQM Collection Type

We estimate an increase of 1,593 submissions due to the proposed addition of three new MVPs. Multiplying the estimated change in submissions (+1,593) by the time per submission by labor category, we estimate a total increase of 8,442 hours at a cost of $1,079,350 as demonstrated in Table D–A14.

TABLE D-A14: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR MVP eCQM COLLECTION TYPE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR AND CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	1,593	1.99	3,170	349,334
Medical and Health Service Managers	135.54	1,593	1.33	2,119	287,209
Licensed Practical Nurses (LPNs)	64.48	1,593	0.66	1,051	67,768
Billing Clerks	49.10	1,593	0.66	1,051	51,604
Physicians	307.74	1,593	0.66	1,051	323,435
Total	N/A	1,593	Varies	8,442	1,079,350

(vi) Summary of Quality Performance Category Estimated Information Collection Burden Change for CY 2027 Performance Period/2029 MIPS Payment Year and CY 2028 Performance Period/2030 MIPS Payment Year

Across the quality performance category collection types for Traditional MIPS and MVPs, we estimate that policy proposals would lead to a decrease in burden of 9,960 hours and a savings of $1,265,176 under OMB control number 0938–1314 (Table D–A15).

TABLE D-A15: SUMMARY OF QUALITY PERFORMANCE CATEGORY ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR AND CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Requirement	Change in Number of Respondents	Change in Time	Change in Cost ($)
Traditional MIPS Quality Submission	(3,416)	(31,912)	(4,012,647)
MVP Registration	3,416	854	94,111
MVP Quality Submission	3,416	21,098	2,653,360
Total	**0***	**(9,960)**	**(1,265,176)**

* Respondents moving from Traditional MIPS to MVPs need to complete MVP registration plus MVP Quality Submission, therefore the net number of new respondents will be 0.

(b) CY 2029 Performance Period/2031 MIPS Payment Year

The following section details the burden estimate for that beginning in the CY 2029 performance period/2031 MIPS payment year, eligible clinicians participating in MIPS, and not reporting the APP, would be required to report the measures and activities in a selected MVP as detailed in section IV.A.3. of this proposed rule.

(i) Traditional MIPS Quality Data Submission

For the CY 2029 performance period/2031 MIPS payment year, we assume that no Quality Performance category submissions will occur via Traditional MIPS due the proposal that eligible clinicians participating in MIPS and not reporting the APP, would be required to report the measures and activities in a selected MVP.

(A) Medicare Part B Claims Measure Collection Type

The following estimates apply to requirements for the traditional MIPS reporting option and submissions by individual clinicians. For the CY 2029 performance period/2031 MIPS payment year, we estimate a decrease of 6,797 submissions due to the proposal to require selection of an MVP for quality performance category reporting. Multiplying the estimated change in submissions (−6,797) by the time per submission by labor category, we estimate a maximum total decrease of 96,517 hours and savings of $11,769,506 as demonstrated in Table D–A16.

TABLE D-A16: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR TRADITIONAL MIPS MEDICARE PART B CLAIMS MEASURE COLLECTION TYPE FOR CY 2029 PERFORMANCE PERIOD/2031 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	(6,797)	8.2	(55,735)	(6,141,997)
Medical and Health Service Managers	135.54	(6,797)	3	(20,391)	(2,763,796)
Licensed Practical Nurses (LPNs)	64.48	(6,797)	1	(6,797)	(438,271)
Billing Clerks	49.10	(6,797)	1	(6,797)	(333,733)
Physicians	307.74	(6,797)	1	(6,797)	(2,091,709)
Total	N/A	(6,797)	Varies	(96,517)	(11,769,506)

(B) MIPS CQM and QCDR Measure Collection Types

For the CY 2029 performance period/2031 MIPS payment year, we estimate a decrease of 17,507 submissions due to the proposal to require selection of an MVP for quality performance category reporting. Multiplying the estimated change in submissions (−17,507) by the time per submission by labor category, we estimate a decrease of 159,016 hours and savings of $19,999,053 as demonstrated in Table D–A17.

TABLE D-A17: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR TRADITIONAL MIPS CQM AND QCDR MEASURE COLLECTION TYPES FOR CY 2029 PERFORMANCE PERIOD/2031 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	(17,507)	4.083	(71,481)	(7,877,206)
Medical and Health Service Managers	135.54	(17,507)	2	(35,014)	(4,745,798)
Licensed Practical Nurses (LPNs)	64.48	(17,507)	1	(17,507)	(1,128,851)
Billing Clerks	49.10	(17,507)	1	(17,507)	(859,594)
Physicians	307.74	(17,507)	1	(17,507)	(5,387,604)
Total	N/A	(17,507)	Varies	(159,016)	(19,999,053)

(C) MIPS eCQM Collection Type

For the CY 2029 performance period/2031 MIPS payment year, we estimate a decrease of 21,237 submissions due to the proposal to require selection of an MVP for quality performance category reporting. Multiplying the estimated change in submissions by the time per submission by labor category, we estimate a decrease of 169,896 hours and savings of $21,725,451 as demonstrated in Table D–A18.

TABLE D-A18: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR TRADITIONAL MIPS eCQM COLLECTION TYPE FOR CY 2029 PERFORMANCE PERIOD/2031 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	(21,237)	3	(63,711)	(7,020,952)
Medical and Health Service Managers	135.54	(21,237)	2	(42,474)	(5,756,926)
Licensed Practical Nurses (LPNs)	64.48	(21,237)	1	(21,237)	(1,369,362)
Billing Clerks	49.10	(21,237)	1	(21,237)	(1,042,737)
Physicians	307.74	(21,237)	1	(21,237)	(6,535,474)
Total	N/A	(21,237)	Varies	(169,896)	(21,725,451)

(ii) MVP Registration: Individuals, Groups, Subgroups, and APM Entities

For the CY 2029 performance period/2031 MIPS payment year, we assume that the total number of individual clinicians, groups, non-Shared Savings Program APM Entities, and subgroups that will complete the MVP registration process is 56,946.

We estimate that the proposed transition to MVPs would result in an increase of 45,541 MVP registrations. Using the currently approved estimate of 0.25/hr per registration, we estimate an annual burden change of +11,385 hours (+45,541 registrations × 0.25 hr/registration) at a cost of +$1,254,627 (+11,385 hr × $110.20/hr for a computer system analyst or equivalent).

(iii) MVP Quality Performance Category Submission

We estimate an increase to the number of annual MVP quality performance category submissions per collection type from our currently approved burden estimates, for the CY 2029 performance period/2031 MIPS payment year due to the proposal to require selection of an MVP for quality performance category submission. These estimates include the figures detailed in section V.B.7.c.(1)(a) of this proposed rule plus our currently approved estimate of 20 subgroup submissions (split evenly across the eCQM and MIPS CQM/QCDR measure collection types). These estimates aggregate individual clinician, group, subgroup, and non-Shared Savings Program APM Entity submissions. All estimates encompass time to review measure specifications unless otherwise noted. Related to this proposal, we are proposing to include virtual groups in MVP reporting beginning in the CY 2029 performance period/2031 MIPS payment year. Because virtual groups are included as groups in the burden estimates there is no additional burden change beyond what is already calculated.

(A) Medicare Part B Claims Measure Collection Type

We estimate an increase of 6,797 submissions due to the proposed transition to MVPs in this proposed rule. Multiplying the estimated change in submissions (+6,797) by the time per submission by labor category, we estimate a total change of +64,164 hours at a cost of +$7,822,315 as demonstrated in Table D–A19.

TABLE D-A19: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR MVP MEDICARE PART B CLAIMS MEASURE COLLECTION TYPE FOR CY 2029 PERFORMANCE PERIOD/2031 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	6,797	5.46	37,112	4,089,742
Medical and Health Service Managers	135.54	6,797	2	13,594	1,842,531
Licensed Practical Nurses (LPNs)	64.48	6,797	0.66	4,486	289,257
Billing Clerks	49.10	6,797	0.66	4,486	220,263
Physicians	307.74	6,797	0.66	4,486	1,380,522
Total	N/A	6,797	Varies	64,164	7,822,315

(B) MIPS CQM and QCDR Measure Collection Type

We estimate an increase of +17,507 submissions due to the proposed transition to MVPs in this proposed rule. Multiplying the estimated change in submissions (+17,507) by the time per submission by labor category, we estimate a total increase of 104,518 hours at a cost of $13,156,170 as demonstrated in Table D–A20.

TABLE D-A20: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR MVP CQM AND QCDR MEASURE COLLECTION TYPES FOR CY 2029 PERFORMANCE PERIOD/2031 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	17,507	2.66	46,569	5,131,904
Medical and Health Service Managers	135.54	17,507	1.33	23,284	3,155,913
Licensed Practical Nurses (LPNs)	64.48	17,507	0.66	11,555	745,066
Billing Clerks	49.10	17,507	0.66	11,555	567,351
Physicians	307.74	17,507	0.66	11,555	3,555,936
Total	N/A	17,507	Varies	104,518	13,156,170

(C) eCQM Collection Type

We estimate an increase of +21,237 submissions due to the proposed transition to MVPs in this proposed rule. Multiplying the estimated change in submissions (+21,237) by the time per submission by labor category, we estimate a total change of +112,555 hours at a cost of +$14,390,821 as demonstrated in Table D–A21.

TABLE D-A21: ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR MVP eCQM COLLECTION TYPE FOR CY 2029 PERFORMANCE PERIOD/2031 MIPS PAYMENT YEAR

Occupation	Wage ($/hr)	Respondents	Time per Submission (hr)	Total Time (hr)	Total Cost ($)
Computer System Analyst	110.20	21,237	1.99	42,262	4,657,272
Medical and Health Service Managers	135.54	21,237	1.33	28,245	3,828,327
Licensed Practical Nurses (LPNs)	64.48	21,237	0.66	14,016	903,752
Billing Clerks	49.10	21,237	0.66	14,016	688,186
Physicians	307.74	21,237	0.66	14,016	4,313,284
Total	N/A	21,237	Varies	112,555	14,390,821

(iv) Summary of Quality Performance Category Estimated Information Collection Burden Change for CY 2029 Performance Period/2031 MIPS Payment Year

Across the quality performance category collection types (Medicare Part B claims, CQM/QCDR, eCQMs) for Traditional MIPS and MVPs, we estimate that policy proposals will not change number of total respondents but will lead to a decrease in burden of 132,807 hours and a savings of $16,870,077 under OMB control number 0938–1314 (Table D–A22).

TABLE D-A22: SUMMARY OF QUALITY PERFORMANCE CATEGORY ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR CY 2029 PERFORMANCE PERIOD/2031 MIPS PAYMENT YEAR

Requirement	Change in Number of Respondents	Change in Time	Change in Cost ($)
Traditional MIPS Quality Submission	(45,541)	(425,429)	(53,494,010)
MVP Registration	45,541	11,385	1,254,627
MVP Quality Submission	45,541	281,237	35,369,306
Total	**0**	**(132,807)**	**(16,870,077)**

* Respondents moving from Traditional MIPS to MVPs need to complete MVP registration plus MVP Quality Submission, therefore the net number of new respondents will be 0.

d. ICRs Regarding Reporting the MIPS Promoting Interoperability Performance Category

We refer readers to § 414.1375 for our previously established policies regarding reporting requirements for the MIPS Promoting Interoperability performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1325 for data submission requirements, and §§ 414.1380(b)(4) and 414.1365(d)(3)(iv) for MIPS Promoting Interoperability performance category scoring. For historic assumptions on reporting requirements for the MIPS Promoting Interoperability performance category, we refer readers to the CY 2024 PFS final rule (88 FR 79449 through 79451).

In the CY 2026 PFS final rule (90 FR 49952), our burden estimates represent an assumed number of 20,881 respondents, which is based on submission data from the CY 2023 performance period/2025 MIPS payment year. In this proposed rule, we updated our burden estimates to represent an assumed number of respondents to 19,325, which is based on submission data from the CY 2024 performance period/2026 MIPS payment year.

In the following paragraphs, we outline the proposed changes to the MIPS Promoting Interoperability performance category reporting requirements discussed in section IV.A.4.d.(4) of this proposed rule. For the first three policy proposals, there are similar proposed policies for the Medicare Promoting Interoperability Program in the FY 2027 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment Systems (IPPS/LTCH PPS) proposed rule (91 FR 19620 through 19629). Our burden assumptions for the MIPS Promoting Interoperability performance category proposals in this proposed rule are consistent with the burden assumptions for the Medicare Promoting Interoperability Program as described in the FY 2027 IPPS/LTCH PPS proposed rule (91 FR 19760 through 19763). For the fourth policy proposal, we propose to change the burden for the MIPS Promoting Interoperability performance category due to the proposed addition of a new required measure. Lastly, we discuss the historical approach for estimating burden for this performance category and propose a reduction in the burden estimate for the proposal to remove the Security Risk Analysis measure.

First, beginning with the CY 2027 performance period/2029 MIPS payment year, we are proposing modifications to the MIPS Promoting Interoperability performance category Certified Electronic Health Record Technology (CEHRT) definition at 42 CFR 414.1305 to align with proposals to remove certain certification criteria from the Office of the National Coordinator for Health IT (ONC Health IT) Certification Program as detailed in Table C–G1 and as outlined in the Assistant Secretary for Technology Policy (ASTP)/ONC (Health Data, Technology, and Interoperability) HTI–5 proposed rule. As these proposed changes will not impact reporting burden for the MIPS Promoting Interoperability performance category, we are not proposing to modify our burden estimate for this proposal.

Second, beginning with the CY 2026 performance period/2028 MIPS payment year, we are proposing to remove the required ONC Direct Review attestation and the optional ONC-Authorized Certified Bodies (ACB) Surveillance attestation from the MIPS Promoting Interoperability performance category to reduce administrative burden. CY 2024 submission data show that 79 percent of MIPS eligible clinicians elect to report this optional ONC–ACB Surveillance attestation. If the proposal to remove the required ONC Direct Review attestation is finalized, we estimate that the removal would decrease burden by 1 minute (0.0167 hr). Therefore, we estimate that removing this attestation would result in an annual decrease in total cost of $35,595 for all responses (−0.0167 hr per response × 19,325 responses)[391] × $110.20/hr for a computer systems analyst to submit Promoting Interoperability data. Similarly, should the proposal to remove the optional ONC–ACB Surveillance attestation be finalized, we estimate that eligible clinicians who elect to submit the optional ONC–ACB Surveillance attestation would experience a decrease in burden of 1 minute (0.0167 hr) which is consistent with the CY 2027 IPPS/LTCH PPS proposed rule (91 FR 19761). Therefore, we estimate that removing this attestation would result in an annual decrease in total cost of $35,595 for all responses (−0.0167 hr per

[391] This figure is rounded to whole number.

response × 19,325 responses) [392] × $110.20/hr for a computer systems analyst to submit Promoting Interoperability data.

Third, we are proposing to modify the Electronic Prior Authorization measure to an optional (bonus) measure for the CY 2027 performance period/2029 MIPS payment year and a required measure starting with the CY 2028 performance period/2030 MIPS payment year. This measure was established in the CMS Interoperability and Prior Authorization final rule (89 FR 8758) and was referenced in the CY 2026 PFS final rule (90 FR 49952). Initially, the implementation of this measure as a requirement of the MIPS Promoting Interoperability performance category was specified starting with the CY 2027 performance period/2029 MIPS payment year. In this proposed rule, we are updating the burden estimates for such measure to reflect the proposal to require the reporting of such measure starting with CY 2028 performance period/2030 MIPS payment year. The proposal to require the use of specific Fast Healthcare Interoperability Resources (FHIR)-enabled ONC-certified health IT modules within CEHRT to complete at least one prior authorization request and determination for at least one medical item or service (excluding prescription drugs) would not impact reporting burden. Under OMB control number 0938–1278 (CMS–10552) the currently approved burden estimate for this measure is 0.5 minutes (0.0083 hours) per eligible MIPS eligible clinicians. Because we are unable to estimate the number of MIPS eligible clinicians who may attest to this as a bonus measure in CY 2027, we are not proposing to modify our burden estimates for CY 2027. If the proposal to require the Electronic Prior Authorization measure starting with CY 2028 performance period/2030 MIPS payment year is finalized, we estimate that the requirement to attest ''Yes''/''No'' to this measure would increase burden by 0.5 minutes (0.0083 hours). Therefore, we estimate the proposal to modify this measure would result in an annual increase in total cost of $17,632 for all responses (+0.0083 hours per response × 19,325 responses) [393] × $110.20/hr for a computer systems analyst to submit Promoting Interoperability data.

Fourth, we are proposing to require a new measure, Electronic Prior Authorization for Prescription Drugs, which would require the use of specific FHIR-enabled health IT modules within CEHRT to complete at least one prior authorization request and determination for prescription drugs and medications starting with the CY 2028 performance period/2030 MIPS payment year. If the proposal is finalized to require the reporting of the Electronic Prior Authorization for Prescription Drugs measure starting with the CY 2028 performance period/2030 MIPS payment year, we estimate that the requirement to attest ''Yes''/''No'' to this measure would increase burden by 0.5 minutes (0.0083 hours). Therefore, we estimate the proposal to add this measure would result in an annual increase in total cost of $17,632 for all responses (+0.0083 hr per response × 19,325 responses) [394] × $110.20/hr for a computer systems analyst to submit Promoting Interoperability data.

Lastly, starting with the CY 2027 performance period/2029 MIPS payment year, we are proposing to remove the Security Risk Analysis measure from the MIPS Promoting Interoperability performance category to reduce burden. While the Security Risk Analysis measure has been required and included in the aggregate estimate for reporting burden for the MIPS Promoting Interoperability performance category (renamed from the Advancing Care Information performance category in the CY 2019 PFS final rule (83 FR 59719)) since the inception of MIPS under the Quality Payment Program as described in the CY 2017 Quality Payment Program final rule (81 FR 77014), we do not have a historic burden estimate attributed to this measure alone.

With the 2015 Medicare EHR Incentive Program final rule serving as the basis for developing the requirements and structure for the Advancing Care Information performance category under MIPS (81 FR 28215 through 28230), we reviewed how burden was historically estimated. We found that the 2015 Medicare EHR Incentive Program estimated burden by objective as follows: 10 minutes to attest to objectives with measures requiring a numerator and denominator to be generated, 1 minute to attest to objectives with measures with ''Yes''/''No'' attestations, and 6 hours to attest the Security Risk Analysis measure (80 FR 62918). The Security Risk Analysis measure requires providers to attest that they are protecting electronic health information which involves conducting or reviewing a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (to include encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process.

In developing the Advancing Care Information performance category under MIPS in the CY 2017 Quality Payment Program final rule, we streamlined the submission requirements that were outlined in the 2015 Medicare EHR Incentive Program final rule and removed two objectives and their associated measures, thereby reducing burden from nearly seven hours in the Medicare EHR Incentive Program final rule to three hours for the MIPS Advancing Care Information performance category (81 FR 77510). In the CY 2026 PFS final rule (90 FR 49952), our finalized burden estimate for the reporting requirements to submit Promoting Interoperability data is 2.7 hours (162 minutes). Applying the same burden assumptions used in the 2015 Medicare EHR Incentive Program final rule of 10 minutes of burden per objectives with measures requiring the generation of a numerator/denominator and 0.5 to 1 minute of time for measures requiring ''Yes''/''No'' attestations to our currently approved requirements for reporting Promoting Interoperability data establishes a burden estimate of 36 minutes, we deduce that the remainder of time (126 minutes) can be attributed to the Security Risk Analysis measure. If the proposal to remove the required Security Risk Analysis measure is finalized, we estimate that the removal would decrease burden by 2.1 hours (126 minutes). Therefore, we estimate the proposal to remove this measure would result in an annual decrease in total cost of $4,472,247 for all responses (−2.1 hr per response × 19,325 responses) [395] × $110.20/hr for a computer systems analyst to submit Promoting Interoperability data beginning with the CY 2027 performance year/2029 MIPS payment year.

Tables D–A23 and D–A24 detail the estimated change in burden for each proposed measure/attestation change by performance year (CY 2027 performance year/2029 MIPS payment year and for the CY 2028 performance year/2030 MIPS payment year respectively) should the proposed policy changes be finalized. Each table includes an estimated total change in annual burden for submitting MIPS Promoting

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Interoperability performance category data.

TABLE D-A23: CHANGE IN ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR

Measure/Attestation	No. of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)*	Labor Cost ($/hr)	Total Cost ($)*
Removal of ONC Direct Review Attestation +	19,325	19,325	(0.0167)	(323)	110.20	(35,595)
Removal of ONC-ACB Surveillance Attestation+	19,325	19,325	(0.0167)	(323)	110.20	(35,595)
Removal of Security Risk Analysis Measure	19,325	19,325	(2.1)	(40,583)	110.20	(4,472,247)
Total	19,325	19,325	(2.13)	(41,228)	110.20	(4,543,326)

*Total Annual Time estimates in the table are rounded to the hour and Total Cost estimates are rounded to the dollar, therefore the Total row may deviate from the sum of all rows.

+The proposals to remove the ONC attestations begin with the CY 2026 performance period/2028 MIPS payment year and will be updated under OMB control number 0938-1314.

If all policy proposals, as identified in Table D–A23 of this proposal rule, are finalized for the CY 2027 performance year/2029 MIPS payment year, we estimate a total reduction of 2.13 hours per response (0.0167 + 0.0167 + 2.1), resulting in an annual decrease in total hours of 41,228 (2.13 hr per response × 19,325 responses) [396] and total savings of $4,543,326 for all responses (−2.13 hr per response × 19,325 responses) [397] × $110.20/hr for a computer systems analyst to submit Promoting Interoperability data.

TABLE D-A24: CHANGE IN ESTIMATED BURDEN FOR PROMOTING INTEROPERABILITY PERFORMANCE CATEGORY DATA SUBMISSION FOR CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR

Measure/Attestation	No. of Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)*	Labor Cost ($/hr)	Total Cost ($)*
Add Electronic Prior Auth Measure	19,325	19,325	.0083	+161	110.20	+$17,632
Add Electronic Prior Auth for Prescription Drugs Measure	19,325	19,325	.0083	+161	110.20	+$17,632
Total	19,325	19,325	.0167	+323	110.20	+$35,595

*Total Annual Time estimates in the table are rounded to the hour and Total Cost estimates are rounded to the dollar, therefore the Total row may deviate from the sum of all rows.

If the two policy proposals, as identified in Table D–A24 of this proposed rule, are finalized starting with the CY 2028 performance year/2030 MIPS payment year, we estimate a total increase in 0.0167 hours per response (0.00833 + 0.00833), resulting in an annual increase in total hours of 323 (0.0167 hr × 19,325 responses) [398] and a cost of $35,595 for all responses (+0.0167 hr per response × 19,325 responses) [399] × $110.20/hr for a computer systems analyst to submit Promoting Interoperability data. The proposed changes relevant to the submission of Promoting Interoperability data requirements and burden will be submitted to OMB for review under control number 0938–1314 (CMS–10621).

e. ICRs Regarding Reporting for the Improvement Activities Performance Category

We refer readers to §§ 414.1355 and 414.1365(c)(3) for our previously established policies regarding reporting for the improvement activities performance category. We also refer readers to § 414.1305 for the definition of attestation, § 414.1360 for data submission requirements, and §§ 414.1380(b)(3) and 414.1365(d)(3)(iii) for improvement activities performance category scoring. For historic assumptions on reporting requirements for the improvement activities performance category, we refer readers to the CY 2024 PFS final rule (88 FR 79454 and 79455).

In section IV.A.4.d.(3) of this proposed rule, we are proposing changes to the Improvement Activities Inventory for the CY 2027 performance period/2029 MIPS payment year and subsequent years. Consistent with our assumptions in the CY 2023 PFS final rule (87 FR 70211), the CY 2024 PFS final rule (88 FR 79519), the CY 2025 PFS final rule (89 FR 98492), the CY 2026 PFS final rule (90 FR 49953), we

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believe clinicians performing improvement activities will continue to perform the same activities because previously finalized improvement activities continue to apply for the current and future years unless otherwise modified via rulemaking (82 FR 54175). We refer readers to section VII.F.11.e.(2)(a) of this proposed rule for additional discussion.

Independent of these proposals, we are updating the number of submissions due to the availability of updated submission data from the CY 2024 performance period/2026 MIPS payment year. While not scored in this rule, the non-policy changes will be submitted to OMB under control number 0938–1314 (CMS–10621).

f. ICRs Regarding the Cost Performance Category

The cost performance category relies on administrative claims data. The Medicare Parts A and B claims submission process (OMB control number 0938–1197; CMS–1500 and CMS–1490S) is used to collect data on cost measures from MIPS eligible clinicians. MIPS eligible clinicians are not required to provide any documentation by Compact Disc or hardcopy. The proposal to update the Operational List of care episode and patient condition groups and codes beginning with the CY 2027 performance period/2029 MIPS payment year, detailed in section IV.A.4.d.(2) of this proposed rule, would not result in the need to add, revise, or delete any claims data fields. Consequently, we are not proposing changes under the aforementioned OMB control number.

g. ICRs Regarding Voluntary Participants Election To Opt Out of Performance Data Display on Compare Tools

As described in section IV.E.2. of this proposed rule, we are proposing to amend § 414.1395(c)(2) to remove the 1-year delay for publicly reporting new improvement activities and Promoting Interoperability measures, objectives, or activities included in a Merit-based Incentive Payment System Value Pathway (MVP), provided the data meet the public reporting standards at § 414.1395(b).

We are not updating our burden estimates under OMB control number 0938–1314 (CMS–10621) as this proposal affects the timing of public reporting for measures and activities included in MVPs but does not modify the existing process by which voluntary participants may elect to opt-out of having their performance data publicly displayed on Care Compare tools, as established under § 414.1395.

h. ICRs Regarding the Virtual Group Election

As described in section IV.A.3.d. of this proposed rule, we are proposing to include Virtual Groups in MVP reporting starting with the CY 2029 performance year/2031 MIPS payment year as the option for Traditional MIPS reporting would no longer be available. We are not updating our burden estimates under OMB control number 0938–1314 (CMS–10621) as the operational details of this proposal have not yet been developed. We will seek OMB approval for changes in burden due to this policy, once implementation details are sufficiently developed.

C. Summary of Proposed Annual Burden Estimates

Tables D–A25 through D–A27 sets out the burden for this rulemaking's proposals that are subject to the PRA. It does not score burden adjustments that are strictly based on updated data and are unrelated to any of this rule's proposals. Table D–A27 sets out the burden for this rulemaking's proposed provisions that are subject to the PRA. It does not score burden adjustments that are strictly based on updated data and are unrelated to any of the provisions.

TABLE D-A25: PROPOSED ANNUAL REQUIREMENTS AND BURDEN ESTIMATES (CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR)

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.802 and 414.804	0938-1921 (CMS-10110)						
§§ 414.802 and 414.804	0938-1921 (CMS-10110)						
§§ 414.1325, 414.1335, 414.1365, and 414.1375 Quality Payment Program (CY 2027 performance period/2029 MIPS payment year)	0938-1314 (CMS-10621)	3,416	3,416	Varies	(51,188)	Varies	(5,808,502)
TOTAL	n/a						

TABLE D-A26: PROPOSED ANNUAL REQUIREMENTS AND BURDEN ESTIMATES (CY 2028 PERFORMANCE PERIOD/2030 MIPS PAYMENT YEAR)

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.1325, 414.1335, 414.1365, and 414.1375 Quality Payment Program (CY 2028 performance period/2030 MIPS payment year)	0938-1314 (CMS-10621)	0	0	Varies	323	Varies	35,595
TOTAL	n/a						

TABLE D-A27: PROPOSED ANNUAL REQUIREMENTS AND BURDEN ESTIMATES (CY 2029 PERFORMANCE PERIOD/2031 MIPS PAYMENT YEAR)

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
§§ 414.1325, 414.1335, 414.1365, and 414.1375 Quality Payment Program (CY 2029 performance period/2031 MIPS payment year)	0938-1314 (CMS-10621)	45,541	45,541	Varies	(132,807)	Varies	(16,870,077)
TOTAL	n/a						

TABLE D-A28: ANNUAL REQUIREMENTS AND BURDEN ESTIMATES

Section(s) Under Title 42 of the CFR	OMB Control Number (CMS ID No.)	No. Respondents	Total Annual Responses	Time per Response (hours)	Total Annual Time (hours)	Labor Cost ($/hr)	Total Cost ($)
Limiting Medicare Coverage of Certain Individuals	0938-1426 (CMS 10797)	32,000	3,200	0.25	800	$24.05	19,240
§§ 427.402(c)(4) and (5), 428.302(c)(4) and (5), and 428.303(c)(4) and (5) (Regarding Rebate Reduction Requests Submitted Under Sections 11101 and 11102 of the Inflation Reduction Act)	0938-1474 (CMS-10858)	20	20	31	620	Varies	76,801.60
Regarding the Medicare Prescription Drug Inflation Rebate Program under Sections 11101 and 11102 of the Inflation Reduction Act	0938-TBD (CMS-10930)	14,000 340B Providers or TPAs	70,000 [(14,000 x 4 submissions per year) + 14,000 registrations]	Varies	462,000	Varies	52,366,440
TOTAL		46,020	59,220	39.25	449,420	Varies	50,054,762

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection requirements. The requirements are not effective until they have been approved by OMB.

To obtain copies of the supporting statement and any related forms for the proposed collections discussed previously, please visit the CMS website at *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing* or call the Reports Clearance Office at 410–786–1326.

We invite public comments on these information collection, that is reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **DATES** and **ADDRESSES** sections of this proposed rule and identify the rule (CMS–1848–P), the ICR's CFR citation, and OMB control number.

VI. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VII. Regulatory Impact Analysis

A. Statement of Need

In this proposed rule, we are proposing payment and policy changes under the Medicare PFS. Our proposed policies in this rulemaking specifically address: changes to the PFS and other changes to Medicare Part B payment policies to ensure that payment systems are updated to reflect changes in medical practice, the relative value of services, and changes in the statute; modifications to the Medicare Shared Savings Program (Shared Savings Program); updates to the Quality Payment Program (MIPS and Advanced APMs); changes to payment policies for drugs and biological products paid under Medicare Part B; changes to the Clinical Laboratory Fee Schedule requirements; other changes to Medicare Part B payment policies for Rural Health Clinics and Federally Qualified Health Centers; and changes to the regulations associated with the Ambulance Fee Schedule. The policies reflect CMS' stewardship of the Medicare program and overarching policy objectives for ensuring equitable beneficiary access to appropriate and quality medical care.

1. Statutory Provisions

a. Clinical Laboratory Fee Schedule (CLFS)—Proposed Revisions Consistent With Recent Statutory Changes

In section III.C. of this proposed rule, we propose the conforming regulations text changes for CLFS data reporting requirements due to the enactment of section 6226 of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75, February 3, 2026). Specifically, section 6226 of the CAA, 2026 revised the next required data reporting period for CDLTs that are not ADLTs to be May 1, 2026 through July 31, 2026, and specified that the applicable data collection period is January 1, 2025 through June 30, 2025. Additionally, section 6226 of the CAA, 2026 amended section 1834A(b)(3) of the Act to specify that the applicable percent was 0 percent for all of CY 2026, meaning that the payment amount determined for a CDLT for CY 2026 shall not result in any reduction in payment as compared to the payment amount for that test for CY 2025, and to extend the statutory phase-in of payment reductions resulting from private payor rate implementation by an additional year, that is, through CY 2029. Therefore, the applicable percent of up to 15 percent would apply for CYs 2027 through 2029.

2. Discretionary Provisions

a. Medicare Shared Savings Program

In section III.G. of this proposed rule, we are proposing modifications to the Shared Savings Program regulations that would accelerate accountable care service delivery, further CMS towards its goal of aligning spending and value in Original Medicare, and support achieving other related strategic objectives. The proposed changes to the Shared Savings Program include the following.

We are proposing changes to Shared Savings Program policies for determining beneficiary assignment, applicable for the performance year starting on January 1, 2028, and subsequent performance years, to exclude from assignment calculations allowed charges for primary care services billed through a non-ACO TIN by an ACO professional used in assignment and modify assignment eligibility criteria and prospective assignment exclusion criteria based on Medicare enrollment status. We are also proposing to revise the definition of primary care services for the performance year starting on January 1, 2027, and subsequent performance years, to align with payment policy proposals and include, among other services for purposes of beneficiary assignment, services for Screening, Brief Intervention, and Referral to Treatment, Vaccine Adverse Effects Management, and Advance Care Planning.

We are proposing to revise the quality performance standard and other quality reporting requirements, by extending the availability of the MIPS CQM collection type and the MIPS CQM reporting incentive for Shared Savings Program ACOs, extending the scoring of Shared Savings Program ACOs reporting Medicare CQMs using flat benchmarks, addressing ACOs' challenges with meeting the MIPS data completeness requirement, revising the Shared Savings Program scoring policy for excluded APP Plus measures and APP Plus measures that lack a benchmark, and updating the APP Plus quality measure set. We are also proposing to simplify the Shared Savings Program CEHRT use requirements by sunsetting existing Shared Savings Program CEHRT use and public reporting requirements, providing new options for ACOs to meet the Shared Savings Program CEHRT use requirement, and requiring that they publicly report their selected option. We are also seeking comment on applying electronic prior authorization measures to ACOs participating in the Shared Savings Program in future years.

We are proposing changes to the Shared Savings Program's benchmarking and financial methodology to strengthen financial incentives for ACOs to participate in the program while mitigating selection issues and benchmark rebasing concerns. We are proposing the following changes that would be applicable to agreement periods beginning on January 1, 2027, and in subsequent years: increasing the sharing rate under Level E of the BASIC track, reducing the maximum weight on the regional adjustment for lower-spending ACOs under the ENHANCED track, modifying the prior savings adjustment to increase the scaling factor, risk adjusting the 5 percent cap on upward adjustments to the historical benchmark, and incentivizing new participation through a growth adjustment to the historical benchmark. We are also proposing to reform the ACPT component of the three-way blended benchmark update factor to improve accuracy and strengthen Shared Savings Program financial incentives.

To expand the tools available to ACOs to support beneficiary engagement, we are proposing to allow eligible Shared Savings Program ACOs that have submitted a Part B cost sharing support application and for which CMS has approved their application to reduce or eliminate Part B cost sharing for eligible beneficiaries. We are also proposing to discontinue availability of the option for prepaid shared savings.

We are proposing to modify the methodology for determining quarterly advance investment payment amounts (for eligible ACOs), by removing use of the area deprivation index and adding instead a rural criterion within an approach where we would use a flat per-beneficiary payment amount. We are also proposing revisions to the definitions of experienced and inexperienced with performance-based risk Medicare ACO initiatives used in determining an ACO's eligibility for certain participation options. Finally, we are proposing to modify Shared Savings Program beneficiary notification requirements, by revising distribution timing of standardized written notices and removing the beneficiary follow-up notice.

b. Drugs and Biological Products Paid Under Medicare Part B

In section III.A.1. of this proposed rule, as part of our continued implementation of section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) (IIJA), which amended section 1847A of

the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug (hereinafter, refundable drug), we discuss one application received for increased applicable percentage.

c. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2. of this proposed rule, we are proposing changes to the payment of Diabetes Self-Management and Training (DSMT) and Medical Nutrition Therapy (MNT) services in RHCs. We are proposing to recognize DSMT and MNT services as qualified visits that are covered and paid as stand-alone billable visits under the RHC benefit. Consequently, we are also proposing to revise § 405.2463(a) and (b)(2) to reflect that DSMT and MNT services would be stand-alone billable visits in RHCs.

In section III.B.3 of this proposed rule, we are proposing to make conforming regulatory text changes at §§ 405.2463(b)(3) and 405.2469(d) since section 6209(d) of the CAA, 2026 extended the abeyance of the RHC and FQHC mental health in-person requirements through December 31, 2027. This provision, as proposed, would require that the in-person visit requirements not apply to any services furnished through to December 31, 2027. We are also proposing technical changes to §§ 405.2464(g) and 405.2469(d).

In section III.B.4 of this proposed rule, we discuss the proposed CY 2027 FQHC PPS market basket update. Section 1834(o)(2)(B)(ii) requires the FQHC PPS base rate be updated annually by the percentage increase in a market basket of FQHC goods and services as issued through regulations, or if such an index is not available, by the percentage increase in the MEI (as defined in section 1842(i)(3) of the Act) for the year involved. For CY 2027, we are proposing to use an estimate of the 2022-based FQHC market basket to update payments to FQHCs based on the best available data. Consistent with CMS practice, we propose to use the update based on the most recent historical data available at the time of publication of the final rule.

d. Ambulatory Specialty Model (ASM)

In section III.D. of this proposed rule, we discuss proposals related to the Ambulatory Specialty Model (ASM), a mandatory alternative payment model that will be tested by the Innovation Center under the authority at section 1115A of the Act. Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and CHIP beneficiaries.

Health care is becoming more fragmented as Medicare beneficiaries are increasingly seeing a greater number of specialists on a more regular basis. We believe there are opportunities to improve coordination between specialists and primary care providers (PCPs) and increase beneficiary engagement in care decisions, particularly with respect to preventing the onset and progression of chronic disease. ASM will evaluate select specialists that furnish a requisite volume of services related to heart failure or low back pain as measured by historic episode-based cost measure (EBCM) episode volume and test whether rewarding them based on measures of quality, cost, care coordination, and Promoting Interoperability results in enhanced quality of care and reduced costs through more effective upstream chronic condition management for ASM's targeted chronic conditions. We expect that a more targeted approach where specialists are evaluated: (1) on a set of relevant performance measures they are required to report; and (2) among specialists furnishing similar sets of services for similar chronic conditions, will produce final scores and subsequent payment adjustments that are more reflective of clinician performance. A more targeted approach to measurement will also offer more insight into how clinical decisions and processes, such as care coordination, affect patient outcomes. We believe this insight is necessary to support and encourage accountable care, increasing beneficiary access to coordinated specialty care.

We believe that ASM's meaningful comparisons of performance to similar specialists furnishing a substantial volume of services related to ASM's targeted chronic conditions when matched with a payment methodology that creates impactful Medicare Part B payment adjustments will encourage quality improvements in specialty care and meaningful engagement with PCPs to both prevent and manage the onset of chronic conditions, all while achieving net savings to Medicare.

We finalized ASM through notice and comment rulemaking in CY 2026 PFS final rule (90 FR 49562 through 49720). The proposals within this proposed rule address policy gaps and make technical or conforming updates to ensure ASM has sound and well-developed technical, administrative, and operational policies.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866, Regulatory Planning and Review, Executive Order 13563, ''Improving Regulation and Regulatory Review;'' Executive Order 14192, ''Unleashing Prosperity Through Deregulation;'' the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4); and Executive Order 13132, Federalism.

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits.

A regulatory impact analysis (RIA) must be prepared for regulatory actions that are significant under section 3(f)(1) of Executive Order 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1)). Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners, and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business

Administration standards. (For details, see the SBA's website at *https://www.sba.gov/document/support-table-size-standards* (refer to the 620000 series).) Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other suppliers, and

providers are considered to be small entities, based upon the SBA standards. There are over 1 million physicians, other practitioners, and medical suppliers that receive Medicare payment under the PFS. Because many of the affected entities are small entities, the analysis and discussion provided in this section, as well as elsewhere in this proposed rule is intended to comply with the RFA requirements regarding significant impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. Medicare does not pay rural hospitals for their services under the PFS; rather, Medicare payment is made under the PFS for physicians' services, which can be furnished by physicians and NPPs in a variety of settings, including rural hospitals. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this rulemaking will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2026, that threshold is approximately $193 million. This rule will impose no mandates on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. Since this rulemaking does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

We prepared the following analysis, which, together with the information provided in the rest of this rule, meets all assessment requirements. The analysis explains the rationale for and purposes of this rule; details the costs and benefits of this rulemaking; analyzes alternatives; and presents the measures we will use to minimize the burden on small entities. As indicated elsewhere in this rule, we discussed various changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services and to implement provisions of the statute. We provide information for each policy change in the relevant sections of this proposed rule. We are unaware of any relevant Federal rules that duplicate, overlap, or conflict with this rule. The relevant sections of this rulemaking describe significant alternatives we considered, if applicable.

C. Executive Order 14192, ''Unleashing Prosperity Through Deregulation''

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations.''

D. Effects of the Proposed Changes in Relative Value Units (RVUs)

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of Medicare Part B expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare expenditures for PFS services compare payment rates for CY 2026 with payment rates for CY 2027 using CY 2025 Medicare utilization. The payment impacts described in this rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual practitioner could vary from the average and will depend on the mix of services they furnish. The average percentage change in total revenues will be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical diagnostic laboratory tests that are paid under the Clinical Laboratory Fee Schedule (CLFS).

As required by section 1848(d)(1)(A) of the Act, beginning in CY 2026, there are two separate conversion factors (CFs): one for items and services furnished by a qualifying APM participant as defined in section 1833(z)(2) of the Act (referred to as the qualifying APM conversion factor) and another for other items and services (referred to as the nonqualifying APM conversion factor), equal to the respective conversion factor for the previous year multiplied by the update established under section 1848(d)(20) of the Act for such respective conversion factor for such year. As specified by section 1848(d)(20) of the Act, the update to the qualifying APM conversion factor for CY 2027 is 0.75 percent while the update to the nonqualifying APM conversion factor for CY 2027 is 0.25 percent.

To calculate the estimated CY 2027 PFS conversion factors, we took the CY 2026 conversion factors without the payment increase of 2.50 percent provided by statute that applied to services furnished from January 1, 2026 through December 31, 2026 and multiplied them by the budget neutrality adjustment required as described in the preceding paragraphs, then multiplied by the qualifying APM and nonqualifying APM updates specified by section 1848(d)(20) of the Act. We estimate the CY 2027 PFS qualifying APM CF to be 33.1693 which reflects a 0.53 percent positive budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.75 percent update adjustment factor specified under section 1848(d)(20) of the Act. We estimate the CY 2027 PFS nonqualifying APM CF to be 32.8409 which reflects a 0.53 percent positive budget neutrality adjustment required under section 1848(c)(2)(B)(ii)(II) of the Act and the 0.25 percent update adjustment factor specified under section 1848(d)(20) of the Act. We estimate the CY 2027 anesthesia qualifying APM CF to be 20.4165 and the CY 2027 anesthesia nonqualifying APM CF to be 20.2143, reflecting the same overall PFS adjustments with the addition of anesthesia-specific PE and MP adjustments.

TABLE D-B1: CALCULATION OF THE CY 2027 PFS QUALIFYING APM CONVERSION FACTOR

CY 2026 Conversion Factor		33.5675
Conversion Factor without One Year 2.50% Increase		32.7488
CY 2027 Qualifying APM Update Factor	0.75 percent (1.0075)	
CY 2027 RVU Budget Neutrality Adjustment	0.53 percent (1.0053)	
CY 2027 Conversion Factor		**33.1693**

TABLE D-B2: CALCULATION OF THE CY 2027 PFS NON-QUALIFYING APM CONVERSION FACTOR

CY 2026 Conversion Factor		33.4009
Conversion Factor without One Year 2.50% Increase		32.5863
CY 2027 Non-Qualifying APM Update Factor	0.25 percent (1.0025)	
CY 2027 RVU Budget Neutrality Adjustment	0.53 percent (1.0053)	
CY 2027 Conversion Factor		**32.8409**

TABLE D-B3: CALCULATION OF THE CY 2027 ANESTHESIA QUALIFYING APM CONVERSION FACTOR

CY 2026 National Average Anesthesia Conversion Factor		20.5998
Conversion Factor without One Year 2.50% Increase		20.0974
CY 2027 Qualifying APM Update Factor	0.75 percent (1.0075)	
CY 2027 RVU Budget Neutrality Adjustment	0.53 percent (1.0053)	
CY 2027 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.30 percent (1.0030)	
CY 2027 Conversion Factor		**20.4165**

TABLE D-B4: CALCULATION OF THE CY 2027 ANESTHESIA NON-QUALIFYING APM CONVERSION FACTOR

CY 2026 National Average Anesthesia Conversion Factor		20.4976
Conversion Factor without One Year 2.50% Increase		19.9976
CY 2027 Non-Qualifying APM Update Factor	0.25 percent (1.0025)	
CY 2027 RVU Budget Neutrality Adjustment	0.53 percent (1.0053)	
CY 2027 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment	0.30 percent (1.0030)	
CY 2027 Conversion Factor		**20.2143**

Table D–B5 shows the impact on PFS payment for physicians' services based on the proposed policies included in this rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table D–B5 (CY 2027 PFS Estimated Impact on Total Allowed Charges by Specialty).

In recent years, we have received requests from interested parties to provide more granular information that separates the specialty-specific impacts by site of service. These interested parties have presented us with high-level information suggesting that Medicare payment policies are directly responsible for consolidating privately owned physician practices and freestanding supplier facilities into larger health systems. Their concerns highlight a need to update the information under the PFS to account for current trends in healthcare delivery, especially concerning independent versus facility-based practices. We published an RFI in the CY 2023 PFS proposed rule to gather feedback on this issue and refer readers to the discussion in the CY 2023 PFS final rule (87 FR 69429 through 69438). As part of our holistic review of how best to update our data and offer interested parties additional information that addresses some of the concerns raised, we have recently improved our current suite of public use files (PUFs) by including a new file that shows estimated specialty payment impacts at a more granular level, specifically by showing ranges of impact for practitioners within a specialty. This file is available on the CMS website under ''downloads'' for the CY 2027 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Some of the proposed policies in this rule are estimated to have differential effects depending on the site of service, therefore, we are publishing the impact tables that include a facility/non-facility breakout of payment changes, as we believed that displaying the total impact by specialty alone, without the setting of care context, could be misleading for interested parties. The following is an

explanation of the information represented in Table D–B5.

- Column A (Specialty): Identifies the specialty for which data are shown.
- Column B (Setting): Identifies the facility or non-facility setting for which data are shown.
- Column C (Allowed Charges): The aggregate estimated PFS allowed charges for the specialty based on CY 2025 utilization and CY 2026 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- Column D (Impact of Work RVU Changes): This column shows the estimated CY 2027 impact on total allowed charges of the changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- Column E (Impact of PE RVU Changes): This column shows the estimated CY 2027 impact on total allowed charges of the changes in the PE RVUs.
- Column F (Impact of MP RVU Changes): This column shows the estimated CY 2027 impact on total allowed charges of the changes in the MP RVUs.
- Column G (Combined Impact): This column shows the estimated CY 2027 combined impact on total allowed charges of all the changes in the previous columns. Column G may not equal the sum of columns D, E, and F due to rounding.

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TABLE D-B5: CY 2027 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)				(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
ALLERGY/IMMUNOLOGY	*TOTAL*	$154	0%	-1%	0%				0%
	Non-Facility	$147	0%	-1%	0%				0%
	Facility	$7	1%	0%	0%				1%
ANESTHESIOLOGY	*TOTAL*	$1,656	0%	0%	0%				0%
	Non-Facility	$332	0%	-1%	0%				-1%
	Facility	$1,324	0%	0%	0%				0%
AUDIOLOGIST	*TOTAL*	$81	1%	-4%	0%				-3%
	Non-Facility	$78	1%	-4%	0%				-3%
	Facility	$3	1%	-1%	0%				0%
CARDIAC SURGERY	*TOTAL*	$146	1%	1%	0%				1%
	Non-Facility	$30	0%	2%	0%				2%
	Facility	$116	1%	0%	0%				0%
CARDIOLOGY	*TOTAL*	$6,464	0%	0%	0%				1%
	Non-Facility	$4,205	0%	1%	0%				1%
	Facility	$2,259	0%	0%	0%				0%
CHIROPRACTIC	*TOTAL*	$626	0%	2%	0%				2%
	Non-Facility	$624	0%	2%	0%				2%
	Facility	$2	0%	0%	0%				0%
CLINICAL PSYCHOLOGIST	*TOTAL*	$729	3%	8%	0%				11%
	Non-Facility	$593	3%	8%	0%				11%
	Facility	$136	3%	5%	0%				8%
CLINICAL SOCIAL WORKER	*TOTAL*	$974	4%	9%	0%				12%
	Non-Facility	$857	3%	9%	0%				13%
	Facility	$116	4%	7%	0%				11%
COLON AND RECTAL SURGERY	*TOTAL*	$147	-1%	-3%	0%				-4%
	Non-Facility	$57	-3%	-6%	0%				-9%
	Facility	$90	0%	-1%	0%				-1%
CRITICAL CARE	*TOTAL*	$348	0%	0%	0%				0%
	Non-Facility	$65	1%	0%	0%				1%
	Facility	$283	0%	-1%	0%				0%
DERMATOLOGY	*TOTAL*	$3,881	-3%	-6%	0%				-9%
	Non-Facility	$3,754	-3%	-6%	0%				-9%
	Facility	$127	-3%	-4%	0%				-7%
DIAGNOSTIC TESTING FACILITY	*TOTAL*	$999	0%	3%	0%				4%
	Non-Facility	$997	0%	3%	0%				4%
	Facility	$2	0%	1%	1%				2%
EMERGENCY MEDICINE	*TOTAL*	$2,581	0%	0%	0%				1%

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)				(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
	Non-Facility	$286	0%	0%	0%	0%			
	Facility	$2,294	0%	0%	0%	1%			
ENDOCRINOLOGY	*TOTAL*	$584	1%	1%	0%	2%			
	Non-Facility	$485	1%	1%	0%	2%			
	Facility	$99	1%	0%	0%	1%			
FAMILY PRACTICE	*TOTAL*	$5,976	1%	1%	0%	1%			
	Non-Facility	$4,927	1%	0%	0%	1%			
	Facility	$1,049	0%	2%	0%	3%			
GASTROENTEROLOGY	*TOTAL*	$1,327	0%	-1%	0%	-1%			
	Non-Facility	$538	0%	-1%	0%	-1%			
	Facility	$788	0%	-1%	0%	-1%			
GENERAL PRACTICE	*TOTAL*	$408	1%	1%	0%	2%			
	Non-Facility	$329	1%	0%	0%	1%			
	Facility	$79	1%	4%	0%	5%			
GENERAL SURGERY	*TOTAL*	$1,517	0%	0%	0%	0%			
	Non-Facility	$480	0%	1%	0%	0%			
	Facility	$1,037	0%	-1%	0%	-1%			
GERIATRICS	*TOTAL*	$203	1%	2%	0%	4%			
	Non-Facility	$131	1%	0%	0%	2%			
	Facility	$72	1%	6%	0%	7%			
HAND SURGERY	*TOTAL*	$278	-1%	-4%	0%	-5%			
	Non-Facility	$160	-2%	-4%	0%	-7%			
	Facility	$117	0%	-2%	0%	-3%			
HEMATOLOGY/ONCOLOGY	*TOTAL*	$1,571	1%	-1%	0%	0%			
	Non-Facility	$1,037	0%	0%	0%	0%			
	Facility	$534	1%	-1%	0%	1%			
INDEPENDENT LABORATORY	*TOTAL*	$380	0%	0%	0%	0%			
	Non-Facility	$371	0%	0%	0%	0%			
	Facility	$9	0%	0%	0%	0%			
INFECTIOUS DISEASE	*TOTAL*	$587	0%	0%	0%	0%			
	Non-Facility	$97	0%	-1%	0%	-1%			
	Facility	$490	0%	0%	0%	0%			
INTERNAL MEDICINE	*TOTAL*	$9,932	1%	1%	0%	1%			
	Non-Facility	$5,203	1%	0%	0%	1%			
	Facility	$4,728	0%	1%	0%	1%			
INTERVENTIONAL PAIN MGMT	*TOTAL*	$880	0%	-1%	0%	-2%			
	Non-Facility	$706	0%	-1%	0%	-2%			
	Facility	$174	0%	0%	0%	-1%			
INTERVENTIONAL RADIOLOGY	*TOTAL*	$545	0%	3%	0%	3%			
	Non-Facility	$361	0%	5%	0%	5%			

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)				(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
	Facility	$183	0%	1%	0%	1%			
MULTISPECIALTY CLINIC/OTHER PHYS	*TOTAL*	$164	-1%	-1%	0%	-2%			
	Non-Facility	$84	-2%	-2%	0%	-4%			
	Facility	$80	0%	0%	0%	0%			
NEPHROLOGY	*TOTAL*	$1,672	0%	0%	0%	0%			
	Non-Facility	$1,054	0%	0%	0%	1%			
	Facility	$619	1%	0%	0%	0%			
NEUROLOGY	*TOTAL*	$1,390	0%	-1%	0%	0%			
	Non-Facility	$923	0%	-1%	0%	-1%			
	Facility	$467	1%	-1%	0%	0%			
NEUROSURGERY	*TOTAL*	$652	0%	-2%	0%	-2%			
	Non-Facility	$128	0%	-1%	0%	-1%			
	Facility	$524	0%	-2%	-1%	-2%			
NUCLEAR MEDICINE	*TOTAL*	$50	0%	2%	0%	2%			
	Non-Facility	$21	0%	2%	0%	2%			
	Facility	$29	0%	1%	0%	2%			
NURSE ANES / ANES ASST	*TOTAL*	$1,130	0%	1%	0%	1%			
	Non-Facility	$19	0%	10%	0%	10%			
	Facility	$1,111	0%	1%	0%	1%			
NURSE PRACTITIONER	*TOTAL*	$7,775	0%	1%	0%	2%			
	Non-Facility	$5,263	0%	-1%	0%	0%			
	Facility	$2,512	0%	6%	0%	6%			
OBSTETRICS/GYNECOLOGY	*TOTAL*	$558	0%	-1%	0%	-1%			
	Non-Facility	$397	0%	-1%	0%	-1%			
	Facility	$162	0%	-1%	-1%	-2%			
OPHTHALMOLOGY	*TOTAL*	$4,548	0%	-3%	0%	-3%			
	Non-Facility	$3,373	0%	-3%	0%	-3%			
	Facility	$1,175	0%	-2%	0%	-2%			
OPTOMETRY	*TOTAL*	$1,498	0%	-2%	0%	-2%			
	Non-Facility	$1,457	0%	-2%	0%	-2%			
	Facility	$41	0%	-1%	0%	0%			
ORAL/MAXILLOFACIAL SURGERY	*TOTAL*	$34	0%	-1%	0%	-1%			
	Non-Facility	$24	0%	-1%	0%	-1%			
	Facility	$10	0%	-1%	0%	-1%			
ORTHOPEDIC SURGERY	*TOTAL*	$3,296	-3%	-4%	-1%	-7%			
	Non-Facility	$1,549	-2%	-4%	0%	-5%			
	Facility	$1,747	-4%	-4%	-1%	-8%			
OTHER	*TOTAL*	$39	0%	-2%	0%	-2%			
	Non-Facility	$29	0%	-3%	0%	-2%			
	Facility	$10	-1%	-1%	0%	-2%			

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)				(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
OTOLARYNGOLOGY	*TOTAL*	$1,199	-3%	-5%	0%		-9%		
	Non-Facility	$982	-4%	-6%	0%		-10%		
	Facility	$217	-1%	-2%	0%		-3%		
PATHOLOGY	*TOTAL*	$777	0%	-1%	0%		0%		
	Non-Facility	$412	0%	-1%	0%		-1%		
	Facility	$364	0%	0%	0%		0%		
PEDIATRICS	*TOTAL*	$61	1%	0%	0%		0%		
	Non-Facility	$42	0%	0%	0%		0%		
	Facility	$19	1%	0%	0%		1%		
PHYSICAL MEDICINE	*TOTAL*	$1,203	0%	1%	0%		1%		
	Non-Facility	$592	0%	-2%	0%		-2%		
	Facility	$611	0%	3%	0%		4%		
PHYSICAL/OCCUPATIONAL THERAPY	*TOTAL*	$4,372	0%	3%	0%		3%		
	Non-Facility	$4,370	0%	3%	0%		3%		
	Facility	$1	0%	0%	0%		0%		
PHYSICIAN ASSISTANT	*TOTAL*	$3,751	-1%	-2%	0%		-3%		
	Non-Facility	$2,699	-1%	-3%	0%		-5%		
	Facility	$1,052	0%	2%	0%		1%		
PLASTIC SURGERY	*TOTAL*	$268	0%	-2%	0%		-3%		
	Non-Facility	$131	-1%	-3%	0%		-4%		
	Facility	$138	0%	-1%	0%		-1%		
PODIATRY	*TOTAL*	$1,969	-2%	-2%	0%		-4%		
	Non-Facility	$1,762	-2%	-2%	0%		-4%		
	Facility	$207	-1%	1%	0%		0%		
PORTABLE X-RAY SUPPLIER	*TOTAL*	$76	0%	-2%	0%		-1%		
	Non-Facility	$72	0%	-2%	0%		-1%		
	Facility	$4	0%	-1%	0%		-1%		
PSYCHIATRY	*TOTAL*	$882	1%	1%	0%		3%		
	Non-Facility	$565	1%	2%	0%		3%		
	Facility	$317	1%	1%	0%		2%		
PULMONARY DISEASE	*TOTAL*	$1,266	1%	0%	0%		0%		
	Non-Facility	$599	1%	0%	0%		1%		
	Facility	$667	0%	0%	0%		0%		
RADIATION ONCOLOGY AND RADIATION THERAPY CENTERS	*TOTAL*	$1,541	0%	3%	0%		3%		
	Non-Facility	$1,054	0%	4%	0%		5%		
	Facility	$486	0%	-1%	0%		-1%		
RADIOLOGY	*TOTAL*	$4,706	0%	2%	0%		2%		
	Non-Facility	$2,075	0%	2%	0%		2%		
	Facility	$2,631	0%	1%	0%		1%		
RHEUMATOLOGY	*TOTAL*	$567	0%	-1%	0%		-1%		

(A) Specialty	(B) Total: Non-Facility/Facility	(C) Allowed Charges (mil)				(D) Impact of Work RVU Changes	(E) Impact of PE RVU Changes	(F) Impact of MP RVU Changes	(G) Combined Impact
	Non-Facility	$514	0%	-1%	0%	-1%			
	Facility	$53	1%	0%	0%	1%			
THORACIC SURGERY	*TOTAL*	$299	1%	1%	0%	1%			
	Non-Facility	$62	0%	2%	0%	2%			
	Facility	$237	1%	0%	0%	0%			
UROLOGY	*TOTAL*	$1,626	-1%	-1%	0%	-2%			
	Non-Facility	$1,178	-1%	-1%	0%	-2%			
	Facility	$448	0%	0%	0%	-1%			
VASCULAR SURGERY	*TOTAL*	$1,015	0%	3%	0%	3%			
	Non-Facility	$747	0%	4%	0%	4%			
	Facility	$268	0%	0%	0%	0%			
TOTAL	***TOTAL***	$91,355	0%	0%	0%	0%			
	Non-Facility	$59,028	0%	0%	0%	0%			
	Facility	$32,327	0%	1%	0%	1%			

* Column G may not equal the sum of columns D, E, and F due to rounding.

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2. CY 2027 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty-level impacts of the RVU changes are generally related to the changes to RVUs for specific services resulting from the misvalued code initiative, including RVUs for new and revised codes. The proposals to update code valuation and improve the accuracy of the practice expense methodology would have a significant positive impact on clinical psychologists and clinical social workers, with smaller increases to physical and occupational therapists, interventional radiology, and vascular surgery. To a lesser degree, projected increases for some specialties would result from the proposed changes to HCPCS code G2211 and the fourth and final year of the behavioral health work update. Increases would also result from proposed increases in valuation for particular services after considering the recommendations from the American Medical Association's (AMA) Relative Value Scale Update Committee (RUC) and CMS review, and increased payments resulting from supply and equipment pricing updates. For independent laboratories, it is important to note that these entities receive approximately 83 percent of their Medicare revenues from services that are paid under the Clinical Lab Fee Schedule.

Specialties that would see a significant decrease include dermatology, otolaryngology, orthopedic surgery, and hand surgery, and to a smaller extent, ophthalmology, podiatry, audiologists, neurosurgery, portable x-ray suppliers, and plastic surgeons. These changes can largely be attributed to the proposed changes to modifier –25 and the proposal to remove the Indirect Practice Cost Index (IPCI) from the calculation of the PE RVUs, although the effects on PE are mitigated by the proposed PE stabilization adjustment. The estimated impacts also reflect decreased payments due to continued implementation of previously finalized code-level reductions that are being phased in over several years.

The proposal to reduce payment when a separately identifiable office/outpatient E/M visit is furnished by the same physician (or a physician in the same group practice) on the same day as a 0-, 10-, or 90-day global procedure and identified on the claim with modifier –25 would have the largest negative impact on otolaryngology, dermatology, and podiatry, and to a smaller extent, hand surgery, physicians assistant, and colon and rectal surgery. These specialties frequently report E/M services with modifier –25 in conjunction with a 0-, 10-, or 90-day global procedure. Most other specialties receive a small increase due to the redistribution of those RVUs. Our utilization estimates for this proposal are reflected in the file titled ''CY 2026 PFS Proposed Rule 2025 Utilization Data Crosswalked to 2027'' available under ''downloads'' for the CY 2027 PFS proposed rule on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The proposal to replace HCPCS code G2211 with a modifier (MOD1) that is set to 16 percent of the total RVUs for the E/M service on the claim is expected to have minimal impact given that the volume previously reported using HCPCS code G2211 would now be reported with the modifier, and that was accounted for using the weighted average of the percent increase for G2211 utilization and adjusted for budget neutrality. The proposal to pay for services furnished in an ACO using a modifier (MOD2) that pays 32 percent of the total RVUs for the E/M service on the claim is expected to increase payment for practitioners that furnish a higher percentage of their services in ACOs. Our utilization estimates for MOD1 and MOD2 are reflected in the file titled ''CY 2026 PFS Proposed Rule 2025 Utilization Data Crosswalked to 2027'' available under ''downloads'' for the CY 2027 PFS proposed rule on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

We often receive comments regarding the changes in RVUs displayed on the specialty impact table (Table D–B5), including comments received in response to the valuations. We remind interested parties that although the estimated impacts are displayed at the specialty level, typically, the changes are driven by the valuation of a relatively small number of new and potentially misvalued codes. The percentage changes in Table D–B5 are based upon aggregate estimated PFS allowed charges summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty and compared to the same summed total from the previous calendar year. Therefore, they are averages and may not necessarily represent what is happening to the particular services furnished by a single practitioner within any given specialty.

As previously discussed, we have reviewed our suite of PUFs and have worked on new ways to offer interested parties' additional information that addresses concerns about the lack of granularity in our impact tables. To illustrate how impacts can vary within specialties, we created a PUF that models the expected percentage change in total RVUs per practitioner. We also note the code level RVU changes are available in the Addendum B PUF available on the CMS website under ''downloads'' for the CY 2027 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The specialty impacts displayed in Table D–B5 reflect changes within the pool of total RVUs. The specialty impacts table, therefore, includes any changes in spending that result from proposed policies that are subject to the statutory budget neutrality requirement at section 1848(c)(2)(B)(ii)(II) of the Act but does not include any changes in spending which result from proposed policies that are not subject to the statutory budget neutrality adjustment, and therefore, have a neutral impact across all specialties. The 0.75 percent and 0.25 percent updates to the CY 2027 and nonqualifying APM conversion factors, respectively, are statutory changes that take place outside of BN, and therefore, are not captured in the specialty impacts displayed in Table D–B5.

b. Impact

Column G of Table D–B5 displays the estimated CY 2025 impact on total allowed charges, by specialty, of all the RVU changes. A table showing the estimated impact of all of the changes on total payments for selected high-volume procedures is available under ''downloads'' on the CY 2027 PFS proposed rule website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. We selected these procedures for the sake of illustration from among the procedures most commonly furnished by a broad spectrum of specialties. The change in both facility rates and non-facility rates are shown. For an explanation of facility and non-facility PE, we refer readers to Addendum A on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

E. Effects of the Proposed Changes Related to Telehealth Services

We are proposing the addition of several codes to the Medicare Telehealth Services List, including HCPCS codes GAPC1, GAPC2, GSMAS, GSLPP, and GADV1. We are proposing to revise the code descriptors for CPT codes G0508 and G0509. We are proposing to allow teaching physicians to bill for services involving residents when either the teaching physician or resident is in the same physical location as the beneficiary. These services, in addition to other Medicare Telehealth Services, are expected to substitute for in-person visits and as such would not have increase overall utilization of these services.

Section 6209(a) and (b) of the Consolidated Appropriations Act, 2026 (CAA, 2026) (Pub. L. 119–75, February 3, 2026) extends the flexibilities for Medicare telehealth services to remove the geographic restrictions, expand the list of acceptable originating sites, and expand the array of practitioners eligible to furnish telehealth services from January 30, 2026 to the extended date of December 31, 2027. Section 6209(d) of the CAA, 2026 delays the in-person visit requirements for mental health services furnished through telehealth from January 30, 2026 to the extended date of January 1, 2028. Section 6209(e) of the CAA, 2026 extends the flexibilities to allow audio-only Medicare telehealth services from January 30, 2026 to the extended date of January 1, 2028. Additionally, section 6209(g) of the CAA, 2026, requires CMS to establish modifiers for telehealth services in certain instances, effective January 1, 2027. We anticipate that our provisions will result in continued utilization of services that can be furnished as Medicare telehealth services during CY 2027 at levels comparable to observed utilization of these services during CY 2026.

F. Other Provisions of the Proposed Rule

1. Impacts Related to Technical Corrections of Comprehensive Outpatient Rehabilitation Facility (CORF) Services Regulations

As discussed in section II.F. of this proposed rule, we are proposing to amend the regulatory text at §§ 410.105 and 414.1105 for accuracy that we overlooked during CY 2008 PFS rulemaking when we amended § 410.100. As such, there are no impacts for the policies in section II.F. of this proposed rule.

2. Impacts Related to Drugs and Biological Products Paid Under Medicare Part B: Discarded Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117–58, November 15, 2021) amended section 1847A of the Act to require manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. The refund amount is either as noted in section 1847A(b)(1)(B) of the Act in the case of a single source drug or biological or as noted in section 1847A(b)(1)(C) of the Act in the case of a biosimilar biological product, multiplied by the amount of discarded drug that exceeds an applicable percentage, which is required to be at least 10 percent, of total charges (subject to certain exclusions) for the drug in a given calendar quarter. In the CY 2023, 2024, and 2025 PFS final rules, we finalized several policies to implement the provision. In December of 2025, CMS sent discarded drug refund reports for CY 2023 ''updated refund quarters'' and CY 2024 ''new refund quarters,'' as defined at § 414.902. The total refunds owed for these quarters amount to over $173 million, which was deposited into the Supplementary Medical Insurance trust fund, as required by law. In section III.A.1 of this proposed rule, we discuss one application (CMS 10835, OMB 0938–1435) for increased applicable percentage which will have no impact on Medicare spending.

3. Impacts Related to Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

In section III.B.2.c. of this proposed rule, to improve access to preventive services in RHCs, we propose changes to the payment of Diabetes Self-Management and Training (DSMT) and Medical Nutrition Therapy (MNT) services in RHCs. We are proposing to

recognize DSMT and MNT services as qualified visits that are covered and paid as stand-alone billable visits under the RHC benefit. A national claims-based analyses of evaluation and management billing patterns indicated that a nominal volume of DSMT and MNT services were bundled within payments to RHCs during 2025.

Since utilization of DSMT and MNT services are generally underutilized by the Medicare population, we believe that increase to Medicare Part B expenditures due to the proposal would be negligible. As discussed in section III.B.2.c of this proposed rule, an analysis of Medicare claims data from 2024 indicate that utilization of DSMT and MNT in RHC settings is substantially lower than in comparable care settings. In CY 2024, DSMT services were furnished to approximately 125 RHC beneficiaries, representing 0.005 percent of the total RHC beneficiary population of approximately 2.3 million. MNT services were furnished to approximately 439 RHC beneficiaries, representing 0.019 percent of the total RHC beneficiary population. On a claims basis, DSMT accounted for 0.002 percent and MNT for 0.007 percent of total RHC claims in CY 2024. By comparison, FQHCs, showed DSMT utilization rates approximately 22 times higher and MNT utilization rates approximately 28 times higher than RHCs on a per-beneficiary basis. On a claim basis, FQHC utilization of DSMT and MNT exceeded RHC utilization by approximately 31 times and 32 times, respectively. Rural physician offices, which share the geographic and demographic characteristics of RHC patient populations, showed DSMT and MNT utilization rates approximately 17 times and 7 times higher than RHCs, respectively, on a per-beneficiary basis. The analysis further demonstrated that within the PFS setting where DSMT and MNT are most readily identifiable in claims data, these services represent a very small share of total Medicare spending—less than 0.01 percent and 0.02 percent of total PFS line payments, respectively, in CY 2024. We believe that while our proposal would support an increase in the furnishing DSMT and MNT at RHCs, we do not expect a significant increase for CY 2027 since RHCs would need to determine potential changes to their care delivery and staffing which may impact timing for uptake.

4. Impacts Related to the Clinical Laboratory Fee Schedule (CLFS): CAA, 2026

In section III.D. of this proposed rule, we outline statutory amendments to section 1834A of the Act that revise the data reporting period, data collection period, and requirements for the phase-in of payment reductions under the CLFS. In accordance with section 6226 of the CAA, 2026, we are proposing to make certain conforming changes to the data reporting and payment requirements at 42 CFR part 414, subpart G. Specifically, we are proposing to revise § 414.502 to update the definitions of both the ''data collection period'' and ''data reporting period,'' specifying that the data collection period is the 6-month period from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period, and that the data reporting period for CDLTs that are not ADLTs is the 3-month period, May 1 through July 31, and for ADLTs is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period.. We are also proposing to revise § 414.504(a)(1) to indicate that initially, data reporting begins January 1, 2017, and is required every 3 years beginning May 1, 2026. In addition, we are proposing to make conforming changes to our requirements for the phase-in of payment reductions to reflect the amendments in section 6226 of the CAA, 2026. Specifically, we are proposing to revise § 414.507(d) to indicate that for CY 2026, payment may not be reduced by more than 0.0 percent as compared to the amount established for CY 2025, and for CYs 2027 through 2029, payment may not be reduced by more than 15 percent as compared to the amount established for the preceding year.

We recognize that private payor rates for CDLTs paid on the CLFS and the volumes paid at each rate for each test, which are used to determine the weighted medians of private payor rates for the CLFS payment rates, have changed since the first data collection period (January 1, 2016 through June 30, 2016) and data reporting period (January 1, 2017, through March 31, 2017). In addition, as outlined in section III.C. of this proposed rule, in the CY 2019 PFS final rule (83 FR 59671 through 59676), we amended the definition of applicable laboratory to include hospital outreach laboratories that bill Medicare Part B using the CMS–1450 14x Type of Bill. As such, the CAA, 2026 amendments to the data reporting period will implement the use of updated private payor rate data to set revised CLFS payment rates for CDLTs that are not ADLTs.

Due to unforeseen changes in private payor rates due to shifts in market-based pricing for laboratory tests and the unpredictable nature of test volumes and their impact on calculating updated CLFS payment rates based on the weighted median of private payor rates, for purposes of this proposed rule, we are unable to estimate a budgetary impact. In other words, to assess the impact of implementation of updated CLFS rates, we will need to calculate weighted medians of private payor rates based on new data and compare the revised rates to the current rates. As such, we believe that we will only know the impact of the CAA, 2026 provisions after collecting actual updated applicable information from applicable laboratories and calculating the updated CLFS rates.

5. Ambulatory Specialty Model (ASM)

In section III.D. of this proposed rule, we discuss the Ambulatory Specialty Model (ASM) tested by the CMS Center for Medicare and Medicaid Innovation (hereinafter ''Innovation Center'') under the authority of section 1115A of the Act. Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. ASM will test whether adjusting payment for eligible specialists who furnish services related to ASM's targeted chronic conditions (that is, heart failure and low back pain) based on performance across targeted measures of quality, cost, care coordination, and meaningful use of certified electronic health record (EHR) technology (CEHRT) results in enhanced quality of care and reduced costs through more effective upstream chronic condition management. By testing ASM, we aim to reduce avoidable hospitalizations and unnecessary procedures, improve patient experience and outcomes, and lower Original Medicare expenditures by incentivizing preventive care, more effective management of chronic conditions, and enhanced coordination and collaboration among specialists and primary care providers. We finalized ASM's provisions in the CY 2026 PFS final rule (90 FR 49562 through 49720), including the framework for identifying ASM participants, performance

evaluation, scoring, and payment adjustments.

a. Proposed Effects of the Ambulatory Specialty Model

Based on feedback we received from interested parties after the publication of the CY 2026 PFS final rule and our own internal review, we propose several technical refinements and adjustments to ASM, including but not limited to revising select definitions, revising and adding ASM participant exceptions from specific ASM requirements, adjusting data submission requirements, incorporating a rural scoring adjustment to final scores, adjusting provisions related to collaborative care arrangements under ASM, and making minor adjustments to specific ASM performance category policies in this proposed rule. We believe these proposals would improve the clarity, practicality, and alignment of ASM implementation. Further, our proposals would not modify the fundamental framework of ASM for identifying ASM participants over the course of the ASM test period, overall performance evaluation, scoring, or payment adjustments and continue to support CMS priorities related to reducing low-value care, promoting preventive care, enhancing management of chronic conditions, and improving coordination and collaboration among specialists and primary care providers.

Accordingly, we believe our proposals in this proposed rule would not increase federal costs or alter the estimated Medicare program savings described in the CY 2026 PFS final rule (90 FR 49969 through 49975). In the CY 2026 PFS final rule, we estimated an impact of $177 million in net savings to the Medicare program due to ASM from January 1, 2029 through December 31, 2033 (90 FR 49972). This estimate reflects relevant finalized provisions including the ASM test period, geographic scope, participant eligibility, ASM risk levels, the amount of ASM incentive pools distributed to ASM participants in the form of payment adjustments, and the estimated amount of Medicare Part B covered professional service payments subject to ASM payment adjustments. We refer readers to the ASM section of the regulatory impact analysis of CY 2026 PFS final rule for additional information on our methodology and sensitivity analysis (90 FR 49969 through 90 FR 49975). Because we do not propose changes to key assumptions used to previously calculate the Medicare program savings estimate, we do not expect that the proposals in this proposed rule to materially affect the Medicare program savings estimates in the CY 2026 PFS final rule. For example, we do not anticipate that the proposed provisions related to ASM participant exceptions from specific ASM requirements would substantially affect the number of ASM participants meeting ASM requirements over the ASM test period because we believe any exceptions would be balanced by other participation provisions that allow for clinicians who newly meet the ASM participant eligibility criteria to be added as ASM participants over the course of the ASM test period. Therefore, ASM's previously estimated financial impact to the Medicare program remains unchanged from the CY 2026 PFS final rule.

6. Limiting Medicare Coverage of Certain Individuals

Section 71201 of the Working Families Tax Cut (WFTC) legislation, which added section 1899C to the Social Security Act (the Act), restricts Medicare eligibility to individuals who meet one of the following criteria: (1) U.S. citizens or nationals; (2) lawful permanent residents; (3) Cuban and Haitian entrants; or (4) individuals who lawfully reside in the United States in accordance with a Compact of Free Association. Individuals who do not meet these criteria and who were enrolled in Medicare on or before July 4, 2025, will have their coverage terminated effective February 1, 2027, which is the date that is 18 months after enactment of the WTFC legislation (July 4, 2025). As established in section 1899C(a) of the Act, individuals enrolled after July 4, 2025, who do not meet the eligibility requirements, are subject to denial or termination under the framework established at proposed §§ 406.14, 406.28 and 407.27.

Based on estimates from OACT, approximately 32,000 individuals are projected to lose Medicare coverage beginning in 2027, representing approximately 0.05 percent of the total Medicare-aged enrollment. OACT's estimate was derived from a 2025 Pew Research study on race and ethnicity in the United States and by using a Congressional report authored by the Department of Homeland Security (DHS). In addition, citing research on lower health care utilization by immigrants, OACT assumes that affected individuals have average Medicare spending equal to approximately two-thirds of the average Medicare beneficiary, reflecting the generally healthier and younger age profile of this population, as well as lower utilization due to increased barriers in accessing health care including language barriers, limited familiarity with the U.S. health system, and concerns related to immigration status that may discourage enrollment and utilization even among those who are eligible. The population captured in this estimate is certain immigrants with temporary protections who no longer meet the revised eligibility requirements, including those with pending asylum applications, parolees, temporary protected status, and victims of crime and violence.

TABLE D-B6: ESTIMATED IMPACT ON MEDICARE SPENDING – LIMITING MEDICARE COVERAGE OF CERTAIN INDIVIDUALS ($ MILLIONS)

Year	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	2027-2036 Total
FY Cash	-$220	-$390	-$420	-$450	-$490	-$520	-$560	-$600	-$640	-$680	-$4,970

Source: Office of the Actuary (OACT), May 1, 2026. Negative values indicate reductions in Medicare program outlays.

The financial impact of this provision is classified as a transfer — specifically, a reduction in Medicare program outlays that would otherwise have been paid to plans and providers on behalf of affected individuals. Based on OACT's estimates, the 10-year reduction in Medicare spending attributable to this provision is approximately $4.97 billion, ranging from approximately $220 million in 2027 to approximately $680 million in 2036 (see Table D–B6).

Disenrollments from Medicare Advantage, Part D, and Medicare cost plans resulting from loss of Part A or Part B entitlement will be processed automatically by CMS when SSA provides updated eligibility and

entitlement records. Plans do not process these disenrollments and are not required to provide additional notification, as SSA provides a loss of entitlement notice directly to affected individuals. All information impacts related to the procedural steps plans must take to receive and process enrollment and disenrollment transactions have already been accounted for under OMB control numbers 0938–0753 (CMS–R–267) and 0938–0964 (CMS–10141). The burden associated with the revision of Medicare initial enrollment forms to support eligibility determinations under this provision is described in the Collection of Information Requirements section of this rule.

Dahl and Forbes (2023) estimate that 46 percent of individuals are willing to pay $638 per person, in 2011 dollars—or approximately $873 when updated for inflation—to avoid switching medical providers (specifically, primary-care physicians).[400] For purposes of this regulatory impact analysis, it is assumed that $873 is a reasonable estimate of an average that includes the 46-percent of WTP amounts above it and the 54-percent below. Multiplying this $873 annual amount by 32,000 disenrollments yields a cost estimate of $28 million. This quantitative estimate is characterized by various forms of uncertainty, including:

- *Tendency toward underestimation.* Switching insurance plans, or newly lacking insurance coverage altogether, involves a more sweeping set of changes than just reestablishing a new primary-care physician, so WTP to avoid the latter probably understates WTP to avoid the former.
- *Tendency toward overestimation.* The relatively low level of churn associated with employer-sponsored insurance (ESI) may offer a greater opportunity to establish doctor-patient relationships than what is available to individuals affected by this provision (due to many of them having non-permanent immigration status), so extrapolating an ESI-derived estimate may overstate the WTP for continuity that would be relevant for this regulatory impact analysis.

7. Medicare Prescription Drug Inflation Rebate Program

In section III.F. of this proposed rule, as part of our continued implementation of the Inflation Reduction Act of 2022 (IRA), which established the Medicare Prescription Drug Inflation Rebate Program under sections 11101 and 11102 of the Act, we are proposing several modifications. For the Medicare Part B Drug Inflation Rebate Program, this rulemaking proposes to modify the excluded product category for Part B rebatable drugs so that the exclusion applies only to certain skin substitute products and clarify what Consumer Price Index for all Urban Consumers (CPI–U) data CMS would use in the event CPI–U data are unavailable. Additionally, we propose to clarify the definition of ''first marketed date'' as used in the context of the Part B Drug Inflation Rebate Program. For the Medicare Part D Drug Inflation Rebate Program, this rulemaking proposes to clarify what CPI–U data CMS would use in the event CPI–U data are unavailable, a modification to the methodology finalized in the CY 2026 PFS final rule to account for 340B-eligible units for AIDS Drug Assistance Programs (ADAPs), and to require all providers and suppliers that are covered entities as defined under § 10.3 (hereinafter collectively ''340B providers'' unless otherwise noted) to submit data elements from their Part D 340B claims to the 340B repository beginning in 2027.

We do not expect the proposed policies regarding the Medicare Part B Drug Inflation Rebate Program and the Medicare Part D Drug Inflation Rebate Program to have a material impact on the calculation of total rebates in aggregate, as these proposals are refinements to regulatory requirements that improve program efficiency and do not otherwise change the current scope of rebatable drugs.

In section III.F.3.c.2.c. of this proposed rule, we are proposing to require all 340B providers to submit data elements from their Part D 340B claims for all covered Part D drugs billed to Medicare Part D by such covered entity or its contractor(s) beginning with claims with a date of service on or after in 2027. 340B providers would be required to follow the processes and requirements that CMS established for voluntary reporting starting in 2026 and the associated information collection currently approved under OMB control number 0938–1485. CMS would require that each 340B provider report data on a quarterly basis (though they may choose to submit more frequently) within 1 calendar quarter following the close of the relevant calendar quarter. CMS would consider all data elements received by the 340B repository to be associated with Part D 340B claims; therefore, the 340B repository would rely on the accuracy and completeness of the submitted, certified data to the 340B repository to verify the 340B status of a claim, and CMS would analyze these data to determine if they could be used reliably in the future to remove 340B units from Part D inflation rebate calculations in accordance with section 1860D–14B(b)(1)(B) of the Act. Under this process, CMS would require, as part of every submission, 340B providers (or an individual or contractor with the delegated authority as an authorized representative of the 340B provider to perform the certification) to certify that the data elements from all claims submitted to the 340B repository are from verified 340B claims and, to the best of the 340B provider's knowledge, its submissions include all Part D 340B claims for the 340B provider at the time of submission for the relevant period. 340B providers, or their authorized representative, would be required to certify the completeness and accuracy of the data submitted and to certify that the submitter is authorized to submit on behalf of the 340B provider.

In section III.F.3.c.1. of this proposed rule, we are proposing a modification to the Prescriber-Pharmacy Methodology whereby all claims for Part D drugs dispensed to beneficiaries identified as having ADAP supplemental coverage would be treated as 340B-eligible and excluded from Part D inflation rebate calculations, with safeguards to prevent double-counting of units already identified under the existing methodology. This proposed modification addresses a limitation to the Prescriber-Pharmacy Methodology that may under-identify 340B units for drug claims associated with ADAPs that use pharmacies not registered in the OPAIS database as contract pharmacies. This change may result in some overestimation of 340B-eligible units associated with ADAPs, although it is expected to have minimal or no impact on the percentage of Part D units identified as 340B eligible for most drug classes with the exception of antiretroviral medications used in the treatment of HIV/AIDS. The proposed change would be effective for Rebate Reports issued for applicable periods beginning October 1, 2025 and subsequent applicable periods.

In sections III.F.2.c. and III.F.3.b. of this proposed rule, we are proposing to amend §§ 427.302, 428.20, and 428.202 to address gaps in monthly CPI–U data by establishing a methodology that uses the first available CPI–U data following any unavailable month. CMS calculates the inflation-adjusted payment amount for Part B rebatable drugs using benchmark and rebate period CPI–U

[400] Dahl, G.B. & Forbes, S.J. (2023). Doctor switching costs. *Journal of Public Economics, 221,* 104858, *https://doi.org/10.1016/j.jpubeco.2023.104858.*

data, with the benchmark period CPI–U determined based on a drug's FDA approval and first marketed date, and the rebate period CPI–U set as the greater of the benchmark CPI–U or the CPI–U from two calendar quarters prior to the applicable quarter. CMS calculates inflation-adjusted payment amount for Part D rebatable drugs using benchmark period and applicable period CPI–U data, with the benchmark period CPI–U determined based on a drug's FDA approval and first marketed date, and the applicable period CPI–U set as the CPI–U for the first month of the applicable period. However, it was necessary to account for situations in which a monthly CPI–U figure is unavailable. Alternative approaches, including the Treasury Department's inflation contingency index, a CMS-calculated inflation factor, or using the prior month's data were considered but not proposed as either less consistent with statutory requirements or administratively impracticable.

We do not anticipate our inflation rebate proposed policies will result in an incrementally significant financial impact on the Medicare program relative to a baseline that reflects the status quo in the absence of any modifications to inflation rebate regulations at parts 427 and 428 as these finalized policies are refinements to regulatory requirements.

8. Medicare Shared Savings Program

a. General Impacts

As of January 1, 2026, the Shared Savings Program has 511 ACOs with over 700,000 healthcare providers and organizations providing care to over 12.6 million assigned beneficiaries.[401] The policies in this proposed rule are designed, in part, to strengthen financial incentives for ACOs to participate in the Shared Savings Program while mitigating selection issues and benchmark rebasing concerns, expand the population of Original Medicare beneficiaries for which ACOs are held accountable for quality and cost of care while minimizing gaming, advance ACO use of digital quality measures and reduce participant burden, and increase beneficiary engagement.

As we described in the CY 2026 PFS final rule (90 FR 32814), the ACOs in the program in PY 2023 combined to cover $128 billion in benchmark target spending. Actual ACO spending totaled approximately $123 billion—about $5.2 billion below combined benchmark. After accounting for $3.1 billion in net shared savings to ACOs, the remaining difference of $2.1 billion would represent federal savings from the program if benchmarks proved to be a perfect counterfactual in aggregate. The Regulatory Impact Analysis in the December 2018 final rule (see 83 FR 68044 through 68050) provided evidence that the benchmarks for PY 2016 combined to represent a lower spending target than the theoretical counterfactual for estimating what spending would have been in the total FFS Medicare Program had ACOs not been present that year. Evidence included all of the following:

- Lower combined market level spending trends observed for cohorts of Hospital Referral Regions (HRRs) with significant ACO formation relative to other HRRs without material ACO activity.
- Spillover effects on spending outside of ACO benchmarks, including non-assigned beneficiaries served by ACO providers and suppliers.
- Program design elements that restrained benchmark levels, including rebasing with agreement periods of only 3 years, feedback of communal ACO effects on national trends used to update benchmarks, and restrictions on risk adjustment.

The Regulatory Impact Analysis in the December 2018 final rule (83 FR 68048) estimated that ACOs may have been responsible for half of the 1.2 percent difference in spending trend observed between national average and the subset of HRRs with minimal ACO activity through 2016. This scaled impact represented about four times the gross savings measured relative to benchmarks, or about 0.5 percent net savings across the entire FFS program after accounting for shared savings payments despite benchmarks only officially showing roughly equivalent overall reductions in spending relative to benchmark compared to total outlays from shared savings payments. Since 2016, changes to the Shared Savings Program have potentially moved the benchmarks closer to what the spending would have been in the absence of the program.

In the CY 2026 PFS final rule (90 FR 49975 through 49976), we explained that updating the earlier study to compare more recent trends for markets with varying levels of ACO activity requires updates to the initial study approach, as ACOs have become active in an increasing majority of markets across the nation. There no longer exists a sufficient number of HRRs with nominal ACO penetration in 2023 to construct a de facto counterfactual similar to the study in the December 2018 final rule. An alternate method, however, continued to show spending trends inversely correlated with ACO penetration over time. Roughly 5 percent of beneficiaries live in HRRs with ACO penetration consistently below the national average by 10 percentage points or more over the 2013 to 2023 time series (''Lagging''), while about 9 percent of beneficiaries live in HRRs with ACO penetration 10 percentage points or more above the national average over the same period (''Leading''). Relative to the 2011 base year immediately preceding the Shared Savings Program's introduction, growth in average unadjusted per capita spending in 2023 for Lagging and Leading markets was 4.3 percent higher and 3.9 percent lower than the national average. The divergence in spending growth was even wider after HCC risk adjustment: 5.3 percent higher for Lagging markets and 4.6 percent lower for Leading markets.

These market trends potentially overstate the impact that ACOs may have had on program spending in 2023. The portion of the difference in spending growth driven by risk adjustment may reflect efforts by ACOs to increase coding intensity. Leading markets may exhibit higher participation rates in CMMI models. ACO participation may naturally flock to markets with lower trend for exogenous reasons. Still, conservatively assuming only 35 percent of the unadjusted trend gap is causally related to Shared Savings Program ACOs would roughly validate the $5.2 billion gross savings indicated by comparing aggregate program benchmarks to actual ACO spending in 2023, and the roughly $2 billion in net savings to FFS Medicare. A more optimistic estimate, assuming Shared Savings Program ACOs were responsible for 50 percent of the risk-adjusted spending growth difference (mirroring assumptions used in the December 2018 final rule), would imply net savings roughly 3 times greater, or roughly $6 billion net savings for FFS Medicare.

In the CY 2026 PFS final rule (90 FR 49976), we explained that a study of benchmark performance for cohorts of ACOs that participated in both PY 2022 and PY 2023 revealed that the BASIC track is the primary driver of net savings (as measured by program benchmark target spending less actual spending and shared savings payments). An updated analysis, summarized in Table D–B7, finds that ACOs remaining in the BASIC track continued to demonstrate roughly 50 percent higher net savings in PY 2024 (2.3 percent of benchmark) than

[401] See CMS, ''Shared Savings Program Fast Facts—As of January 1, 2026'', available at *https://www.cms.gov/files/document/2026-shared-savings-program-fast-facts.pdf*.

ACOs that remained in the ENHANCED track over the same three year period (1.5 percent of benchmark)—where 'net savings' is calculated as the difference in combined cohort spending from combined cohort benchmark spending net of combined cohort shared savings outlays, expressed as percentage of combined cohort benchmark (column D in Table D–B7). Meanwhile, ACOs moving into the ENHANCED track from the BASIC track show a marked decline in net savings. Thirty-eight ACOs moved from the BASIC track in PY 2022 (with net savings of 2.5 percent) to the ENHANCED track by PY 2024 with net savings dropping to 1.7 percent of benchmark.

TABLE D-B7: WEIGHTED AVERAGE FINANCIAL PERFORMANCE BY ACO COHORT DEFINED BY PATH OF PARTICIPATION OVER PY 2022 TO PY 2024 ($ BILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

Participation Pathway From PY22 to PY24	ACO Count	Benchmark ($B) [A]	Gross Savings % of Benchmark [B]			Shared Savings % of Benchmark [C]			Net Difference % of Benchmark [D]		
			2022	2023	2024	2022	2023	2024	2022	2023	2024
BASIC All 3 Years	210	51	-3.1	-3.4	-4.1	1.3	1.4	1.8	-1.8	-2.0	-2.3
BASIC->ENHANCED	38	14	-4.5	-5.8	-6.3	2.0	3.5	4.6	-2.5	-2.4	-1.7
ENHANCED All 3 Years	123	50	-4.8	-5.1	-5.8	3.5	3.8	4.3	-1.2	-1.4	-1.5

Notes: "Participation Pathway" are the following groups of ACOs, identified by the track/level of their participation in PY 2022, PY 2023 and PY 2024: "BASIC All 3 Years" are ACOs that remained in the BASIC track (Level A, B, C, D, or E) for PY 2022, PY2023, and PY 2024; "BASIC->ENHANCED" are ACOs that participated in BASIC in PY 2022 and either (a) remained in BASIC in PY 2023 before then advancing to the ENHANCED track in PY2024, or (b) advanced to the ENHANCED track in PY 2023 and remained in the ENHANCED track in PY 2024; and "ENHANCED ALL 3 Years" are ACOs that remained in the ENHANCED track for PY 2022, PY 2023, and PY 2024.
"Benchmark" **[A]** is the total PY 2024 benchmark spending for each cohort, in billions of dollars.
"Gross Savings % of Benchmark" **[B]** is the percentage that a cohort's combined spending deviated from their combined benchmark spending (a negative percentage implies savings).
"Shared Savings % of Benchmark" **[C]** is the cohort's combined shared savings (and losses) paid to (from) ACOs expressed as a percentage of benchmark.
"Net Difference % of Benchmark" **[D]** is the sum of "Gross Savings % of Benchmark" [B] and "Shared Savings % of Benchmark" [C] and represents the portion of gross savings (as measured by program benchmarks) retained by the Trust Funds.

Favorable regional adjustments have helped selective ACOs maximize earnings in the ENHANCED track without taking on a high degree of real risk. Only about 2 percent of ENHANCED track ACOs owed losses in PY 2024 while 90 percent earned shared savings. The ENHANCED track has grown from including only 14 percent of ACOs in 2020 to 58 percent in 2026.

The first impact estimate in this section assesses the coordinated set of proposals to rebalance the incentives between the BASIC track and ENHANCED track. These proposals include reducing the maximum weight used in calculating the positive regional adjustment for lower-spending ACOs under the ENHANCED track from 50 percent to 35 percent, increasing the prior savings adjustment's scaling factor from 50 percent to 75 percent, and increasing the shared savings rate for BASIC track Level E from 50 percent to 60 percent. A stochastic modeling approach consistent with the regulatory impact analysis from previous rules was employed to simulate the impact this set of proposals would have on existing ACOs and potential new ACOs over the 10 year scoring period. The changes will reduce the propensity for ACOs to be able to passively earn shared savings at the highest sharing rate by solely relying on baseline efficiency through the regional adjustment to the benchmark and instead will place a stronger incentive on generating new efficiency over the agreement period. Such incentive for new efficiency will also be incentivized by the increase in the prior savings adjustment's scaling factor. That change, combined with the higher sharing rate in BASIC track Level E, will likely attract a greater number of new ACOs serving populations, often with high spending at baseline relative to the regional average. The increase to the prior savings adjustment scaling factor would strengthen the degree that such higher spending ACOs would continue to share in savings originally made in their first agreement period despite then facing rebasing into a subsequent agreement period—a dynamic further enhanced by the proposal to risk adjust the cap on benchmark adjustments (currently defined as 5 percent of unadjusted national average assignable per capita spending). These proposals are together estimated to better allocate shared savings payments to ACOs creating new gains in efficiency as opposed to ACOs merely maintaining their historical baseline efficiency, resulting in $4.59 billion lower spending over 10 years, ranging from $6.42 billion lower spending to $2.88 billion lower spending at the 10th and 90th percentiles, respectively. The annual and 10-year total projections for the changes to Shared Savings Program participation options are detailed in Table D–B8.

TABLE D-B8: PROJECTED IMPACT OF FINANCIAL METHODOLOGY PROPOSALS TO REDUCE THE REGIONAL ADJUSTMENT WEIGHTING FOR ENHANCED TRACK ACOS, INCREASE SHARING RATE FOR BASIC TRACK LEVEL E, AND INCREASE THE PRIOR SAVINGS ADJUSTMENT PERCENTAGE ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	−580	−650	−720	−850	−980	−100	−140	−170	−190	−210	**−4,590**
Estimate Range:											
Low Estimate (10th Percentile)	−730	−810	−930	−1,150	−1,310	−300	−380	−420	−480	−510	**−6,420**
High Estimate (90th Percentile)	−450	−480	−510	−560	−680	100	70	70	70	100	**−2,880**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The second area of material impact on program spending is for the creation of a growth adjustment to incentivize new participation among providers and suppliers that have not been part of a Medicare ACO within the past five years. As described in sections III.G.5.a and III.G.5.f of this proposed rule, participation in the Shared Savings Program has grown substantially since the program began in 2012, from approximately 3 million assigned beneficiaries assigned in its first year to more than 12 million assigned beneficiaries as of January 2026. This growth has occurred alongside strong program performance: We have observed that when participation in the program increases, we see increases in both quality improvements for beneficiaries and increased savings to the Trust Funds. The Shared Savings Program has had eight consecutive years of generating savings for Medicare relative to benchmarks, with over $12 billion in total savings,[402] with an upward trend in savings year over year. (As noted previously in this discussion, these savings measured by benchmarks are reasonably substantiated by lower observed per capita spending trend in markets with early ACO adoption versus higher average per capita spending trend in markets with lagging ACO adoption.) Additionally, we have observed that ACOs in the Shared Savings Program have demonstrated improved quality over time and higher quality relative to other physician groups, suggesting that the Shared Savings Program is achieving savings while improving quality of care.

This historical experience supports our expectation that expanding participation would extend the program's quality benefits to additional beneficiaries and create further opportunities for Medicare savings. The growth adjustment is part of a complementary package of proposed modifications to the benchmark methodology intended to realign financial incentives and grow participation, thus expanding the reach of quality improvements demonstrated in the Shared Savings Program, and encourage further savings.

The proposed growth adjustment would be applied on top of the highest of the existing benchmark adjustments, including regional adjustment, prior savings adjustment, or population adjustment (if eligible), and would not exceed a risk adjusted 5 percent cap for consistency with the proposed approach to capping other upward adjustments to the historical benchmark. The proposal is estimated to have the greatest impact on new ACOs that would have the greatest potential to bring in beneficiaries who have not been previously assigned to ACOs. The growth adjustment proposal is projected to increase ACO shared savings payments by $5.3 billion over 10 years, but most of that cost would be offset by new savings on reduced benefit spending from bringing additional populations into care management under Shared Savings Program ACOs. As a result, the estimated net cost to the program is estimated to be considerably less than the increase in net sharing to ACOs. This proposal is estimated to result in a net increase in spending by $1.67 billion over 10 years, with the annual increase declining in later years as savings from increased participation grow while the effect of the growth adjustment on benchmarks eventually moderates. We have observed that beneficiaries receive higher quality of care (as evidenced by ACOs' quality performance) when assigned to ACOs in the Shared Savings Program, and increasing participation in the Shared Savings Program through the growth adjustment has the potential to broaden higher quality of care to additional Medicare FFS beneficiaries. The range of uncertainty spans costs of $1.13 billion to $2.28 billion at the 10th and 90th percentiles, respectively. The annual and 10-year total projections for these provisions are detailed in Table D–B9.

[402] Additional information on past years Shared Savings Program Performance Year Finance and Quality Results is available at: *https://data.cms.gov/medicare-shared-savings-program/performance-year-financial-and-quality-results.*

TABLE D-B9: PROJECTED IMPACT FOR GROWTH ADJUSTMENT INCENTIVE TO ENCOURAGE NEW PARTICIPATION ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	290	270	310	320	330	20	10	30	50	40	**1,670**
Estimate Range:											
Low Estimate (10th Percentile)	240	210	250	300	300	-60	-120	-100	-80	-70	**1,130**
High Estimate (90th Percentile)	330	270	380	370	420	140	120	120	150	160	**2,280**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The third portion of our impact estimate is for the proposed changes to beneficiary assignment, including removing from assignment calculations allowed charges for primary care services billed through a non-ACO TIN by an ACO professional used in assignment, and modifying regulatory criteria that exclude from eligibility for assignment Medicare FFS beneficiaries with any months of Part A only or Part B only enrollment, or Medicare or group health plan enrollment (including MA) during the assignment window. These changes would marginally increase the number of beneficiaries assigned to a given ACO. More importantly, they would improve the ability for the program to hold ACOs accountable for more of the patients actually served by ACO clinicians, including those with accentuated need for care management. The first proposal would reduce the ability for an ACO, through billings for primary care services by ACO professionals used in assignment, to 'lemon drop'—a potential form of gaming where patients with high needs are purposefully billed services through a TIN external to the ACO to engineer their assignment away from the ACO. The second proposal helps reduce a notable blind spot in the current assignment methodology. As enrollment in Medicare Advantage (MA) has grown over recent years, so has the number of beneficiaries switching back to OM from MA—a population that the proposed revised assignment criteria would more nimbly pick up for inclusion in ACO assignment. This proposal would also improve the symmetry in assignment for ACOs relative to the national and regional assignable populations because the Shared Savings Program does not currently employ the same exclusions based on Medicare enrollment status for identifying the assigned and assignable populations. Together these proposals are estimated to reduce program spending by $2.3 billion over 10 years, ranging from $2.97 billion to $1.69 billion savings at the 10th and 90th percentiles, respectively. Savings from these changes could effectively be materially higher if gaming of assignment were to otherwise significantly grow in popularity at baseline.

TABLE D-B10: PROJECTED IMPACT FOR CHANGES TO ASSIGNMENT METHODOLOGY ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	−380	−280	−220	−200	−200	−300	−230	−190	−160	−140	**−2,300**
Estimate Range:											
Low Estimate (10th Percentile)	−410	−330	−300	−300	−320	−410	−350	−320	−310	−290	**−2,970**
High Estimate (90th Percentile)	−350	−230	−140	−100	−80	−210	−120	−80	−10	−20	**−1,690**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The last provision estimated to have a material impact on spending is the proposal to revise the methodology for the ACPT. The current policy includes a discretionary option for CMS to reduce the weight on the ACPT's contribution to the three-way blended update to ACO benchmarks if unforeseen circumstances arise. The proposed changes would create uniform annual one-year growth projections common to ACOs in overlapping agreement periods—eliminating reliance on multi-year projections that the ACPT currently employs—and a policy that, for agreement periods beginning on or after January 1, 2027, would limit the effect of under-projection or over-projection as compared to actual retrospective national expenditure trend such that an effective ACPT trend (cumulatively from BY3 to a given performance year) is no more than one percentage point below (or no more than 1.5 percentage points above) national growth. The asymmetry of these guardrails preserves a limited degree of margin related to the ideal scenario where ACOs as a group cause national trend to slow relative to projected trend over the course of a given agreement period, but more importantly has several notable advantages relative to the current methodology with potential down-weighting. It protects the validity of benchmark updates by limiting how

far the projected trend used in the ACPT portion of the three-way blended update factor would be allowed to deviate from observed national trend, and does so under an objective formula that eliminates the subjectiveness of the current down-weighting policy that would otherwise likely be invoked to a greater degree in years where down-weighting would favor ACOs as opposed to public pressure to maintain the one-third weighting in years where over-projection could favor ACOs. The proposal would also improve on the current down-weighting policy because it would preserve the role of national trend in the overall update, which can help preserve the incentive for neighboring ACOs to collectively lower spending in their overlapping service area (an outcome that down-weighting would penalize by increasing the effective weighting on regional trends in calculating benchmark updates). Despite estimating higher spending in 2027 and 2028 related partly to our separate proposal to only apply the lower 1.0 percentage point threshold for ACOs in existing agreement periods, the total impact over ten years is estimated to be a savings of $350 million, ranging from a $1.11 billion savings to a $340 million cost at the 10th and 90th percentiles, respectively. The estimates are shown in table D–B11:

TABLE D-B11: PROJECTED IMPACT FOR CHANGES TO ACPT AND ASSOCIATED GUARDRAILS ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	130	70	−10	−50	−70	−80	−90	−90	−80	−70	**−350**
Estimate Range:											
Low Estimate (10th Percentile)	−60	−40	−90	−140	−200	−250	−290	−300	−200	−190	**−1,110**
High Estimate (90th Percentile)	350	200	80	10	20	30	30	40	20	30	**340**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The remaining changes to the Shared Savings Program regulations, as described in section VII.A.2.a. of this proposed rule, are not estimated to have an impact on program spending at the aggregate level.

The proposals detailed above are expected to increase assignment to ACOs in the program by 0.5 to 1.0 million beneficiaries on average per year. The combined impacts from all Shared Savings Program provisions on federal spending are shown in Table D–B12. Because estimates are rounded to the nearest $10 million, and because the percentiles are independently sorted for each year and for the 10-year totals, the annual estimates may not sum to exactly match the total 10-year estimates. Together these proposals are estimated to reduce program spending by $5.5 billion over 10 years, ranging from $8.9 billion to $2.3 billion savings at the 10th and 90th percentiles, respectively.

TABLE D-B12: PROJECTED IMPACT OF MEDICARE SHARED SAVINGS PROGRAM PROVISIONS (INDIVIDUALLY SHOWN IN TABLES D-B8 THROUGH D-B11) ($ MILLIONS; NEGATIVE VALUES REPRESENT SAVINGS TO THE PROGRAM)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	−580	−640	−690	−830	−960	−410	−400	−360	−330	−340	**−5,550**
Estimate Range:											
Low Estimate (10th Percentile)	−970	−1,010	−1,090	−1,280	−1,510	−920	−980	−970	−890	−910	**−8,870**
High Estimate (90th Percentile)	−180	−300	−300	−400	−420	40	80	130	160	190	**−2,310**

Note: Projections at the 10th and 90th percentiles are distinct at the annual level from the corresponding percentiles of the 10-year totals and therefore the sum of the annual percentiles will not necessarily match the corresponding percentiles of the 10-year totals.

The proposals are expected to both decrease and increase net shared savings payments across the overall distribution of ACOs. The mean projection is an overall increase in such payments by $1.05 billion over 10 years, ranging from a $2.6 billion decrease to a $4.63 billion increase at the 10th and 90th percentiles, respectively. The increase in shared savings payments to ACOs is driven by the proposed growth adjustment policy, and without this proposed policy the majority of savings to Medicare would be achieved through reductions in shared savings payments. Annual and total projections for the impact on shared savings net of shared losses are shown in Table D–B13.

TABLE D-B13: PROJECTED IMPACT OF MEDICARE SHARED SAVINGS PROGRAM PROVISIONS ON SHARED SAVINGS PAYMENTS TO ACOS ($ MILLIONS; POSITIVE VALUES REPRESENT INCREASED NET PAYMENTS TO ACOS)

	2027	2028	2029	2030	2031	2032	2033	2034	2035	2036	Total
Impact Estimate	−220	−230	−200	−260	−300	270	350	450	560	640	**1,050**
Estimate Range:											
Low Estimate (10th Percentile)	−620	−560	−580	−700	−900	−220	−210	−150	10	50	**−2,600**
High Estimate (90th Percentile)	210	130	200	180	230	720	850	990	1,060	1,180	**4,630**

b. Compliance with Requirements of Section 1899(i)(3) of the Act

Certain policies, including both existing policies and the new proposed policies described in proposed rule, rely upon the authority granted in section 1899(i)(3) of the Act to use other payment models that the Secretary determines will improve the quality and efficiency of items and services furnished under the Medicare program, and that do not result in program expenditures greater than those that would result under the statutory payment model. The following proposed policies require the use of our authority under section 1899(i) of the Act: modifications to the ACPT component of the three-way blended benchmark update factor (described in section III.G.5.g of this proposed rule); discontinuing availability of the option for prepaid shared savings (described in section III.G.6.b of this proposed rule); and changes to the calculation methodology for quarterly advance investment payments (described in section III.G.7 of this proposed rule). When considered together, these changes to the Shared Savings Program are expected to improve the quality and efficiency of items and services furnished under the Medicare program by improving the accuracy of the benchmark update factor and strengthening financial incentives under the Shared Savings Program, decreasing administrative burden and conserving resources by discontinuing the availability of the prepaid shared savings option given low uptake and anticipated limited participation, and simplifying the calculation of quarterly amounts of advance investment payment (for eligible ACOs) while encouraging ACO formation in rural areas. These changes are not expected to result in a situation in which the payment methodology under the Shared Savings Program, including all policies we have adopted under the authority of section 1899(i) of the Act, results in more spending under the program than would have resulted under the statutory payment methodology in section 1899(d) of the Act.

In the CY 2023 PFS final rule (87 FR 70195 and 70196), we estimated that the projected impact of the payment methodology that incorporates all policies finalized by that final rule would result in $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excluded the policies that we have enacted relying on the authority of section 1899(i)(3) of the Act. The marginal impact of the changes in the CY 2024 PFS final rule (88 FR 79496) were estimated to lower net spending by $330 million over the subsequent 10-year period (2024 through 2033) for all new policies combined. The marginal impact of the changes in the CY 2025 PFS final rule (89 FR 98527) were estimated to lower net spending by an additional $200 million in total through 2034. The marginal impact of the changes in the CY 2026 PFS final rule (90 FR 49978) were estimated to be a $20 million reduction in net spending through 2035. The marginal impact of the changes in this proposed rule is estimated to be $5.5 billion reduction in net spending through 2036. The incremental changes have been estimated to improve program financial savings since the CY 2023 PFS final rule, and hence the cumulative impact of all policies (including those in this proposed rule) is estimated to result in more than the previously-estimated $4.9 billion in greater program savings compared to a hypothetical baseline payment methodology that excludes the policies we have enacted relying on section 1899(i)(3) of the Act as authority. Therefore, we estimate that program expenditures associated with the implementation of the provisions in this proposed rule, in combination with other policies associated with the statutory payment model and current policies we have adopted under the authority of section 1899(i)(3) of the Act, are expected to improve the quality and efficiency of items and services furnished under the Medicare program and would not be expected to increase program expenditures relative to those of the statutory payment model.

We will continue to reexamine this projection in the future to ensure that an alternative payment model does not result in additional program expenditures and so continues to satisfy the requirement under section 1899(i)(3)(B) of the Act. Additional Shared Savings Program data accumulating after the end of the PHE for COVID–19, along with emerging information on the characteristics of, and performance trends for, new entrants in the Shared Savings Program for agreement periods beginning on January 1, 2024, January 1, 2025, and January 1, 2026, are anticipated to gradually improve our ability to reevaluate program impacts in a comprehensive fashion. If we later determine that the payment model that includes policies established under section 1899(i)(3) of the Act no longer meets this requirement, we will undertake notice and comment rulemaking to adjust the payment model to ensure continued compliance with the statutory requirements.

9. Changes to the Regulations Associated With the Ambulance Fee Schedule

As outlined in section III.H.2. of this proposed rule, section 6203 of the Consolidated Appropriations Act, 2026 amended section 1834(l)(12)(A) and (l)(13) of the Act to extend the payment add-ons sets forth in those sections through December 31, 2027. The ambulance extender provisions are enacted through legislation that is self-implementing. We are proposing to revise dates at § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to

these self-implementing statutory requirements.

A plain reading of the statute requires only a ministerial application of the mandated rate increase and does not require any substantive exercise of discretion on the part of the Secretary. As a result, there are no policy proposals associated with these legislative provisions. We have estimated the cost of these provisions to be $260 million over the 10-year period and the Congressional Budget Office (CBO)'s estimated cost of these provisions was $52 million in FY 2026, $111 million in FY 2027, and $34 million in FY 2028 with minimal costs for the remaining 10 year period, resulting in a net effect of $197 million from FY 2026 to FY 2035 *(https://www.cbo.gov/system/files/2026-01/hr7148-CAA-2026.pdf, page 4).*

As discussed in section III.H.4., of this proposed rule, we are proposing to make use of the revised OMB delineations as set forth in OMB's July 21, 2023 bulletin (No. 23–01) and the most recent modifications of the RUCA codes for purposes of payment under the AFS. If we adopt OMB's revised delineations and the updated RUCA codes, ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be Micropolitan or otherwise outside of MSAs based on OMB's revised delineations or in a rural census tract of an MSA based on the updated RUCA codes (but are currently within urban areas) may experience increases in payment for such transports because they may become eligible for the rural adjustment factors discussed previously, while those ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be urban based on OMB's revised delineations and the updated RUCA codes (but are currently in Micropolitan Areas or otherwise outside of MSAs, or in a rural census tract of an MSA) may experience decreases in payment for such transports because they would no longer be eligible for the rural adjustment factors discussed previously.

The use of the revised OMB delineations and the updated RUCA codes would mean the recognition of new urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2010 and 2020. As discussed previously in this section, we are proposing to use the updated 2020 RUCA codes to identify rural census tracts within MSAs, such that the census tracts falling at or above RUCA level 4.0 would continue to be designated as rural areas.

Based on our analysis, the geographic designations for approximately 95.87 percent of ZIP codes would be unchanged by using OMB's revised delineations and the updated RUCA codes. There are more ZIP codes that would change from urban to rural (1,172, or 2.73 percent) than rural to urban (602, or 1.40 percent). In general, it is expected that ambulance providers and suppliers in 1,172 ZIP codes within 47 States and Puerto Rico may experience payment increases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from urban to rural. The State of Maryland would have the most ZIP codes changing from urban to rural with a total of 49, or 7.78 percent. Ambulance providers and suppliers in 602 ZIP codes within 43 States may experience payment decreases if we adopt the revised OMB delineations and the updated RUCA codes, as these areas would be redesignated from rural to urban. The State of South Carolina would have the most ZIP codes changing from rural to urban (20, or 3.68 percent). Adoption of the revised OMB delineations and the updated RUCA codes would have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the revised OMB delineations and the updated RUCA codes. We estimate that the adoption of the revised OMB delineations and the updated RUCA codes will have a minimal fiscal impact on the Medicare program.

10. Updates to the Quality Payment Program

In this section of the proposed rule, we estimate the impacts of the Quality Payment Program policies. We estimate participation, final scores, and payment adjustments for eligible clinicians participating through MIPS the Advanced APMs, and MVPs. For Advanced APMs, we estimate the impacts on the number of Qualified Participants (QPs) that are associated with our proposed policies.

a. Overall Impact Modeling Approach and Data Assessment

(1) MIPS Impact Modeling Approach

For this proposed rule, we used a similar modeling approach as the CY 2026 PFS final rule (90 FR 49266 through 50481). We created two MIPS impact models: a baseline and a proposed policies model. Our baseline model includes previously finalized policies that are still in effect for the CY 2027 performance period/2029 MIPS payment year and in the absence of any of the new policies in this proposed rule. Examples of previously finalized policies included in the baseline model are revised administrative claims quality measure benchmarking methodology, modifications to the Total Per Capita Cost measure, and removal of the topped-out measure scoring cap and application of the defined topped out measure benchmarks to 19 quality measures identified for CY 2026 performance period/2028 MIPS payment year. Please refer to CY2026 PFS final rule for a comprehensive, detailed discussion of finalized policies (90 FR 49266).

The policies model builds on the baseline model and incorporates the new MIPS policies we are proposing for the CY 2027 performance period/2029 MIPS payment year included in this proposed rule. By comparing the baseline model to the proposed policies model, we are able to estimate the impact of the policies in this proposed rule.

Our modeling approach utilizes the same scoring engine that is used to determine MIPS payment adjustments. This approach enables our model to align as much as possible with actual MIPS scoring

(2) Data Used to Estimate Future MIPS Performance

In the CY 2026 PFS proposed and final rules, we used data from performance year 2023 to construct baseline and policies model simulations. For this proposed rule, we used data from performance year 2024. This is the most recent available data and reflects our most up-to-date information on program participation, final scores, and payment adjustments.

b. APM Incentive Payments to QPs in Advanced APMs and Other Payer Advanced APMs

Beginning with QP Performance Period 2017 (payment year 2019), through the Medicare Option, eligible clinicians who are determined to have a sufficient percentage of their Medicare Part B payments for covered professional services or Medicare patients through Advanced APMs are QPs for the applicable QP performance period and the corresponding payment year. In payment years 2019 through 2024, these QPs received a lump-sum APM Incentive Payment equal to 5 percent of their estimated aggregate paid amounts for covered professional services furnished during the base year (the calendar year immediately preceding the payment year). In payment year 2025, eligible clinicians

who attained QP status for QP Performance Period 2023 will receive a lump-sum APM Incentive Payment equal to 3.5 percent of their estimated aggregate paid amounts for covered professional services furnished during CY 2024. In payment year 2026, eligible clinicians who attained QP status in QP Performance Period 2024 will receive a lump-sum APM Incentive Payment equal to 1.88 percent of their estimated aggregate paid amounts for covered professional services furnished during CY 2025. In payment year 2028, eligible clinicians who attained QP status in QP Performance Period 2026 will receive a lump-sum APM Incentive Payment equal to 3.1 percent of their estimated aggregate paid amounts for covered professional services furnished during CY 2027.

Beginning with QP Performance Period 2019 (payment year 2021), in addition to the Medicare Option, the All-Payer Combination Option also affords eligible clinicians an opportunity at QP status. The All-Payer Combination Option allows eligible clinicians to become QPs by assessing a combination of both Medicare Part B covered professional services furnished or patients through Advanced APMs and services furnished or patients through Other Payer Advanced APMs. Eligible clinicians who become QPs for a given QP Performance Period are not subject to MIPS reporting requirements and payment adjustments for the contemporaneous MIPS performance period/payment year. Eligible clinicians who do not become QPs but meet a lower threshold requirement to become Partial QPs for the year may elect to (or not to) report to MIPS. If they elect to report, they are subject to MIPS scoring and payment adjustment. Partial QPs are not eligible to receive the APM Incentive Payment.

If an eligible clinician does not attain either QP or Partial QP status and is not excluded from MIPS on another basis, the eligible clinician will be subject to the MIPS reporting requirements and will receive the corresponding MIPS payment adjustment.

Separately from the APM Incentive Payment, beginning in payment year 2026, there are two separate PFS CFs—one for QPs for the year (the qualifying APM CF), and the other for all non-QP eligible clinicians and other suppliers paid under the PFS (the non-qualifying APM CF). The update to the qualifying APM CF for a year is 0.75 percent, whereas the update to the non-qualifying APM CF for a year is 0.25 percent. Such updates produce approximately a 0.5 percent difference in the two conversion factors each year.

The thresholds to achieve QP status in the 2027 QP Performance Period (2029 payment year) are set to 75 percent for the payment amount, and 50 percent for the patient count. Overall, we estimated that for the 2026 QP Performance Period, between 517,800 and 530,900 eligible clinicians will become QPs, and therefore will be excluded from MIPS reporting requirements and payment adjustments.

In the CY2026 PFS final rule, we finalized our proposal to use two new definitions, ''Covered professional service attribution-eligible beneficiary'' and ''E/M attribution-eligible beneficiary'' such that we conduct two determination calculations, one that includes any beneficiary who has received a covered professional service furnished by the eligible clinician (NPI) for whom we are making the QP determination and one that continues to use Evaluation and Management services furnished by the eligible clinician (NPI) for whom we are making the QP determination. We also finalized our proposal to add a QP determination at the individual level for all Advanced APM participants, beginning with the 2026 QP Performance Period.

We project the number of eligible clinicians who will be QPs, and thus excluded from MIPS, using several sources of information. First, the projections are anchored in the most recently available public information on Advanced APMs. The projections reflect Advanced APMs that will be operating during the 2027 QP Performance Period. The following APMs are expected to be Advanced APMs for the 2027 QP Performance Period:

- Enhancing Oncology Model (EOM);
- Kidney Care Choices Model (Comprehensive Kidney Care Contracting Options, Professional Option and Global Option);
- Long Term Enhanced ACO Design (LEAD) Model;
- Medicare Shared Savings Program (Level E of the BASIC Track and the ENHANCED Track);
- States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model; and
- Transforming Episode Accountability Model (TEAM)

We used the Participation Lists and Affiliated Practitioner Lists, as applicable (see § 414.1425(a) for information on the APM Participant Lists used for QP determinations) for the 2024 QP performance period third snapshot QP determination date to estimate the number of QPs for the 2027 QP Performance Period. For models starting in the 2027 QP Performance Period we estimated performance based on projected participation. We examined the extent to which Advanced APM participants will meet the QP Thresholds of having at least 75 percent of their Part B covered professional services or at least 50 percent of their Medicare beneficiaries were attribution eligible thresholds.

c. Estimated Number of MIPS Eligible Clinicians in the CY 2027 Performance Period/2029 MIPS Payment Year

(1) Initial Population of Clinicians Included in the RIA Baseline and Proposed Policies Models

For this proposed rule, we applied the same assumptions as in the CY 2026 PFS final rule (90 FR 49980) to estimate our initial population of clinicians using 2024 performance data. Specifically, we used the CY 2024 final reconciled eligibility determination file, same as the 2023 file described in the CY 2026 PFS final rule (90 FR 49980). This file reconciles eligibility from two determination periods and aligns with the CY 2024 performance period submissions data on which we based this model. Our analysis included 1,984,786 clinicians with PFS claims in this initial population. This initial population of clinicians was used to determine eligibility using the methodology described in the following sections.

(2) Estimated Number of MIPS Eligible Clinicians After Applying Eligibility Assumptions

(a) Methods and Assumptions Used To Estimate Eligibility

After identifying the clinician population with PFS claims, we applied the same eligibility assumptions and determination process described in the CY 2026 PFS final rule (90 FR 49980). We did not propose any modifications to MIPS eligibility requirements and the same eligibility assumptions apply to both the baseline and proposed policies model.

For our impact analysis, we established the ''required eligibility'' category, which means the clinician exceeds the low-volume threshold in all three criteria (§§ 414.1305 and 414.1310(b)(1)(iii)) and is subject to a MIPS payment adjustment. We based this estimate on the CY 2024 performance period data described in this section of this proposed rule, which includes the three low-volume criteria.

Our next two eligibility assumptions concern clinicians participating in MIPS through groups. They may voluntarily participate in MIPS, but are not required to participate. First, our group eligibility, includes clinicians with a

group submission, and their group exceeds all three low-volume threshold criteria. Second, we apply our opt-in eligibility assumptions. Individuals or groups who exceed the low-volume threshold in at least one criterion, but not all three, may elect to opt in. Based on the number of individuals who opted in to MIPS in performance year 2024, our model estimates that these clinicians will continue to opt in to MIPS in CY2027 performance period/2029 MIPS payment year.

Additionally, we estimate the number of ''Potentially MIPS Eligible'' clinicians. These clinicians are not included in our total number of MIPS eligible clinicians. These clinicians are potentially eligible because they are either opt-in eligible but did not opt-in or group eligible but did not report.

Finally, we estimate the number of clinicians who are neither MIPS eligible nor potentially MIPS eligible. They include clinicians who are below all three low-volume threshold criteria (both as an individual and as a group), QPs, and clinicians excluded from MIPS for other reasons, such as those with a non-MIPS-eligible clinician type or newly enrolled in Medicare.

After applying these assumptions to our initial population, we estimate that there will be 586,925 MIPS eligible clinicians with ~$51.70 billion in allowed charges in the CY2027 performance period/2029 MIPS payment year.

(b) MIPS Eligibility Estimates

In our policies model, we estimate to have 586,925 MIPS eligible clinicians Table D–B14 summarizes our eligibility estimates for the policies model after applying our assumptions outlined in this section of this proposed rule.

TABLE D-B14: ESTIMATION OF MIPS ELIGIBILITY STATUS FOR CY 2027 PERFORMANCE PERIOD/2029 MIPS PAYMENT YEAR USING THE CY 2027 PFS PROPOSED RULE ASSUMPTIONS

Eligibility Status	Predicted Participation Status in MIPS Among Clinicians	Number of Clinicians	PFS allowed charges ($ in mil)[1]
MIPS Eligible Clinicians			
MIPS eligible (always subject to a MIPS payment adjustment because individual clinicians exceed the low-volume threshold in all 3 criteria)	Reported to MIPS	94,895	$28,668
	Did not Report to MIPS	36,898	$11,100
Group eligibility (only subject to payment adjustment because clinicians' groups exceed low-volume threshold in all 3 criteria)	Had a group submission	451,654	$11,710[2]
Subgroup Eligible	MVP Subgroup reporting	286	$14
Opt-In eligibility assumptions (only subject to a positive, neutral, or negative adjustment because the individual or group exceeds the low-volume threshold in at least 1 criterion but not all 3, and they elect to opt-in to MIPS)	Opted-in To MIPS	3,192	$204
Total Number of MIPS Eligible Clinicians and the associated PFS allowed charges		**586,925**	**$51,695**
Potentially MIPS Eligible Clinicians			
Potentially MIPS Eligible (not subject to payment adjustment for non-participation; could be eligible for one of two reasons: (1) meet group eligibility; or (2) opt-in eligibility criteria)	Opt-in Eligible; Do not opt-in	176,361	$5,594
	Group Eligible; Did not Report	497,433	$11,590
Total Number of Clinicians Potentially MIPS Eligible		673,794	$17,184
Not MIPS Eligible Clinicians			
Below the low-volume threshold (never subject to payment adjustment; both individual and group is below all 3 low-volume threshold criteria)	Not applicable	130,199	$807
Excluded for other reasons (Non-eligible clinician type, newly enrolled)	Not applicable	91,962	$635
Qualified Participant (QP)	Not applicable	501,906	$23,259
Total Number of Clinicians Not MIPS Eligible		**1,397,861**	**$41,885**
Total Number of Clinicians (MIPS and Not MIPS Eligible)		**1,984,786**	**$93,580**

[1]Allowed charges estimated in 2024 dollars and projected to 2029 dollars (payment year. Low-volume threshold is calculated using allowed charges. MIPS payment adjustments are applied to the paid amount.

[2]Most clinicians are represented by Group submissions yet are below LVT and have low allowed charges.

d. Modeling Approach and Methods for MIPS Value Pathways (MVPs) and Traditional MIPS

(1) Summary of Approach

In this proposed rule, we present several proposals that impact the measures and activities, the performance category scores, final scores, and MIPS payment adjustments for MIPS eligible clinicians. In section IV.A. of this proposed rule, we outline these changes in more detail and describe our methodology to estimate MIPS payment adjustments for the CY 2027 performance period/2029 MIPS payment year. We then present the impact of the policies in the CY 2027 performance period/2029 MIPS payment year by comparing select metrics to the baseline model. By comparing model outputs between the baseline model and the proposed policies model, we are able to observe the impact of the policies proposed for the CY 2027 performance period/2029 MIPS payment year. MIPS eligible clinicians' final scores are calculated based on the clinicians' performance on measures and activities specified under the four MIPS performance categories: quality, cost, improvement activities, and Promoting Interoperability. MIPS eligible clinicians can participate in the

four MIPS performance categories as an individual, group, virtual group, APM Entity, and via traditional MIPS, the APM Performance Pathway (APP), or MVP reporting options. MIPS APM participants who are ACOs participating in the shared saving program are required to report through the APP/APP+ measure set. The APP or APP+ reporting option only scored on three performance categories: quality, improvement activities, and Promoting Interoperability. Our simulation applies the proposed and baseline policies to the existing scoring engine.

(2) Methodology To Assess Impact for MIPS Value Pathways

At § 414.1365(b), we required MVP Participants (which can be a group, individual, subgroup, or APM entity) to register to report a particular MVP prior to submitting. We assessed whether to use 2024 MVP registration data to estimate MVP participation and policy impact but elected not to simulate the impact for MVP because we do not have sufficient MVP scoring data for modeling and simulation. Thus, modeling based on limited data is less reliable for impact assessment. As more MVP scoring data becomes available in the future, we will reassess our methodology for estimating MVP participation, final scores, and payment adjustments.

(3) Methodology To Assess Impact for Traditional MIPS

To estimate the impact of the policies on MIPS eligible clinicians, we use the data from performance year 2024, including data submitted for the quality, cost, improvement activities, and Promoting Interoperability performance categories and claims data for the cost performance category.

We supplemented this information with the most recent data available for CAHPS for MIPS and CAHPS for ACOs, administrative claims data for certain quality measures, and other data sets. For the CY 2027 performance period/2029 MIPS payment year, we calculate hypothetical final scores for the baseline and policies models for each MIPS eligible clinician by applying appropriate measure level, performance category, and final scoring policies.

(a) Methodology To Estimate the Quality Performance Category Score

We used the CY 2026 PFS final rules as the starting point of our baseline model (90 FR 49982). This includes our policies regarding the new benchmark for Administrative Claims measures and scoring topped out measures impacted by limited measure choice. Please refer to the CY 2026 PFS final rule for a comprehensive, detailed discussion of finalized policies (90 FR 49266).

Our policies model incorporates the following policies from this proposed rule:

- In section IV.B.1.b.(3) of this proposed rule, to facilitate fairer scoring, we proposed to remove the scoring cap and change the benchmarking approach for additional topped out measures applicable to clinicians facing both limited measure choice and limited scoring opportunities as well as MIPS Core Measures. We do not simulate the addition or removal of quality measures outlined in section IV.A.4.d.(1) of this proposed rule because current data from the CY 2024 performance period do not include new measures, and we cannot estimate the impact of removing measures since we are not able to predict clinician response in measure selections.

In section IV.B.1.b.(1) of this proposed rule, we proposed to remove the requirement to submit one outcome or high priority measures and instead require the submission of a MIPS Core Measure. We propose that small practices with no more than 15 clinicians would be exempt from the MIPS Core Measure requirement. CMS internal analysis found 57 percent of the MVP submissions in performance year 2024 did not contain any of the proposed MIPS Core measures. Modeling quality performance category score with insufficient historical submission data will introduce uncertainty and complexity to the modeling simulation. Working under this limitation, we believe the previous outcome/high-priority reporting requirement and scoring rules reflected in the performance year 2024 data can serve as a proxy for core measure reporting in the models. As a result, we do not simulate the MIPS Core Measure reporting proposal. We did, however, model the impact of the core measure exemption for small practices.

(b) Methodology To Estimate the Cost Performance Category Score

We estimate the cost performance category score using the same methodology as described in the CY 2026 PFS final rule (90 FR 49982) for the baseline and the proposed policies models.

We do not model the impact of the Acute Kidney Injury requiring New Inpatient Dialysis (AKI) measure because it was suppressed for the CY 2024 performance period/2026 MIPS payment year. Therefore, there was no performance data available in 2024 to model the impact of the Acute Kidney Injury requiring New Inpatient Dialysis (AKI) measure.

(c) Methodology To Estimate the Promoting Interoperability Performance Category Score

We estimate the Promoting Interoperability performance category score using the same methodology as described in the CY 2026 PFS final rule (90 FR 49982) for the baseline model and the proposed models.

For the proposed policy model, we simulate the following changes:

In section IV.A.4.d.(4) of this proposed rule, we propose the removal of three attestations in the Promoting Interoperability performance category: ONC Direct Review, ONC–ACB Surveillance, and Security Risk Analysis.

(d) Methodology To Estimate the Improvement Activities Performance Category Score

For the baseline model, we use the same method to estimate the improvement activities performance category score as described in the CY 2026 PFS final rule (90 FR 49983), including alignment with the clarification provided regarding IA automatic weighting for APM participants (89 FR 79366).

In section IV.A.4.d.(3) of this proposed rule, we propose updates to the Improvement Activities inventory, such as removing activities. There is no historical data reflecting IA inventory updates, such as activity removal, for us to estimate potential impact. Our RIA models cannot predict how clinicians will alter their behavior once activities are removed.

(e) Methodology To Estimate the Complex Patient Bonus Points

This proposed rule does not include proposals to modify the complex patient bonus. Therefore, for the baseline and proposed policies RIA model, we used the previously established method to calculate the complex patient bonus as described in the CY 2022 PFS final rule (86 FR 64996).

(f) Methodology To Estimate the Final Score

We do not propose any changes to how we calculate the MIPS final score. Our baseline and proposed policies models assign a final score for each TIN/NPI by multiplying each estimated performance category score by the corresponding performance category weight, adding the products together, multiplying the sum by 100 points,

adding the complex patient bonus, and capping at 100 points.

For both models, after adding any applicable complex patient bonus, we reset any final scores that exceeded 100 points to equal 100 points. For MIPS eligible clinicians who were assigned a weight of zero percent for any performance category, we redistributed the weights according to § 414.1380(c).

For the purposes of this model, if a MIPS eligible clinician was approved for reweighting of one or more performance categories in the baseline model according to the data from the CY 2024 performance period/2026 MIPS payment year, we continue to apply that reweighting in our proposed policy model by assigning them a neutral score equal to the performance threshold if all categories were reweighted or assigning the applicable weights to the categories which were reweighted. Although it is unlikely (but possible) that the exact same clinicians will apply for and receive reweighting in both the CY 2024 performance period/2026 MIPS payment year (which our data is based on) and the CY 2027 performance period/2029 MIPS payment year (which we are simulating), we believe that this assumption accurately reflects future clinician behavior for two reasons. First, while the exact same MIPS eligible clinicians may not receive reweighting in two different years, we believe that this assumption allows us to quantify the impact of the reweighting on a population level. In other words, even if the same clinicians do not apply for and receive reweighting in these two different years, the absolute number of reweighting and the characteristics of practices that receive reweighting are likely to remain similar. Secondly, if we were not to assign reweighting to those MIPS eligible clinicians, many of them would receive a very low final score because they did not submit data for one or more performance categories during the year in which they received reweighting. We do not believe that it is a realistic assumption that, in the absence of reweighting, those clinicians will continue not to submit data. For these reasons, we assume that clinicians who received reweighting in the CY 2024 performance period/2026 MIPS payment year are also approved for reweighting in the CY 2027 performance period/2029 MIPS payment year. These clinicians are assigned a score of the performance threshold (75) in our model because this corresponds with a neutral (0 percent) payment adjustment.

(g) Methodology To Estimate the MIPS Payment Adjustment

For the baseline and proposed policies models, we applied the hierarchy as finalized in the CY 2024 PFS final rule (86 FR 65536 through 65537) to determine which final score should be used for the payment adjustment for each MIPS eligible clinician when more than one final score is available. We then calculate the parameters of an exchange function in accordance with the statutory requirements related to the linear sliding scale, budget neutrality, and minimum and maximum adjustment percentages.

For the baseline model, we apply the performance threshold of 75 points finalized in the CY 2026 PFS final rule. In this proposed rule, we do not make any changes to the performance threshold. Therefore, for both the baseline and proposed policies models, we use a performance threshold of 75 to calculate the exchange function for MIPS payment adjustments. We note that the results of this exchange are not identical between the baseline and proposed policies models. This is because the scaling factor used to determine positive adjustments is dependent on the total dollar amount of negative payment adjustments, and those adjustments differ as final scores are not identical between both models.

For both the baseline and proposed policies models, we use these resulting parameters to estimate the positive or negative MIPS payment adjustment based on the estimated final score and the allowed charges for covered professional services furnished by the MIPS eligible clinician.

(4) Methodology To Assess Impact for APM Performance Pathways

Shared Savings Program Accountable Care Organizations, participating in MIPS through a MIPS APM are scored on performance in the quality, Promoting Interoperability, and Improvement Activities performance categories. We included the following previously finalized policies for SSP ACOs participating in a MIPS APM into the CY 2027 baseline model:

- In 2024, the CMS Web Interface continued to be a collection type available to Shared Savings Program Accountable Care Organizations (SSP ACOs) reporting under the Advanced Payment Pathway. Because our model simulation relies on data from performance year 2024, including CMS Web Interface submissions, we are unable to predict which collection type SSP ACOs will adopt in lieu of the web interface for CY 2027 performance period/2029 MIPS payment year, given that the Web Interface collection type was no longer available after the CY 2025 performance period/2027 MIPS payment year.

We do incorporate the following proposals into the proposed model:

- In section IV.B.1.c.(1) of this proposed rule, we proposed to score all Medicare CQMs using flat benchmarks retroactively beginning in CY 2026.

(5) Simulation Results and Projected Impact to MIPS Eligible Clinicians

Based on the methodology described in section VII.F.11.d(3) of the proposed rule, we create a baseline and proposed policies simulation. Using this simulation, we estimate the impact of the policies of this proposed rule.

(a) Impact on Clinician Eligibility

In section VII.F.11.(c) of this proposed rule, we noted that we do not modify clinician eligibility and therefore there is no difference in the total number of MIPS eligible clinicians between our models.

(b) Impact on Clinician's Final Scores for Traditional MIPS

Table D–B15 shows the median final score by practice size and the percentage of MIPS eligible clinicians of each practice size with a positive, neutral, or negative adjustment.

TABLE D-B15: CY 2027 FINAL SCORE ESTIMATES BY PRACTICE SIZE

Practice Size[1]	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate[2]	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
(1) Solo	15,427	75.00	34.98	26.27	38.75
(a) Reporting	7,326	89.61	73.66	9.00	17.35
(b) Non-Reporting[3]	8,101	24.7	0.00	41.90	58.10
(2) Small (2 to 15)	60,634	87.98	67.60	14.84	17.36
(a) Reporting	47,596	91.35	86.37	4.02	9.62
(b) Non-Reporting[4]	13,040	75	0.04	54.33	45.64
(3) Medium (16 to 99)	115,077	88.63	89.91	7.17	11.92
(4) Large (100+)	395,787	89.20	94.19	1.67	4.14
Overall	586,925	88.83	87.30	4.76	7.94
Proposed Policies					
(1) Solo	15,427	75.00	34.77	26.28	38.95
(a) Reporting	7,325	90.23	73.23	9.00	17.77
(b) Non-Reporting	8,101	24.70	0.00	41.90	58.10
(2) Small (2 to 15)	60,634	88.61	67.65	14.83	17.52
(a) Reporting	47,596	91.84	86.17	4.01	9.82
(b) Non-Reporting	13,040	75	0.04	54.33	45.64
(3) Medium (16 to 99)	115,077	89.14	81.08	7.14	11.78
(4) Large (100+)	395,787	89.48	94.80	1.63	3.57
Overall	586,925	89.21	87.73	4.72	7.55

[1]Practice size refers to the number of NPIs in a TIN

[2]The median final score includes clinicians who receive reweighting for all MIPS performance categories our policies at § 414.1380(c)(2). These clinicians who have all performance categories reweighted are assigned a score of 75 (neutral payment adjustment) in our model.

[3]52.51% of the solo practitioners did not report by not submitting any data

[4]21.51% of the small practice providers did not report by not submitting any data

MIPS performance and financial distribution remain stable with marginal improvements in the overall median final scores and slightly higher overall percentage of clinicians receiving a positive payment adjustment. The overall median final score is 88.83 in the baseline model and 89.21 in the proposed policies model, a slight increase for all practice sizes. About 87.3 percent of eligible clinicians receive a positive payment adjustment in the baseline model and 87.73 percent in the proposed policies model Overall, the percentage of eligible clinicians with negative payment adjustment will drop slightly, from 7.94 percent baseline to 7.55 percent proposed.

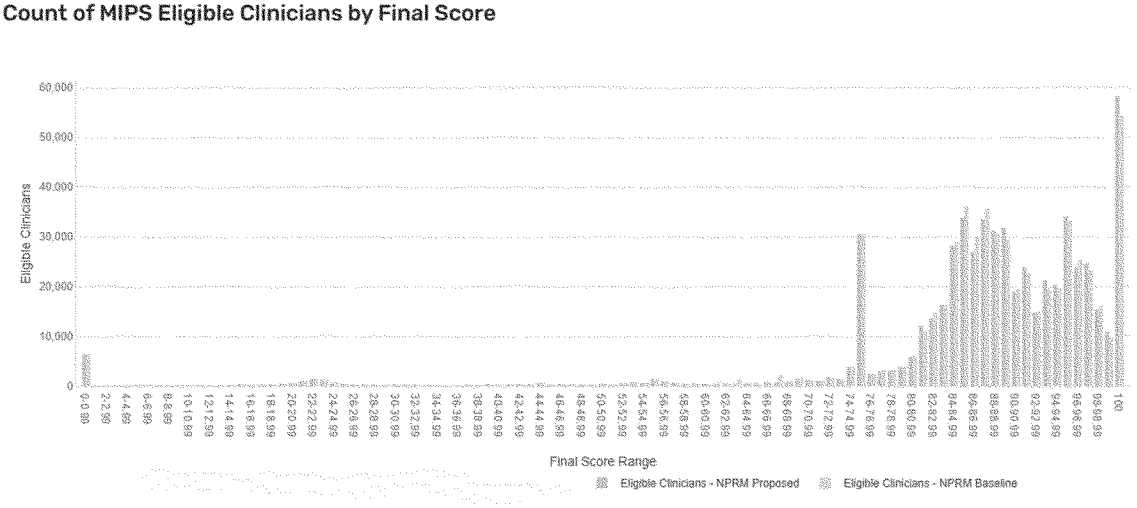
Table D–B16 shows the median quality category score for MIPS eligible clinicians who are scored on the quality performance category for the baseline and proposed policies model. Overall, the median quality performance category score showed a marginal increase from 83.16 to 83.72. Solo practitioners, who actively report, experience the most noticeable increase (+2.25) in median quality performance category score compared to those of other practice sizes.

TABLE D-B16: CY 2027 QUALITY SCORE ESTIMATES BY PRACTICE SIZE

Practice Size	MIPS Eligible Clinicians Receiving Quality Score	Total Number of MIPS Eligible Clinicians	Percent of MIPS Eligible Clinicians Receiving Quality Score	Median Quality Score Estimate
Baseline				
Solo (1)	11,289	15,427	73.18	52.61
(a) Reporting	6,602	7,326	90.12	85.95
(b) Non-reporting	4,687	8,101	57.86	0
Small (2-15)	49,995	60,634	82.45	86.31
(a) Reporting	44,043	47,594	92.54	89.15
(b) Non-reporting	5,952	13,038	45.65	0
Medium (16-99)	97,892	115,077	85.07	81.89
Large (100+)	377,846	395,787	95.47	83.29
Overall	**537,022**	**586,925**	**91.50**	**83.16**
Proposed Policies				
Solo (1)	11,288	15,427	73.17	51.91
(a) Reporting	6,601	7,325	90.12	88.2
(b) Non-reporting	4,687	8,102	57.85	0
Small (2-15)	49,999	60,634	82.46	87.93
(a) Reporting	44,047	47,596	92.54	90.63
(b) Non-reporting	5,952	13,038	45.65	0
Medium (16-99)	97,926	115,077	85.10	83.13
Large (100+)	378,001	395,787	95.51	83.72
Overall	**537,214**	**586,925**	**91.53**	**83.72**

Figure D–B1 shows the distribution of final scores for all MIPS eligible clinicians. Note that there is a noticeable size of MIPS eligible clinicians with a final score of 75. MIPS eligible clinicians whom we approved for reweighting all MIPS performance categories in accordance with our reweighting policies at § 414.1380(c)(2) are assigned a final score of exactly the performance threshold (75). Overall, the distribution is left skewed, indicating that many more clinicians would receive final scores on the higher side.

FIGURE D-B1: Count of MIPS Eligible Clinicians by Final Score



(i) Impact to Small and Solo Practices

Across both the baseline and proposed policy models, approximately 15,427 MIPS-eligible clinicians are solo practitioners, accounting for 2.63 percent of all MIPS-eligible clinicians.

The median final score for solo practitioners who actively report data is 89.61 in the baseline model and 90.23 in the proposed policies model. However, the median final scores for solo practitioners who do not report data are substantially lower: 24.7 in both baseline and proposed policies models. The portion of all solo practitioners receiving a positive adjustment is starkly different between reporting and non-reporting solo practitioners. About 73.66 percent (baseline) and 73.23 percent (proposed) reporting solo practitioners will receive a positive payment adjustment; whereas 0 percent (both baseline and proposed) non-reporting solo practitioners will receive a positive payment adjustment.

Many solo practitioners do not actively submit data to MIPS despite being MIPS eligible clinicians. Based on the 2024 performance data, we estimate that about 52.51 percent of solo practitioners receiving a MIPS payment adjustment do not submit any data to MIPS.

Table D–B17 shows that, even among reporting solo practitioners, the percentage receiving a positive payment adjustment is lower than that of clinicians from small, medium, or large practices. Similarly, even for reporting solo practitioners, a higher proportion of them face negative payment adjustments compared to those in small, medium, and large practices Figure D–B2 shows the distribution of final scores for solo practitioners. Both baseline and proposed policies box plots show identical final score distributions, and both baseline and proposed policies models show a large distance between the lower and upper quartiles. Figure D–B3 shows the final score distribution for all MIPS eligible clinicians between the baseline and the proposed policies models. These box plots also show identical final score distributions; however, the distance between lower and upper quartiles is substantially narrower for all MIPS eligible clinicians than it is for solo practitioners.

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FIGURE D-B2: Distribution of Final Scores for Solo Practitioners

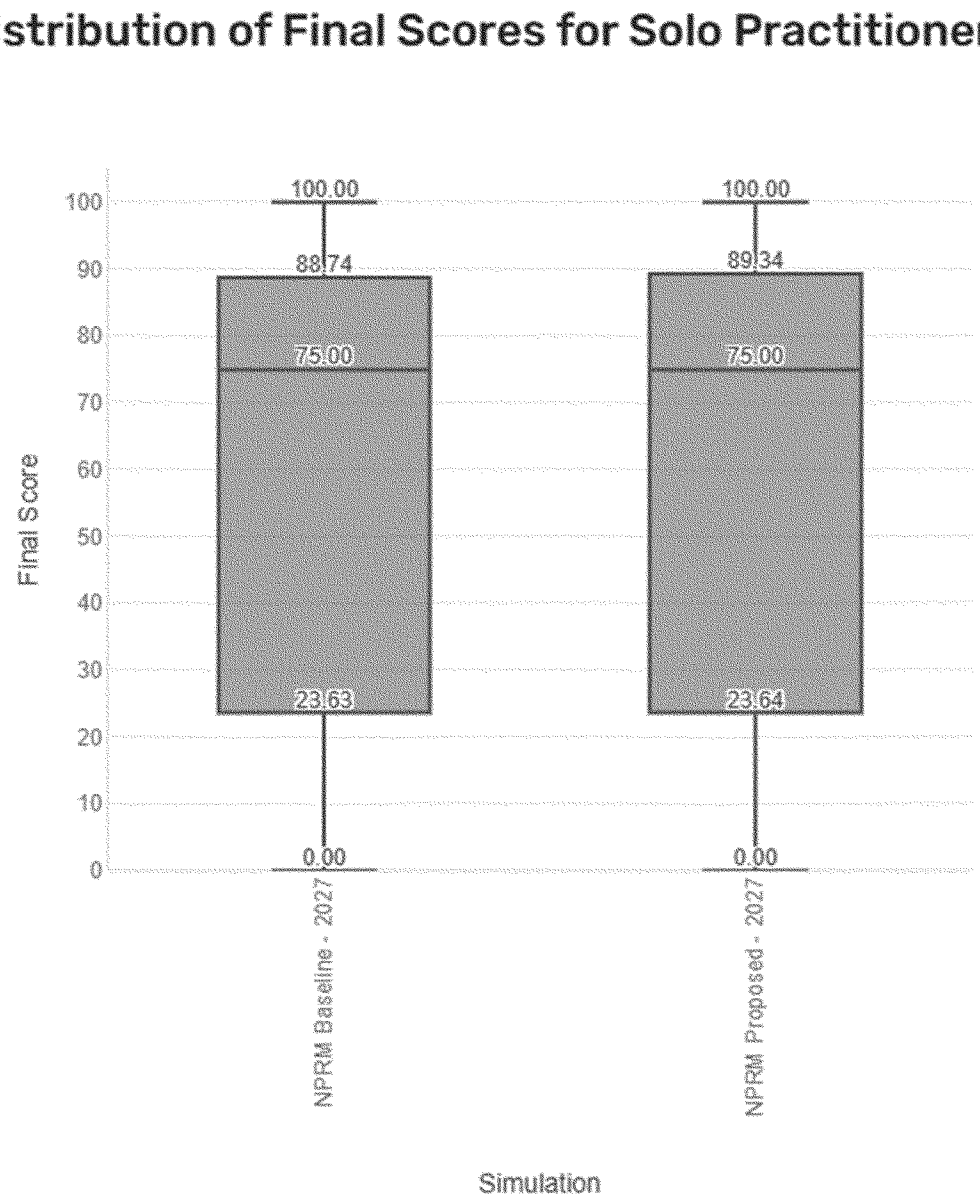
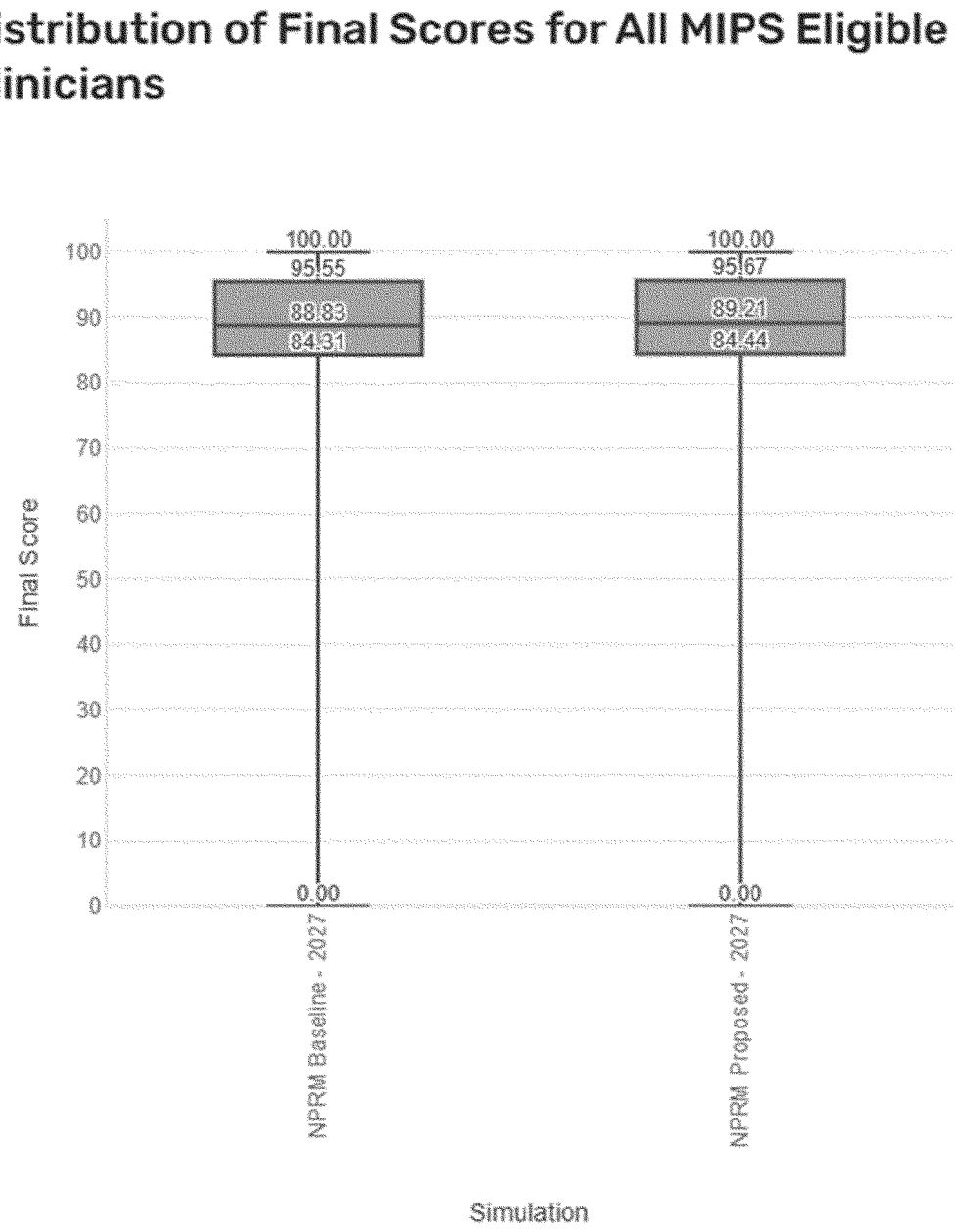


FIGURE D-B3: Distribution of Final Scores for All MIPS Eligible Clinicians



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Small practices, defined at § 414.1305 as groups with 2 to 15 clinicians, have a median final score of 87.98 in the baseline and 88.61 in the policies model. However, as shown in Table D–B15, the median final score for the reporting small practice providers is 91.35 (baseline) and 91.84 (proposed), substantially higher than the median final score of 75—in both baseline and proposed policies models—for the non-reporting small practice providers. They are also higher than the median final scores for all MIPS eligible clinicians who submit data, which are 89.85 in the proposed policy model and 89.66 in the baseline model. This indicates that small practice providers who submit MIPS data can perform better than it is for the medium-sized and large practice providers. Table D–B17 shows the percentage of clinicians, by practice size, either do or do not submit data to MIPS and their corresponding median final scores. Note that, in the proposed policies model, the median final scores for small, medium, and large practice clinicians who do not submit data are 75. This indicates that many small, medium or large practice clinicians who do not submit data to MIPS have been approved for reweighting of all of their MIPS performance categories under our policies at § 414.1380(c)(2). In contrast, the median final scores for solo clinicians, who do not submit data are 24.70. This indicates that many of them are either not being eligible for or not applying for our reweighting policies for extreme uncontrollable circumstances or hardships. Over 90 percent of the medium-sized and large practice clinicians submit data to MIPS. It is possible that the remaining 10 percent

or less MIPS eligible clinicians who do not submit data to MIPS are primarily those who have received reweighting under our policies at § 414.1380(c)(2).

TABLE D-B17: PERCENTAGE OF MIPS ELIGIBLE CLINICIANS WHO SUBMIT DATA AND MEDIAN FINAL SCORE

	Percent of MIPS Eligible Clinicians who Submit Data (by practice size)	Median Final Score of MIPS Eligible Clinicians who Submit Data	Median Final Score of MIPS Eligible Clinicians who Do not submit data.
Baseline			
(1) Solo	47.49	89.61	24.70
(2) Small (2 to15)	78.49	91.35	75.00
(3) Medium (16 to 99)	90.67	89.74	75.00
(4) Large (100+)	97.67	89.37	75.00
Overall	**93.00**	**89.66**	**75.00**
Proposed Policies			
(1) Solo	47.48	90.23	24.70
(2) Small (2 to 15)	78.50	91.84	75.00
(3) Medium (16 to 99)	90.71	90.26	75.00
(4) Large (100+)	97.71	89.66	75.00
Overall	**93.03**	**89.85**	**75.00**

(ii) Impact to Rural Providers

In our data we assign rural practitioners a special status. Impact assessment of this group of clinicians indicates that their overall final scores are slightly lower than the overall MIPS eligible clinicians. Table D–B18 shows the median final score and the percentage of eligible clinicians with a positive, neutral, or negative adjustment by practice size for rural practitioners.

TABLE D-B18: CY 2027 FINAL SCORE ESTIMATES BY PRACTICE SIZE FOR RURAL PRACTITIONERS ONLY

Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
Solo (1)	1,941	75.00	39.41	16.80	43.79
(a) Reporting	1,038	88.34	73.70	5.68	20.62
(b) Non-reporting[1]	903	22.74	0.00	29.57	70.43
Small (2-15)	8,652	88.58	72.03	9.50	18.47
(a) Reporting	7,218	90.92	86.34	2.47	11.19
(b) Non-reporting[2]	1,434	26.77	0.00	44.91	55.09
Medium (16-99)	20,529	89.21	84.70	4.25	11.04
Large (100+)	35,683	87.23	96.07	1.48	2.45
Overall	**66,805**	**87.37**	**87.82**	**3.82**	**8.37**
Proposed Policies					
Solo (1)	1,941	75.00	39.26	16.80	43.95
(a) Reporting	1,038	88.9	73.41	5.68	20.91
(b) Non-reporting[1]	903	22.74	0.00	29.57	70.43
Small (2-15)	8,652	89.08	72.11	9.50	18.39
(a) Reporting	7,218	91.33	86.44	2.47	11.10
(b) Non-reporting[2]	1,434	26.77	0.00	44.91	55.09
Medium (16-99)	20,524	89.8	84.63	4.23	11.14
Large (100+)	35,684	87.22	96.09	1.42	2.49
Overall	**66,801**	**87.46**	**87.81**	**3.77**	**8.41**

[1]46.52% of the rural, solo practitioners did not report by not submitting any data[2]14.22% of the rural, small practice providers did not report by not submitting any data.

The overall median final score for rural practitioners is 87.37 in the baseline model and 87.46 in the policies model. This is slightly lower than the median final score for all MIPS eligible clinicians, which is 88.83 in the baseline model and 89.21in the policies model. According to the results from the proposed policies model, rural clinicians in large practices have a slightly lower median final score (87.22) than it is for reporting, rural, solo practitioners (88.9), reporting, rural, small practice providers (91.33), and rural medium-size practice providers (89.80).

(iii) Impact to Safety Net Providers

(A) Updated Definition of Safety Net Providers

In the CY 2022 PFS final rule (87 FR 70094), we finalized our complex patient bonus methodology. This bonus is composed of two distinct calculations which are added together: Medical Complexity and Social Risk. Medical Complexity is determined based on a MIPS eligible clinicians Hierarchical Conditions Categories risk score and social risk is determined based on the proportion of a MIPS eligible clinicians Medicare patient population who are dually eligible for both Medicare and Medicaid.

In the 2024 PFS final rule (88 FR 79513), we compared the performance of clinicians who received the complex patient bonus with our overall population. As we further developed our model, we decided to adopt a more precise definition of safety net providers. We believe that by narrowing our definition of safety net providers to clinicians fall in the top 20 percentile for their percentage of patients who are dually eligible for Medicare and Medicaid, we can identify providers who care for a large proportion of socially vulnerable individuals.

Table D–B19 shows the median final score estimates for safety net providers under this definition. In the proposed policies model, safety net providers have a higher median final score (93.22) than the overall MIPS eligible clinicians (89.21). Safety net solo practitioners who actively report data have a substantially higher median final score (93.84 in the proposed model) than that from the non-reporting, safety net, solo practitioners (29.41 in the proposed model). Almost 57 percent of safety net solo practitioners and over 30 percent of safety net small practice providers did not report by not submitting any MIPS data, compared to ~53 percent and ~22 percent of the overall solo practitioners and small practice providers, respectively.

TABLE D-B19: CY 2027 FINAL SCORE ESTIMATES BY PRACTICE SIZE FOR SAFETY NET PRACTITIONERS ONLY

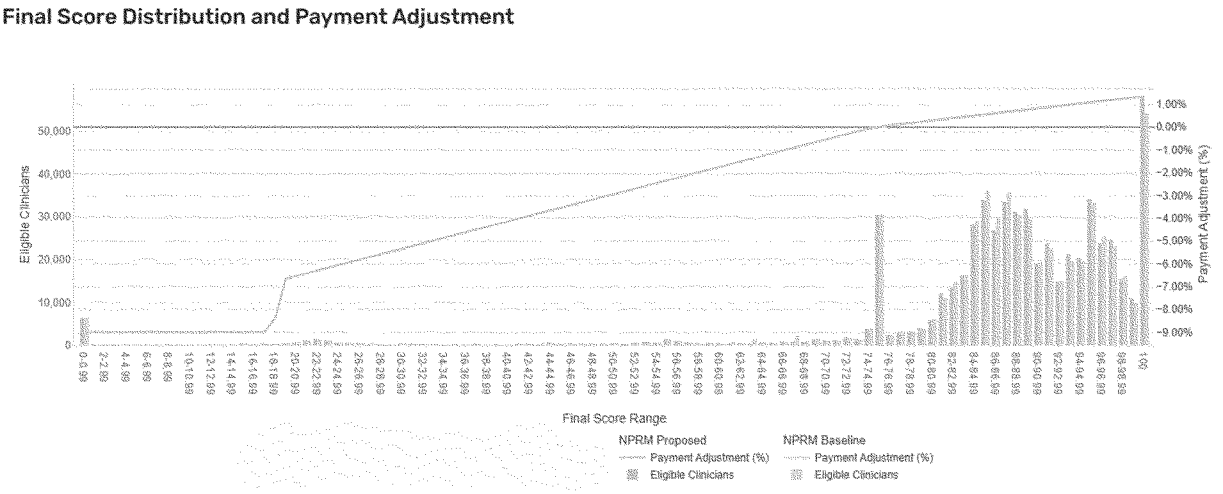
Practice Size	Total Number of MIPS Eligible Clinicians	Median Final Score Estimate	Percent Eligible Clinicians with Positive Payment Adjustment	Percent Eligible Clinicians with Neutral Payment Adjustment	Percent Eligible Clinicians with Negative Payment Adjustment
Baseline					
(1) Solo	4,396	75.00	32.21	30.94	36.85
(a) Reporting	1,918	93.35	73.83	10.74	15.43
(b) Non-Reporting[1]	2,478	29.41	0.00	46.57	53.43
(2) Small (2 to 15)	11,557	85.70	58.48	18.36	23.16
(a) Reporting	8,060	94.35	83.80	5.19	11.02
(b) Non-Reporting[2]	3,497	59.21	0.11	48.73	51.16
(3) Medium (16 to 99)	27,009	91.38	78.14	7.99	13.87
(4) Large (100+)	75,673	93.42	93.90	1.20	4.90
Overall	**118,635**	**92.54**	**84.58**	**5.52**	**9.90**
Proposed Policies					
(1) Solo	4,396	75.00	32.19	30.94	36.87
(a) Reporting	1,918	93.84	73.77	10.74	15.48
(b) Non-Reporting	2,478	29.41	0.00	46.57	53.43
(2) Small (2 to 15)	11,557	85.75	58.72	18.35	22.93
(a) Reporting	8,060	95.44	84.14	5.17	10.68
(b) Non-Reporting	3,497	59.22	0.11	48.73	51.16
(3) Medium (16 to 99)	27,004	92.59	78.87	7.95	13.18
(4) Large (100+)	75,677	93.93	96.74	1.09	2.18
Overall	**118,634**	**93.22**	**86.57**	**5.44**	**7.99**

[1]56.37% of the safety-net, solo practitioners did not report by not submitting any data
[2]30.26% of the safety-net, small practice providers did not report by not submitting any data

(c) Impact to MIPS Eligible Clinicians' Payment Adjustments

We did not propose to increase the performance threshold in this final rule. Table D–B21 shows that the payment adjustments are very similar between the baseline and proposed policies model. This is because our proposed policies can maintain program stability. The maximum positive payment adjustment is 1.37 percent in the baseline model and 1.34 percent in the proposed policies model. The baseline model estimates redistributing $332 million, and the proposed policies model estimates redistributing $330 million. This slight decrease is due to slightly higher proportions of clinicians receiving positive payment adjustments in the proposed policies model (87.73 percent) than it is in the baseline model (87.30 percent). As the proportion of MIPS eligible clinicians receiving a positive payment adjustment increases slightly, the portion of clinicians receiving a negative payment adjustment also slightly decreases accordingly (7.55 percent in the proposed policies model vs. 7.94 percent in the baseline model). As the proportion of MIPS eligible clinicians receiving negative payment adjustments decreases slightly, the budget neutral funds available for redistribution also decrease somewhat.

FIGURE D-B5: Final Score Distribution and Payment Adjustment



We also report on the median positive and negative payment adjustments by practice size in Table D–B20.

TABLE D-B20: CY 2027 MEDIAN POSITIVE AND NEGATIVE PAYMENT ADJUSTMENT ESTIMATES BY PRACTICE SIZE

Practice Size	Median Positive Payment Adjustment[1]	Median Negative Payment Adjustment
Baseline		
Solo (1)	+1.01	-6.43
(a) Engaged	+1.01	-2.67
(b) Non-Reporting	N/A[2]	-9.00
Small (2-15)	+0.96	-6.08
(a) Reporting	+0.96	-1.50
(b) Non-Reporting	+0.08	-6.74
Medium (16-99)	+0.87	-1.92
Large (100+)	+0.81	-1.35
Overall	+0.83	-2.46
Proposed Policies Model		
Solo (1)	+1.03	-6.42
(a) Engaged	+1.03	-2.53
(b) Non-Reporting	N/A	-9.00
Small (2-15)	+0.97	-6.06
(a) Reporting	+0.97	-1.47
(b) Non-Reporting	+0.08	-6.74
Medium (16-99)	+0.88	-1.92
Large (100+)	+0.80	-2.08
Overall	+0.83	-2.62

[1]Final score above the performance threshold. The median negative adjustment is defined as the medium payment adjustment among clinicians with a final score below the performance threshold. Neither median includes clinicians with a final score equal to the performance threshold.

[2]There are no solo practitioners who did not report data and received a Positive payment adjustment. The maximum they could receive is from the Quality Admins Claims, and even if they received excellent scores, it would still be less than the performance threshold.

The overall median negative payment adjustment in the proposed policies model is slightly lower than it is in the baseline model. That is because the proposed policies model has a higher mean final score than the baseline model (89.21 proposed vs. 88.83 baseline).

e. Additional Impacts from Outside Payment Adjustments

(1) Burden Overall

In addition to policies affecting payment adjustments, we are proposing several policies that, if finalized, will impact burden. In section V.B.7. of this proposed rule, we estimate the burden impacts of proposed policy provisions.

(2) Additional Impacts to Clinicians

We provide additional burden discussions for policy provisions that we are unable to quantify.

(a) Modifications to the MIPS Improvement Activities Inventory

As discussed in section IV.A.4.d.(3) of this proposed rule, we are proposing updates to the MIPS Improvement Activities Inventory beginning with the CY 2027 performance period/2029 MIPS payment year. We do not expect these changes to affect our burden estimates for the number of estimated respondents or response time, as most of the improvement activities in the MIPS Improvement Activities Inventory remain unchanged for the CY 2027 performance period/2029 MIPS payment year. We refer readers to section IV.A.4.d.(3) of this proposed rule for details on the changes to the MIPS Improvement Activities Inventory.

(b) Qualifying Alternative Payment Model (APM) Participant (QP) Determinations

In section IV.F.2. of this proposed rule, we are proposing to modify the application of the QP and partial QP status. We note that year-over-year participation changes have historically had outsized impacts on our projections. For example, ACOs frequently add or remove participants as part of their operations. These changes in participation make it difficult to project how these proposals will impact clinicians who are determined to be QPs, Partial QPs, or previously reported MIPS (at the individual, group, subgroup, or APM Entity level), if at all. Accordingly, we have not adjusted our estimates related to performance category submissions due to these proposals. For details on these policies, see section IV.F.2. of this proposed rule.

(c) Third Party Intermediaries

In section IV.C. of this proposed rule, we are proposing to (1) add a requirement that CMS-approved third-party intermediaries may be terminated after failure to submit data for 1 year ; and (2) clarify that if a third party intermediary does not submit data for one year, they would be required to provide documentation and would be terminated if documentation cannot be provided and/or the documentation shows that they would not be submitting data for the given MIPS performance period. Due to the technical nature of these changes, there is no data available to quantify the burden for third party intermediaries during the CY 2027 performance period/2029 MIPS payment year. We refer readers to section IV.C. of this proposed rule for additional information on the policy proposals related to third party intermediaries.

G. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when we exercise agency discretion, presents rationale for our policies, and, where relevant, alternatives that were considered. For purposes of the payment impact on PFS services of the policies contained in this proposed rule, we presented previously in this section the estimated impact on total allowed charges by specialty.

X. Alternatives Considered Related to the Ambulatory Specialty Model

In section X.E. of this proposed rule, we discuss the mandatory ASM. We will test whether ASM leads to improved chronic condition management, higher quality care, and reduced costs by incentivizing ASM participants with the opportunity for positive payment adjustments to Medicare Part B covered professional services payments based on their performance on data reported on quality, cost, improvement activities, and CEHRT interoperability.

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. This proposed rule provides descriptions of the requirements that we would mandate and presents rationales for our decisions and, where relevant, alternatives that we considered. For example, we considered whether we should waive the requirement for ASM participants in rural areas to attest to complete IA–2: Establishing Communication and Collaboration Expectations with Primary Care using Collaborative Care Arrangements (CCAs) instead of providing the proposed rural scoring adjustment to an ASM participant's final score. Although ASM participants in rural areas may face challenges forming partnerships with primary care providers due to limited primary care availability, we believe that a rural scoring adjustment more broadly accounts for challenges that could affect ASM participant performance across the four ASM performance categories compared to only waiving IA–2.

We solicit comments on our proposals and on the alternatives that we have identified in this proposed rule.

H. Impact on Beneficiaries

As noted previously, we estimate that a combination of proposals for the Shared Savings Program, including introducing a growth adjustment, the increase to the sharing rate in BASIC track Level E, and the increase in the scaling factor for the prior savings adjustment, are expected to increase the number of ACOs in the program and correspondingly the size of the population of beneficiaries assigned to ACOs by up to one million beneficiaries per year, with roughly two-thirds of such increase attributable to the proposed growth adjustment. This growth in participation is likely to feature beneficiaries who might particularly benefit from care management because the growth adjustment is designed to attract new providers without experience in the program who are serving beneficiaries new to value-based care. Additionally, the proposed increase to the scaling factor for the prior savings adjustment, together with risk-adjusting the 5 percent cap on benchmark adjustments, could moderate the rebasing ratcheting effect and thereby improve the business case for ACOs serving high needs populations to invest additional resources in care management.

We note that in PY 2024, ACOs performed better on certain patient-experience and performance measures than physician groups participating in MIPS (90 FR 50003 and 50004). We refer readers to our discussion in the CY 2026 PFS final rule for additional details on ACOs' measure performance (90 FR 50002).

2. Quality Payment Program

There are several changes in this proposed rule that are expected to have a positive effect on beneficiaries. In general, we believe that many of these changes, including the MVP and subgroup provisions, will lead to meaningful feedback to beneficiaries on the type and scope of care provided by clinicians. Additionally, beneficiaries could use the publicly reported information on clinician performance in subgroups to identify and choose clinicians in multispecialty groups relevant to their care needs. Consequently, we anticipated the policies in this proposed rule will improve the quality and value of care provided to Medicare beneficiaries.

For example, several of the new quality measures include patient-reported outcome-based measures, which could be used to help patients make more informed decisions about treatment options. Patient-reported outcome-based measures provide information on a patient's health status from the patient's point of view and could also provide valuable insights on factors such as quality of life, functional status, and overall disease experience, which will not otherwise be available through routine clinical data collection. Patient-reported outcome-based measured are factors frequently of interest to patients when making decisions about treatment.

3. Ambulatory Specialty Model

We believe that the refinements to ASM proposed in this proposed rule would not change the potential effects of ASM on beneficiaries. We continue to believe that ASM would have no impact on cost to beneficiaries because ASM payment adjustments will not affect Medicare beneficiary coinsurance amounts. The coinsurance will be calculated based on the Medicare allowed amounts before any ASM payment adjustment multipliers are applied to Medicare Part B payments for covered professional services.

I. Estimating Regulatory Familiarization Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this rulemaking, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on this rule will be the number of reviewers on of this last year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rulemaking. It is possible that not all commenters will review this rule in detail, and it is also possible that some reviewers will choose not to comment on this rule. For these reasons, we believe that the number of commenters will be a fair estimate of the number of reviewers of this year's rule.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimated that the cost of reviewing this rulemaking is $113.42, including overhead and fringe benefits *https://www.bls.gov/oes/current/oes_nat.htm*. Assuming an average reading speed, we estimate that it would take approximately 8.0 hours for the staff to review half of this proposed rule. For each facility that reviews the rule, the estimated cost is $907.36 (8.0 hours × $113.42). Therefore, we estimated that the total cost of reviewing this regulation is $12,239,821 ($907.36 × 13,549 reviewers on this year's proposed rule).

J. Accounting Statement

As required by OMB Circular A–4 (available at *https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf*), in Tables D–BXX and D–BXX (Accounting Statements), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2026 to CY 2027 based on the FY 2027 President's Budget baseline.

TABLE D-B21: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

CATEGORY	TRANSFERS
CY 2027 Annualized Monetized Transfers	Estimated decrease in expenditures of $2.1 billion for PFS CF update.
Bearers of Transfer Gain	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE D-B22: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

CATEGORY	TRANSFER
CY 2027 Annualized Monetized Transfers of beneficiary cost coinsurance.	-$0.4 billion
Bearers of Transfer Gain	Beneficiaries to Federal Government.

TABLE D-B23: ACCOUNTING STATEMENT FOR PROVISIONS FOR MEDICARE SHARED SAVINGS PROGRAM (CYS 2027 to 2036) ($ MILLIONS)

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation
BENEFITS				
Annualized monetized: Discount rate: 3%	-$565 million	-$1,058 million	-$115 million	Tables D-B8 through D-B11; summarized in total in Table D-B12
Annualized monetized: Discount rate: 7%	-$579 million	-$1,063 million	$134 million	Tables D-B8 through D-B11; summarized in total in Table D-B12

Notes: Negative values reflect a reduction in Federal net cost resulting from care management by ACOs. Estimates may be a combination of benefits and transfers. To the extent that the incentives created by Medicare payments change the amount of resources society uses in providing medical care, the more accurate categorization of effects would be as costs (positive values) or benefits/cost savings (negative values), rather than as transfers.

K. Conclusion

The analysis in the previous sections, together with the remainder of this proposed rule, provided an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this rule, provides an RIA. In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 10, 2026.

List of Subjects

42 CFR Part 400

Grant programs-health, Health facilities, Health maintenance organizations (HMO), Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 405

Administrative practice and procedure, Diseases, Health facilities, Health professions, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 406

Health facilities, Diseases, and Medicare.

42 CFR Part 407

Medicare.

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Biologics, Diseases, Drugs, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 417

Administrative practice and procedure, Grant programs-health, Health care, Health insurance, Health maintenance organizations (HMO), Loan programs-health, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 422

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 423

Administrative practice and procedure, Emergency medical services, Health facilities, Health maintenance organizations (HMO), Health professionals, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 427

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 428

Administrative practice and procedure, Biologics, Inflation rebates, Medicare, Prescription drugs.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Privacy, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 400—INTRODUCTION; DEFINITIONS

■ 1. The authority for part 400 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 44 U.S.C. Chapter 35.

■ 2. Section 400.200 is amended by adding a definition for ''Eligible noncitizen'' in alphabetical order to read as follows:

§ 400.200 General definitions.

* * * * *

Eligible noncitizen means an individual who, effective July 4, 2025, is an—

(1) Alien lawfully admitted for permanent residence under the Immigration and Nationality Act;

(2) Alien who has been granted the status of Cuban and Haitian entrant, as defined in section 501(e) of the Refugee Education Assistance Act of 1980; or

(3) Individual who lawfully resides in the United States in accordance with a Compact of Free Association referred to in 8 U.S.C. 1612(b)(2)(G).

* * * * *

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 3. The authority citation for part 405 continues to read as follows:

Authority: 42 U.S.C. 263a, 405(a), 1302, 1320b-12, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr, and 1395ww(k).

■ 4. Section 405.2463 is amended by—

■ a. Adding paragraph (a)(1)(iii);

■ b. In paragraph (b)(2) introductory text, removing the phrase ''a FQHC patient'' and adding in its place the phrase ''an FQHC patient or a RHC patient''; and

■ c. In paragraph (b)(3), removing the phrase ''Not before October 1, 2025'' and adding in its place the phrase ''Not before January 1, 2028'';

The addition reads as follows:

§ 405.2463 What constitutes a visit.

(a) * * *

(1) * * *

(iii) Furnished under the direct supervision of the RHC practitioner, a face-to-face encounter between a patient and either of the following:

(A) A qualified provider of medical nutrition therapy services as defined in part 410, subpart G, of this chapter.

(B) A qualified provider of outpatient diabetes self-management training services as defined in part 410, subpart H, of this chapter.

* * * * *

§ 405.2464 [Amended]

■ 5. Section 405.2464 is amended by—

■ a. In paragraph (b)(1), removing the phrase ''paragraphs (d) and (e) of this section'' and adding in its place the phrase ''paragraphs (c) through (h) of this section'';

■ b. In paragraph (b)(2)(i), removing the reference ''§ 405.2462(c)(1)'' and adding in its place the reference ''§ 405.2462(e)(1)'';

■ c. In paragraph (b)(2)(ii), removing the reference ''§ 405.2462(c)(2)'' and adding in its place the reference ''§ 405.2462(e)(2)''; and

■ d. In paragraph (g), removing the term ''an encounter'' wherever it appears and adding in its place the term ''services''.

■ 6. Section 405.2469 is amended by revising paragraph (d) to read as follows:

§ 405.2469 FQHC supplemental payments.

* * * * *

(d) *Per visit supplemental payment.* A supplemental payment required under this section is made to the FQHC when a covered face-to-face encounter, or an encounter furnished using interactive, real-time, audio and video telecommunications technology, or audio-only interactions in cases where the patient is not capable of, or does not consent to, the use of video technology, for the purposes of diagnosis, evaluation, or treatment of a mental health disorder, occurs between a Medicare Advantage enrollee and a practitioner as set forth in § 405.2463. A mental health encounter furnished using interactive, real-time, audio and video telecommunications technology, or audio-only interactions, is not payable unless the FQHC is in compliance with the in-person requirements set forth in § 405.2463(b)(3).

PART 406—HOSPITAL INSURANCE ELIGIBILITY AND ENTITLEMENT

■ 7. The authority for part 406 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395i-2, 1395i-2a, 1395p, 1395q, and 1395hh.

■ 8. Section 406.5 is amended by revising paragraph (a) to read as follows:

§ 406.5 Basis of eligibility and entitlement.

(a) *Hospital insurance without premiums.* Hospital insurance is available to most individuals without payment of a premium if they meet the following conditions:

(1) The individual—

(i) Is age 65 or over;

(ii) Has received social security or railroad retirement disability benefits for 25 months; or

(iii) Has end-stage renal disease. Subpart B of this part explains the requirements such individuals must meet to obtain hospital insurance without premiums.

(2) Effective July 4, 2025, the individual is a citizen or national of the United States or an eligible noncitizen as defined in 42 CFR 400.200.

* * * * *

■ 9. Section 406.6 is amended by revising paragraph (b) and adding paragraph (f) to read as follows:

§ 406.6 Application or enrollment for hospital insurance.

* * * * *

(b) *Individuals who need not file an application for hospital insurance.* An individual who meets the requirements of § 406.5(a)(2), and any of the following conditions need not file an application for hospital insurance:

* * * * *

(f) *Special rules for eligible noncitizens.* Individuals who only meet the requirements of § 406.5(a)(1), but do not also meet the requirements of § 406.5(a)(2), may subsequently meet both § 406.5(a)(1) and (2) due to a change in U.S. citizenship, U.S. nationality, or immigration status or category. For these individuals, the following requirements apply:

(1) An individual who meets the conditions of paragraph (b) of this section must contact SSA to initiate entitlement to hospital insurance. Entitlement may be retroactive for up to 6 months, but not earlier than the first month in which the individual met all of the requirements of § 406.5(a).

(i) If acceptable evidence establishes the month in which the individual first satisfied § 406.5(a)(2), SSA will use that month, subject to the applicable retroactivity limits noted in the paragraph (f)(1) of this section.

(ii) If the earliest month of eligibility cannot be established based on acceptable documentary evidence, entitlement will begin on the first day of the month in which SSA verifies that the individual satisfies § 406.5(a)(2), based on applicable data made available by the Department of Homeland Security.

(2) An individual who meets the conditions of paragraph (c) of this section must contact SSA to file an application for hospital insurance. Entitlement may be retroactive for up to 6 months, but not earlier than the first month in which the individual met all of the requirements of § 406.5(a).

(i) If acceptable evidence establishes the month in which the individual first satisfied § 406.5(a)(2), SSA will use that month, subject to the applicable retroactivity limits noted in the paragraph (fx)(2) of this section.

(ii) If the earliest month of eligibility cannot be established based on acceptable documentary evidence, entitlement will begin on the first day of the month in which SSA verifies that the individual satisfies § 406.5(a)(2), based on applicable data made available by the Department of Homeland Security.

■ 10. Section 406.10 is amended by revising paragraph (a) and adding paragraph (b)(3) to read as follows:

§ 406.10 Individual age 65 or over who is entitled to social security or railroad retirement benefits, or who is eligible for social security benefits.

(a) *Requirements.* An individual is entitled to hospital insurance benefits under section 226 of the Act under the following conditions:

(1) The individual has attained age 65 and is—

(i) Entitled to monthly social security benefits under section 202 of the Act;

(ii) A qualified railroad retirement beneficiary who has been certified as such to the Social Security Administration by the Railroad

Retirement Board in accordance with section 7(d) of the Railroad Retirement Act of 1974; or

(iii) Effective January 1, 1981, eligible for monthly social security benefits under section 202 of the Act and has filed an application for hospital insurance.

(2) Effective July 4, 2025, the individual is a citizen or national of the United States or an eligible noncitizen as defined in 42 CFR 400.200.

(b) * * *

(3) Entitlement continues until the date entitlement is terminated in accordance with § 406.14(b) or (c).

■ 11. Section 406.11 is amended by revising paragraph (b)(2) to read as follows:

§ 406.11 Individual age 65 or over who is not eligible as a social security or railroad retirement benefits beneficiary, or on the basis of government employment.

* * * * *

(b) * * *

(2) *Residence and citizenship.* He or she is a resident of the United States and is

(i) A citizen or national of the United States;

(ii) An alien lawfully admitted for permanent residence under the Immigration and Nationality Act who has continuously resided in the United States for 5 years immediately preceding the first month in which he or she meets all other requirements for entitlement to hospital insurance;

(iii) An alien who has been granted the status of Cuban and Haitian entrant, as defined in section 501(e) of the Refugee Education Assistance Act of 1980; or

(iv) An individual who lawfully resides in the United States in accordance with a Compact of Free Association (COFA), as referred to in 8 U.S.C. 1612(b)(2)(G).

* * * * *

■ 12. Section 406.12 is amended by revising paragraph (a) and adding paragraph (d)(2)(v) to read as follows:

§ 406.12 Individual under age 65 who is entitled to social security or railroad retirement disability benefits.

(a) *Basic requirements.* An individual under age 65 is entitled to hospital insurance benefits under the following conditions:

(1) If, for 25 months, the individual has been—

(i) Entitled or deemed entitled to social security disability benefits as an insured individual, child, widow, or widower who is ''under a disability''; or

(ii) A disabled qualified beneficiary certified under section 7(d) of the Railroad Retirement Act.

(2) Effective July 4, 2025, the individual is a citizen or national of the United States or an eligible noncitizen as defined in 42 CFR 400.200.

* * * * *

(d) * * *

(2) * * *

(v) The date entitlement is terminated in accordance with § 406.14(b) or (c).

* * * * *

■ 13. Section 406.13 is amended by revising paragraphs (c) and (f) to read as follows:

§ 406.13 Individual who has end-stage renal disease.

* * * * *

(c) *Requirements.* An individual who has been medically determined to have ESRD is entitled to hospital insurance benefits under the following conditions:

(1) He or she is—

(i) Fully or currently insured under the social security program (title II of the Act) or would be fully or currently insured if his or her employment (after 1936) as defined under the Railroad Retirement Act were considered ''employment'' under the Act;

(ii) Entitled to monthly social security or railroad retirement benefits; or

(iii) The spouse or dependent child of a person who meets the requirements of paragraph (c)(1)(i) or (c)(1)(ii) of this section.

(2) He or she has filed an application for Medicare Part A.

(3) He or she has satisfied the waiting period explained in paragraph (e) of this section.

(4) Effective July 4, 2025, the individual is a citizen or national of the United States or an eligible noncitizen, as defined in 42 CFR 400.200.

* * * * *

(f) *End of entitlement.* Entitlement ends under any of the following conditions:

(1) With the end of the 12th month after the month in which a regular course of dialysis ends.

(2) With the end of the 36th month after the month in which the individual received a kidney transplant. Beginning January 1, 2023, an individual who is no longer entitled to Part A benefits due to this paragraph may be eligible to enroll in Part B solely for purposes of coverage of immunosuppressive drugs as described in § 407.55 of this subchapter.

(3) With the date entitlement is terminated in accordance with § 406.14(b) or (c).

* * * * *

■ 14. Section 406.14 is added to read as follows:

§ 406.14 End of entitlement due to change in U.S. citizenship, U.S. nationality, or immigration status or category.

(a) *Basis.* Individuals whose U.S. citizenship, U.S. nationality, or immigration status or category changes such that they no longer meet the requirements of § 406.5(a)(2) of this part will lose entitlement to hospital insurance benefits without premiums.

(b) For individuals who were entitled to, or enrolled for, hospital insurance benefits without premiums as of July 4, 2025, the SSA must, not later than 1 year after July 4, 2025, complete a review of individuals for purposes of identifying individuals not described by § 406.5(a)(2). SSA must notify each individual identified under such review that if SSA determines that an individual does not meet the requirements of § 406.5(a)(2), the individual's entitlement to, or enrollment for, hospital insurance benefits will be terminated in accordance with paragraph (d) of this section.

(c) Entitlement will end as provided under paragraph (d) of this section for individuals who were entitled to, or enrolled for, hospital insurance benefits without premiums who were not identified and notified by the SSA per § 406.14(b) and were subsequently determined by the SSA as not meeting the requirements of § 406.5(a)(2).

(d) *Termination notice.* The SSA will send notice to individuals if they no longer satisfy the requirements of § 406.5(a)(2). The notice contains the following information:

(1) Specifies the individual's appeal rights in accordance with 20 CFR part 404, subpart J.

(2) States the effective date of the hospital insurance benefits entitlement termination action, which will be the end of the month following the month in which the termination notice is dated.

(3) States that the individual should contact the SSA if their citizenship, nationality, or immigration status or category changes such that they may be entitled to, or enrolled for, hospital insurance benefits under this part.

(e) *Resumption of benefits.* An individual whose hospital insurance benefits were terminated under paragraph (d) of this section may request resumption of benefits if the individual's U.S. citizenship, U.S. nationality, or immigration status or category changes such that the individual meets the requirements of § 406.5(a)(2) of this part. To request resumption of entitlement, the individual must contact SSA and provide information sufficient to

establish that the requirements of § 406.5(a)(2) are met.

■ 15. Section 406.20 is amended by revising paragraph (b)(2) and adding paragraph (c)(5) to read as follows:

§ 406.20 Basic requirements.

* * * * *

(b) * * *

(2) Is a resident of the United States and, effective July 4, 2025, is—

(i) A citizen or national of the United States;

(ii) An alien lawfully admitted for permanent residence under the Immigration and Nationality Act who has continuously resided in the United States for 5 years immediately preceding the first month in which they meet all other requirements for entitlement to hospital insurance;

(iii) An alien who has been granted the status of Cuban and Haitian entrant, as defined in section 501(e) of the Refugee Education Assistance Act of 1980; or

(iv) An individual who lawfully resides in the United States in accordance with a Compact of Free Association referred to in 8 U.S.C. 1612(b)(2)(G).

* * * * *

(c) * * *

(5) Meets the eligibility requirements in paragraph (b)(2) of this section.

■ 16. Section 406.27 is amended by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) to read as follows:

§ 406.27 Special enrollment periods for exceptional conditions.

* * * * *

(f) *Special enrollment period for eligible noncitizens.* An SEP exists for individuals who have not been entitled to, or enrolled for, Medicare due to failure to meet the requirements of § 406.20(b)(2), but subsequently meet the requirements or whose Medicare entitlement or enrollment was terminated due to loss of U.S. citizenship, U.S. nationality, or eligible noncitizen status, who subsequently meet the citizenship, nationality, or immigration status or category requirements specified in § 406.20(b)(2).

(1) *SEP parameters.* (i) An individual is eligible for this SEP if the individual otherwise met the eligibility requirements for Medicare, except for § 406.20(b)(2), and the individual subsequently meets the applicable Medicare eligibility requirements, including § 406.20(b)(2).

(ii)An individual is eligible for this SEP if the individual's prior Medicare entitlement or enrollment was terminated because the individual did not meet the requirements of § 406.20(b)(2) and the individual subsequently meets the applicable Medicare eligibility requirements, including § 406.20(b)(2).

(iii) An individual does not need to miss an enrollment period to be eligible for this SEP.

(2) *SEP duration.* The SEP begins on the first day of the month in which the individual contacts the SSA and provides information sufficient to establish that the requirements of § 406.20(b)(2) are met and ends on the last day of the fifth month after the month in which the SEP began.

(3) *Effective date of coverage.* Coverage under this paragraph begins on the first day of the month following the month of enrollment.

* * * * *

■ 17. Section 406.28 is amended by adding new paragraph (g) to read as follows:

§ 406.28 End of entitlement due to change in citizenship, nationality, or immigration status or category.

* * * * *

(g) *Loss of eligibility due to lack of U.S. citizenship, U.S. nationality, or eligible noncitizen status.* Individuals whose U.S. citizenship, U.S. nationality, or immigration status or category changes such that they no longer meet the requirements of § 406.20(b) of this part will lose entitlement to premium hospital insurance benefits.

(1) For individuals who were entitled to, or enrolled for, premium hospital insurance benefits as of July 4, 2025, the SSA must, not later than 1 year after July 4, 2025, complete a review of individuals for purposes of identifying individuals not described by § 406.20(b)(2). SSA must notify each individual identified under such review that if SSA determines that an individual does not meet the requirements of § 406.20(b)(2), the individual's entitlement to, or enrollment for, premium hospital insurance benefits will be terminated in accordance with paragraph (g)(3) of this section.

(2) Entitlement will end as provided under paragraph (g)(3) of this section for individuals who were entitled to, or enrolled for, premium hospital insurance benefits who were not identified and notified by the SSA per § 406.28(g)(1) and were subsequently determined by the SSA as not meeting the requirements of § 406.20(b)(2).

(3) *Termination notice.* The SSA will send notice to individuals if they no longer satisfy the requirements of § 406.20(b)(2). The notice contains the following information:

(i) Specifies the individual's appeal rights in accordance with 20 CFR part 404, subpart J.

(ii) States the effective date of the hospital insurance benefits entitlement termination action, which will be the end of the month following the month in which the termination notice is dated.

(iii) States that the individual should contact the SSA if their eligibility status changes such that they may be entitled to, or enrolled for, hospital insurance benefits under this part.

■ 18. Section 406.50 is amended by revising the section heading and paragraph (a) to read as follows:

§ 406.50 Nonpayment of benefits on behalf of eligible noncitizens.

(a) Hospital insurance benefit payments may not be made for services furnished to any eligible noncitizen, as defined in 42 CFR 400.200, for any month in which his or her monthly social security benefits are suspended (or would be suspended if he or she were entitled to those benefits) because the eligible noncitizen remains outside the United States for more than 6 months.

(b) Benefits will be payable beginning with services furnished in the first full calendar month the eligible noncitizen is back in the United States.

* * * * *

PART 407—SUPPLEMENTARY MEDICAL INSURANCE (SMI) ENROLLMENT AND ENTITLEMENT

■ 19. The authority for part 407 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1395p, 1395q, and 1395hh.

■ 20. Section 407.10 is amended by revising paragraph (a) to read as follows:

§ 407.10 Eligibility to enroll.

(a) *Basic rule.* Except as specified in paragraph (b) of this section, an individual is eligible to enroll for SMI if he or she—

(1) Is entitled to hospital insurance under any of the rules set forth in §§ 406.10 through 406.15 of this chapter; or

(2) Meets the following requirements:

(i) Has attained age 65. (An individual is considered to have attained age 65 on the day before the 65th anniversary of his or her birth.)

(ii) Is a resident of the United States and, effective July 4, 2025, is—

(A) A citizen or national of the United States;

(B) An alien lawfully admitted for permanent residence under the Immigration and Nationality Act, who

has resided continuously in the United States during the 5 years preceding the month in which he or she applies for enrollment;

(C) An alien who has been granted the status of Cuban and Haitian entrant, as defined in section 501(e) of the Refugee Education Assistance Act of 1980; or

(D) An individual who lawfully resides in the United States in accordance with a Compact of Free Association as referred to in 8 U.S.C. 1612(b)(2)(G).

* * * * *

■ 21. Section 407.23 is amended by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) to read as follows:

§ 407.23 Special enrollment periods for exceptional conditions.

* * * * *

(f) *Special enrollment period for eligible noncitizens.* An SEP exists for individuals who have not been entitled to, or enrolled for, Medicare due to failure to meet the requirements of § 407.10(a)(2), but subsequently meet the requirements or whose Medicare entitlement or enrollment was terminated due to loss of U.S. citizenship, loss of U.S. nationality, or eligible noncitizen status, who subsequently meet the citizenship, nationality, or immigration status or category requirements specified in § 407.10(a)(2).

(1) *SEP parameters.* (i) An individual is eligible for this SEP if the individual otherwise met the eligibility requirements for Medicare, except for § 407.10(a)(2), and the individual subsequently meets the applicable Medicare eligibility requirements, including § 407.10(a)(2).

(ii) An individual is eligible for this SEP if the individual's prior Medicare entitlement or enrollment was terminated because the individual did not meet the requirements of § 407.10(a)(2) and the individual subsequently meets the applicable Medicare eligibility requirements, including § 407.10(a)(2).

(iii) An individual does not need to miss an enrollment period to be eligible for this SEP.

(2) *SEP duration.* The SEP begins on the first day of the month in which the individual contacts the SSA and provides information sufficient to establish that the requirements of § 407.10(a)(2) are met and ends on the last day of the fifth month after the month in which the SEP began.

(3) *Effective date of coverage.* Coverage under this paragraph begins on the first day of the month following the month of enrollment.

* * * * *

■ 22. Section 407.27 is amended by adding paragraph (e) to read as follows:

§ 407.27 Termination of entitlement: Individual enrollment.

* * * * *

(e) *Loss of eligibility due to lack of U.S. citizenship, U.S. nationality, or eligible noncitizen status.* Individuals whose U.S. citizenship, U.S. nationality, or immigration status or category changes such that they do not meet the requirements of § 407.10(a)(2)(ii) of this part will lose entitlement to SMI.

(1) For individuals who were entitled to, or enrolled for, SMI as of July 4, 2025, the SSA must, not later than 1 year after July 4, 2025, complete a review of individuals for purposes of identifying individuals not described by § 407.10(a)(2). SSA must notify each individual identified under such review that if SSA determines that an individual does not meet the requirements of § 407.10(a)(2), the individual's entitlement to, or enrollment for, SMI will be terminated in accordance with paragraph (e)(3) of this section.

(2) Entitlement will end as provided under paragraph (e)(3) of this section for individuals who were entitled to, or enrolled for, SMI who were not identified and notified by the SSA per § 407.27(e)(1) and were subsequently determined by the SSA as not meeting the requirements of § 407.10(a)(2)(ii).

(3) *Termination notice.* The SSA will send notice to individuals if they no longer satisfy the requirements of § 407.10(a)(2). The notice contains the following information:

(i) Specifies the individual's appeal rights in accordance with 20 CFR part 404, subpart J.

(ii) States the effective date of the SMI entitlement termination action, which will be the end of the month following the month in which the termination notice is dated.

(iii) States that the individual should contact the SSA if their citizenship, nationality, or immigration status or category changes such that they may be entitled to, or enrolled for, SMI under this part.

■ 23. Section 407.55 is amended by revising paragraph (a) to read as follows:

§ 407.55 Eligibility to enroll.

(a) *Basic rules.*

(1) Except as specified in paragraph (b) of this section, an individual is eligible to enroll, be deemed enrolled, or reenroll in the Part B–ID benefit if their Part A entitlement ends as described in § 406.13(f)(2) of this subchapter.

(2) Effective July 4, 2025, the individual must meet the eligibility criteria set forth in § 407.10(a)(2)(ii).

* * * * *

■ 24. Section 407.62 is amended by redesignating paragraph (f) as paragraph (g) and adding a new paragraph (f) to read as follows:

§ 407.62 Termination of coverage.

* * * * *

(f) Enrollment in the Part B–ID benefit ends the date entitlement is terminated in accordance with § 407.27(e) due to the individual's failure to meet the citizenship, nationality, or eligible noncitizen requirements described in § 407.10(a)(2).

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 25. The authority for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

■ 26. Section 410.78 is amended by—

■ a. Revising paragraph (a)(3);

■ b. Adding paragraphs (b)(2)(xiii), (b)(3)(xiv)(D), (b)(3)(xv), and (b)(6); and

■ c. Revising paragraph (f);

The revisions and additions read as follows:

§ 410.78 Telehealth services.

(a) * * *

(3) *Interactive telecommunications system* means, except as otherwise provided in this paragraph (a)(3), multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

(i) An interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a patient in their home on or before December 31, 2027.

(ii)(A) For telehealth services furnished after December 31, 2027 date, interactive telecommunications system may also include two-way, real-time audio-only communication technology for any telehealth service furnished to a patient in their home if the distant site physician or practitioner is technically capable of using an interactive telecommunications system as defined in this paragraph (a)(3), but the patient is not capable of, or does not consent to, the use of video technology.

(B) The following modifiers must be appended to a claim for telehealth services furnished using two-way, real-time audio-only communication technology to verify that the conditions set forth in paragraph (a)(3)(ii)(A) of this section have been met:

* * * * *

(b) * * *

(2) * * *

(xiii) Occupational therapists, physical therapists, speech-language pathologists, or audiologists, through December 31, 2027.

* * * * *

(3) * * *

(xiv) * * *

(D) Consistent with section 6209(d) of the CAA, 2026, in-person visit requirements for the purposes of diagnosis, evaluation, or treatment of a mental health disorder do not apply through December 31, 2027.

* * * * *

(6) Consistent with section 6209(a) of the CAA, 2026, the geographic requirements specified in paragraph (b)(4) of this section do not apply through December 31, 2027.

* * * * *

(f) *Process for adding or deleting services.* Except as otherwise provided in this paragraph (f), changes to the list of Medicare telehealth services are made through the annual physician fee schedule rulemaking process. CMS maintains the list of services that are Medicare telehealth services under this section, including the current HCPCS codes that describe the services on the CMS website.

§ 410.105 [Amended]

■ 27. Section 410.105 is amended in paragraph (b)(3)(ii) by removing the reference ''§ 410.100(m)'' and adding in its place the reference ''§ 410.100(1)''.

■ 28. Section 410.175 is amended by revising paragraphs (a) and (b) to read as follows:

§ 410.175 Alien absent from the United States.

(a) Medicare does not pay Part B benefits for services furnished to an eligible noncitizen, as defined in 42 CFR 400.200, if those services are furnished in any month for which the individual is not paid monthly social security cash benefits (or would not be paid if he or she were entitled to those benefits) because he or she has been outside the United States continuously for 6 full calendar months.

(b) Payment of benefits resumes with services furnished during the first full calendar month the eligible noncitizen, as defined in 42 CFR 400.200, is back in the United States.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 29. The authority citation for part 414 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395hh, and 1395rr(b)(l).

■ 30. Section 414.502 is amended by revising the definitions of ''Data collection period'' and ''Data reporting period'' to read as follows:

§ 414.502 Definitions.

* * * * *

Data collection period is the 6 months from January 1 through June 30, during which applicable information is collected and that precedes the data reporting period.

Data reporting period for CDLTs that are not ADLTs is the 3-month period, May 1 through July 31, and for ADLTs is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period.

* * * * *

§ 414.504 [Amended]

■ 31. Section 414.504 is amended in paragraph (a)(1) by removing the date ''January 1, 2026'' and adding in its place the date ''May 1, 2026''.

■ 32. Section 414.507 is amended by—

■ a. Revising paragraph (d) introductory text and paragraph (d)(9); and

■ b. Adding paragraph (d)(12).

The revisions and addition read as follows:

§ 414.507 Payment for clinical diagnostic laboratory tests.

* * * * *

(d) *Phase-in of payment reductions.* For years 2018 through 2029, the payment rates established under this section for each CDLT that is not a new ADLT or new CDLT, may not be reduced by more than the following amounts for—

* * * * *

(9) 2026—0.0 percent of the payment rate established in 2025.

* * * * *

(12) 2029—15 percent of the payment rate established in 2028.

* * * * *

■ 33. Section 414.523 is amended by revising paragraph (a)(1)(v) to read as follows:

§ 414.523 Payment for laboratory specimen collection fee and travel allowance.

(a) * * *

(1) * * *

(v) For a specimen collected from a Medicare beneficiary in a skilled nursing facility or on behalf of a home health agency, the specimen collection fee otherwise payable under paragraph (a)(1) of this section is increased by $2.00.

■ 34. Section 414.610 is amended by—

■ a. Revising paragraph (c)(1)(ii) introductory text; and

■ b. In paragraph (c)(5)(ii) removing the date ''September 30, 2025'' and adding in its place the date ''December 31, 2027''.

The revision reads as follows:

§ 414.610 Basis of payment.

* * * * *

(c) * * *

(1) * * *

(ii) For services furnished during the period July 1, 2008 through December 31, 2027, ambulance services originating in either of the following:

* * * * *

■ 35. Section 414.1105 is amended by revising paragraph (c) introductory text to read as follows:

§ 414.1105 Payment for Comprehensive Outpatient Rehabilitation Facility (CORF) services.

* * * * *

(c) *Payment for supplies and durable medical equipment, prosthetic and orthotic devices.* Supplies and durable medical equipment that are CORF services under § 410.100(k), prosthetic device services that are CORF services under § 410.100(f), and orthotic devices that are CORF services under § 410.100(g) are paid the lesser of 80 percent of the following:

* * * * *

■ 36. Section 414.1305 is amended by revising the definitions of ''APM Incentive Payment'', ''Certified Electronic Health Record Technology (CEHRT)'' paragraph (2), ''Collection type'', ''MVP participant'' and ''Participant List'' to read as follows:

§ 414.1305 Definitions.

* * * * *

APM Incentive Payment means the lump sum incentive payment for a year as described in section 414.1450(b)(1) and that is paid for an eligible clinician who is a QP for the applicable year.

* * * * *

Certified Electronic Health Record Technology (CEHRT) * * *

(2) * * *

(i) For CY 2019 through CY 2026, at 45 CFR 170.315(a)(12) (family health

history) and 45 CFR 170.315(e)(3) (patient health information capture); and

(ii) * * *

(A) For CY 2019 through CY 2026, the applicable measure calculation certification criterion at 45 CFR 170.315(g)(1) or (2) for all certification criteria that support a meaningful use objective with a percentage-based measure.

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3), and for CY 2019 through CY 2026, optionally (c)(4), and can be electronically accepted by CMS.

* * * * *

Collection type means a set of quality measures with comparable specifications and data completeness criteria, as applicable, including, but not limited to: Electronic clinical quality measures (eCQMs); MIPS clinical quality measures (MIPS CQMs); QCDR measures; Medicare Part B claims measures; CMS Web Interface measures (except as provided in paragraph (1) of this definition, for the CY 2017 through CY 2022 performance periods/2019 through 2024 MIPS payment years); the CAHPS for MIPS survey measure; administrative claims measures; Medicare Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare CQMs); and Medicare Electronic Clinical Quality Measures for Accountable Care Organizations Participating in the Medicare Shared Savings Program (Medicare eCQMs).

* * * * *

MVP participant means an individual MIPS eligible clinician, multispecialty group, single-specialty group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. For the CY 2026 performance period/2028 MIPS payment year and future years, MVP participant means an individual MIPS eligible clinician, single-specialty group, multispecialty group that meets the requirements of a small practice, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories. Beginning in the CY 2029 performance period/2031 MIPS payment year, MVP participant means an individual MIPS eligible clinician, single specialty group, multispecialty group that meets the requirements of a small practice, virtual group, subgroup, or APM Entity that is assessed on an MVP in accordance with § 414.1365 for all MIPS performance categories.

* * * * *

Participation List means the list of participants in an APM Entity that is compiled from a CMS-maintained list where practicable.

* * * * *

■ 37. Section 414.1330 is amended by revising paragraph (c)(2)(iv) to read as follows.

§ 414.1330 Quality performance category.

(c) * * *

(2) * * *

(iv) Whether the quality measure is designated as high priority or not, through the CY 2026 performance period/2028 MIPS payment year.

* * * * *

■ 38. Section 414.1335 is amended by—

■ a. Revising paragraphs (a)(1)(i) introductory text, (a)(1)(ii), and (a)(4)(i);

■ b. Adding paragraph (a)(1)(iii);

■ c. Revising paragraph (a)(4)(i); and

■ d. Adding paragraph (a)(5).

The revisions and additions read as follows:

§ 414.1335 Data submission criteria for the quality performance category.

(a) * * *

(1) * * *

(i) For the CY 2017 through 2026 performance periods/2019 through 2028 MIPS payment years, except as provided in paragraph (a)(1)(ii) of this section, submits data on at least six measures, including at least one outcome measure. If an applicable outcome measure is not available, reports one other high priority measure. If fewer than six measures apply to the MIPS eligible clinician, group, virtual group, or APM Entity, reports on each measure that is applicable. Beginning in the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians, except as provided in paragraphs (a)(1)(ii) and (a)(1)(iii) of this section, submits data on at least six measures, including at least one MIPS core measure. If there is not an available and applicable MIPS core measure, a MIPS eligible clinician must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure. If fewer than six measures apply then the MIPS eligible clinician, group, virtual group, or APM Entity must report on each measure that is applicable.

* * * * *

(ii) For the CY 2017 through 2026 performance periods/2019 through 2028 MIPS payment years, a MIPS eligible clinician, group, virtual group, and APM Entity that report on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one outcome measure. If an applicable outcome measure is not available, report one other high priority measure. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, group, virtual group, or APM Entity, report on each measure that is applicable. Beginning in the CY 2027 performance period/2029 MIPS payment year, except as provided in paragraph (a)(1)(iii) of this section, a MIPS eligible clinician that reports on a specialty or subspecialty measure set, as designated in the MIPS final list of quality measures established by CMS through rulemaking, must submit data on at least six measures within that set, including at least one MIPS core measure. If there is not an available and applicable MIPS core measure, a MIPS eligible clinician must attest to not having an available and applicable MIPS core measure and submit data on a separate MIPS quality measure within that set. If the set contains fewer than six measures or if fewer than six measures within the set apply to the MIPS eligible clinician, report on each measure that is applicable.

* * * * *

(iii) *Small practices.* Beginning with the CY 2027 performance period/2029 MIPS payment year, MIPS eligible clinicians in small practices are not required to submit at least one MIPS core measure or attest to not having an applicable and available MIPS core measure. MIPS eligible clinicians in small practices must submit data on at least six measures, if applicable.

* * * * *

(4) *For Medicare CQMs.* (i) A MIPS eligible clinician, group, and APM Entity reportingquality data on beneficiaries eligible for Medicare CQMs as defined at § 425.20) within the APP measure set or APP Plus measure set (as applicable) and administering the CAHPS for MIPS Survey as required under the APP.

(ii) [Reserved]

(5) *For Medicare eCQMs.* (i) A MIPS eligible clinician, group, and APM Entity reporting on the Medicare eCQMs (reporting quality data on beneficiaries eligible for Medicare eCQMs as defined at § 425.20) within the APP Plus measure set and administering the CAHPS for MIPS Survey as required under the APP.

(ii) [Reserved]

* * * * *

■ 39. Section 414.1340 is amended by—
■ a. Revising paragraphs (d) and (e); and
■ b. Adding paragraph (f).

The revisions and additions read as follows:

§ 414.1340 Data completeness criteria for the quality performance category.

* * * * *

(d) APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations meeting reporting requirements under the APP, submitting quality measure data on Medicare CQMs must submit data on the following:

(1) At least 75 percent of the applicable beneficiaries eligible for the Medicare CQM, as defined at § 425.20, who meet the measure's denominator criteria for MIPS payment year 2026 and future MIPS payment years.

(e) APM Entities, specifically Medicare Shared Savings Program Accountable Care Organizations meeting reporting requirements under the APP, submitting quality measure data on Medicare eCQMs must submit data on the following:

(1) At least 75 percent of the applicable beneficiaries eligible for the Medicare eCQM, as defined at § 425.20, who meet the measure's denominator criteria for MIPS payment years 2029 and future MIPS payment years.

(2) [Reserved]

(f) If quality data are submitted selectively such that the submitted data are unrepresentative of a MIPS eligible clinician, group, virtual group, subgroup, or APM Entity's performance, any such data would not be true, accurate, or complete for purposes of § 414.1390(b) or § 414.1400(a)(5).

■ 40. Section 414.1365 is amended by—
■ a. Adding paragraph (a)(2); and
■ b. Revising paragraphs (c)(1) introductory text and (c)(1)(ii).

The revisions and additions read as follows:

§ 414.1365 MIPS Value Pathways.

(a) * * *

(2) Beginning in the CY 2029 performance period/2031 MIPS payment year, except for MIPS eligible clinicians reporting under the APM Performance Pathway in accordance with § 414.1367, all MIPS eligible clinicians must report an MVP.

* * * * *

(c) * * *

(1) *Quality.* Through the CY 2026 performance period/2028 MIPS payment year, except as provided in paragraph (c)(1)(i) of this section, an MVP participant must select and report, if applicable, four quality measures, including one outcome measure (or, if an outcome measure is not available, one high priority measure), included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section. Beginning in the CY 2027 performance period/2029 MIPS payment year, except as provided in paragraphs (c)(1)(i) and (c)(1)(ii) of this section, an MVP participant must select and report, if applicable, four quality measures, including one MIPS core measure available in the MVP, excluding the population health measure required under paragraph § 414.1365(c)(4)(ii). If there is not an available and applicable MIPS core measure, an MVP participant must attest to not having an available and applicable MIPS core measure and submit a separate MIPS quality measure within the MVP.

* * * * *

(ii) *Small practices.* Beginning with the CY 2027 performance period/2029 MIPS payment year, an MVP participant that meets the requirements of a small practice is not required to submit at least one MIPS core measure or attest to not having an available and applicable MIPS core measure. Except as provided in paragraph (c)(1)(i) of this section, an MVP participant that meets the requirements of a small practice must select and report, if applicable, at least four quality measures included in the MVP, excluding the population health measure required under paragraph (c)(4)(ii) of this section.

* * * * *

■ 41. Section 414.1375 is amended is amended by revising paragraphs (b)(2)(ii)(A) and (b)(3)(i) introductory text to read as follows:

§ 414.1375 Promoting Interoperability (PI) performance category.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(A) Through the 2028 MIPS payment year, report that the MIPS eligible clinician completed the actions included in the Security Risk Analysis measure during the year in which the performance period occurs;

* * * * *

(3) * * *

(i) *Supporting providers with the performance of CEHRT (SPPC).*

From the 2019 MIPS payment year through the 2027 MIPS payment year, to engage in activities related to supporting providers with the performance of CEHRT, the MIPS eligible clinician—

* * * * *

■ 42. Section 414.1380 is amended by—
■ a. Revising paragraphs (b)(1)(ii)(E) and (b)(1)(ii)(F);
■ b. Adding paragraphs (b)(1)(ii)(G) and (H), and (b)(1)(iv)(D);
■ c. Revising paragraphs (b)(3)(i) and (b)(4)(ii)(C)(*3*);
■ d. Adding paragraph (b)(4)(ii)(C)(*4*); and
■ e. Revising paragraphs (c)(2)(i)(A)(*10*) and (c)(2)(i)(C)(*12*).

The revisions and additions read as follows:

§ 414.1380 Scoring.

* * * * *

(b) * * *

(1) * * *

(ii) * * *

(E) Beginning with the CY 2025 performance period/2027 MIPS payment year, CMS will publish a list of topped out measures determined to be impacted by limited measure choice on a yearly basis. Measures included on the list are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the performance threshold for the corresponding performance year.

(F) *Medicare CQMs collection type benchmarks.*

(*1*) Beginning in the CY 2025 performance period/2027 MIPS payment year, measures of the Medicare CQMs collection type use flat benchmarks for their first two performance periods in MIPS.

(*2*) Beginning with the CY 2026 performance period/2028 MIPS payment year, measures of the Medicare CQMs collection type use flat benchmarks.

(G) *Medicare eCQMs collection type benchmarks.*

(*1*) Beginning with the CY 2027 performance period/2029 MIPS payment year, measures of the Medicare eCQMs collection type use flat benchmarks.

(*2*) [Reserved]

(H) Beginning in the CY 2027 performance period/2029 MIPS payment year, MIPS core measures, which are required under § 414.1335(a)(1)(i) and (ii), for which the benchmark for the applicable collection type is identified as topped out for 2 or more consecutive years, are scored from 1 to 10 measure achievement points according to defined topped out measure benchmarks calculated from performance data in the baseline period in which a performance rate of 97 percent corresponds to 10 percent of the

performance threshold for the corresponding performance year.

* * * * *

(iv) * * *

(D) Beginning with the CY 2027 performance period/2029 MIPS payment year, MIPS core measures, which are required under § 414.1335(a)(1)(i) and (ii), are not subject to the 7 measure achievement point cap specified in paragraph (b)(1)(iv)(B) of this section.

* * * * *

(3) * * *

(i) For MIPS eligible clinicians participating in APMs, the improvement activities performance category score is at least 50 percent.

* * * * *

(4) * * *

(i) * * *

(C) * * *

(ii) * * *

(C) * * *

(3) Beginning with the CY 2026 performance period/2028 MIPS payment year, the total number of bonus points available to be earned when reporting one optional measure, more than one optional measure, or all optional measures under the Public Health and Clinical Data Exchange objective is a total of 5 bonus points.

(4) For the CY 2027 performance period/2029 MIPS payment year, the total number of bonus points available to be earned when reporting the Electronic Prior Authorization optional measure is a total of 10 bonus points.

* * * * *

(c) * * *

(2) * * *

(i) * * *

(A) * * *

(10) Beginning with the 2026 MIPS payment year, for the quality and improvement activities performance categories, CMS determines based on documentation provided to the agency that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category(ies) on behalf of the MIPS eligible clinician in accordance with applicable deadlines. To determine whether to apply reweighting to the affected performance category(ies), CMS will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category(ies); whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category(ies) in accordance with applicable deadlines.

(i) For the 2026 MIPS payment year, requests must be submitted by November 1st of the year preceding the relevant MIPS payment year.

(ii) Beginning with the 2027 MIPS payment year, requests must be submitted by December 31st of the year preceding the relevant MIPS payment year.

* * * * *

(C) * * *

(12) Beginning with the 2026 MIPS payment year, CMS determines based on documentation provided to the agency that data for a MIPS eligible clinician are inaccessible or unable to be submitted due to circumstances outside of the control of the clinician because the MIPS eligible clinician delegated submission of the data to their third party intermediary, evidenced by a written agreement between the MIPS eligible clinician and third party intermediary, and the third party intermediary did not submit the data for the performance category on behalf of the MIPS eligible clinician in accordance with applicable deadlines. To determine whether to apply reweighting to the Promoting Interoperability performance category, CMS will consider: whether the MIPS eligible clinician knew or had reason to know of the issue with its third party intermediary's submission of the clinician's data for the performance category; whether the MIPS eligible clinician took reasonable efforts to correct the issue; and whether the issue between the MIPS eligible clinician and their third party intermediary caused no data to be submitted for the performance category in accordance with applicable deadlines.

(i) For the 2026 MIPS payment year, requests must be submitted by November 1st of the year preceding the relevant MIPS payment year.

(ii) Beginning with the 2027 MIPS payment year, requests must be submitted by December 31st of the year preceding the relevant MIPS payment year.

* * * * *

§ 414.1395 [Amended]

■ 43. Section 414.1395 is amended by removing and reserving paragraph (c)(2).

■ 44. Section 414.1400 is amended by—

■ a. Revising paragraphs (b)(3)(iii), (b)(3)(v)(E)(*1*),

■ b. Redesignating paragraph (b)(3)(vi) and (viii) as (b)(3)(vii)(A) and (B), respectively;

■ c. Adding paragraph (b)(3)(vii)(C);

■ d. Reserving paragraphs (b)(3)(vi) and (viii);

■ e. Revising paragraphs (b)(3)(x), (b)(3)(xiv), and (c)(1) introductory text;

■ b. Adding paragraphs (c)(2); and

■ c. Revising paragraph (e)(5);

The revisions and additions read as follows:

§ 414.1400 Third party intermediaries.

* * * * *

(b) * * *

(3) * * *

(iii) Beginning with the CY 2021 performance period/2023 MIPS payment year, the QCDR or qualified registry must provide performance feedback at least 4 times a year and provide specific feedback on how they compare to other clinicians who have submitted data on a given measure within the QCDR or qualified registry. Feedback must be provided at the level at which data is submitted. Exceptions to this requirement may occur if the QCDR or qualified registry submits notification to CMS within the performance period promptly within the month of realization of the impending deficiency and provides sufficient rationale as to why they do not believe they would be able to meet this requirement (for example, if the QCDR does not receive the data from their clinician until the end of the performance period).

* * * * *

(v) * * *

(E) * * *

(*1*) If the intermediary submits MIPS data to CMS for fewer than 10 Quality Payment Program participants, the data validation audit sample must include all Quality Payment Program participants. If the intermediary submits data for 10 or more Quality Payment Program participants, it must use a sample size of at least 3 percent of a combination of the individual MIPS eligible clinicians, groups, virtual groups, subgroups and APM entities for which the QCDR or qualified registry will submit data to CMS, except that the sample size may be no fewer than a combination of 10 individual clinicians, groups, virtual groups, subgroups and APM entities, no more than a combination of 50 individual clinicians, groups, virtual groups, subgroups and APM entities.

(*2*) If there are fewer than 5 patient records, the patient record audit sample must include all patient records. If there

are 5 or more patient records, the intermediary must use a sample that includes at least 25 percent of the patients of each individual clinician, group, virtual group, subgroup or APM entity in the sample, except that the sample for each individual clinician, group, virtual group, subgroup or APM entity must include a minimum of 5 patients and need not include more than 50 patients.

* * * * *

(vi) [Reserved].

(vii) Participation plan for third party intermediary not submitting data.

(A) For the CY 2024 performance period/2026 MIPS payment year through CY 2026 performance period/2028 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for either of the 2 years preceding the applicable self-nomination period must submit a participation plan for CMS' approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(B) Beginning with the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry that was approved but did not submit any MIPS data for the year preceding the applicable self-nomination period must submit a participation plan for CMS' approval. This participation plan must include the QCDR's and/or qualified registry's detailed plans about how the QCDR or qualified registry intends to encourage clinicians to submit MIPS data to CMS through the QCDR or qualified registry.

(viii) [Reserved].

* * * * *

(x) For the CY 2017 performance period/2019 MIPS payment year through CY 2026 performance period/CY 2028 MIPS payment year, a QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one outcome measure.

(A) For the CY 2017 performance period/2019 MIPS payment year through CY 2026 performance period/CY 2028 MIPS payment year, if no outcome measure is available, a QCDR or qualified registry must be able to submit to CMS results for at least one other high priority measure.

(B) Beginning with CY 2027 performance period/2029 MIPS payment year, a QCDR or a qualified registry must be able to submit to CMS data for at least six quality measures including at least one MIPS core measure.

* * * * *

(xiv) A QCDR or a qualified registry must attest that the information listed on the qualified posting is accurate. Changes to information (for example, cost, services included) on the qualified posting must be included and finalized during the qualified posting review period. Third party intermediaries will not be permitted to make changes after the qualified posting is publicly posted on the Quality Payment Program Resource Library page.

* * * * *

(c) * * *

(1) For the CY 2021 performance period/2023 MIPS payment year through the CY 2024 performance period/2026 MIPS payment year, health IT vendors must be able to submit data for the MIPS performance categories as follows:

* * * * *

(2) Beginning with the CY 2025 performance period/2027 MIPS payment year, health IT vendors cannot submit MIPS data.

* * * * *

(5) *Termination for third party intermediary not submitting data.*

(i) Beginning with the CY 2024 performance period/2026 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under paragraph (b)(3)(viii) of this section, but does not submit MIPS data for the applicable performance period for which they self-nominated under paragraph (b)(3)(viii) of this section, will be terminated.

(ii) Beginning with the CY 2027 performance period/2029 MIPS payment year, a QCDR or qualified registry that submits a participation plan as required under paragraph (b)(3)(viii) of this section, but does not submit MIPS data for the applicable performance period for which they self-nominated under paragraph (b)(3)(viii) of this section, will be queried by CMS before the end of the calendar year for the given MIPS performance period requesting documentation that they have contracted with Quality Payment Program participants who will submit data for the given MIPS performance period. If documentation cannot be provided or the third-party intermediary will not be submitting MIPS data or both for the given MIPS performance period, the third-party intermediary will be terminated.

■ 45. Section § 414.1425 is amended by—

■ a. Revising paragraph (c)(5); and

■ b. Adding paragraphs (c)(8) and (d)(5).

The revision and additions read as follows:

§ 414.1425 Qualifying APM participant determination: In general.

* * * * *

(c) * * *

(5) * * *

(ii) The APM Entity voluntarily or involuntarily terminates from an Advanced APM at a date on which the APM Entity would not bear financial risk for that QP performance period under the terms of the Advanced APM, even if such termination date occurs within such QP Performance Period.

* * * * *

(8) Beginning in the 2027 QP Performance Period, application of QP determination is limited strictly to eligible clinicians as defined at § 414.1305 and that meet the definition of Qualifying APM participant (QP) as defined at § 414.1305 by participating in an Advanced APM during the QP performance period.

* * * * *

(d) * * *

(5) Beginning in the 2027 QP Performance Period, application of Partial QP determination is limited strictly to eligible clinicians as defined at § 414.1305 that meet the definition of Partial Qualifying APM Participant (Partial QP) as defined at § 414.1305 by participating in an Advanced APM during the QP performance period.

* * * * *

■ 46. Section § 414.1430 is amended by revising paragraphs (a), (b(1)(i), (2)(i), (3)(i), and (4)(i) to read as follows:

§ 414.1430 Qualifying APM participant determination: QP and partial QP thresholds.

(a) * * *

(1) *QP payment amount threshold.* The QP payment amount thresholds are the following values for the indicated payment years: (i) 2019 and 2020: 25 percent.

(ii) 2021 through 2026: 50 percent.

(iii) 2027: 75 percent.

(iv) 2028: 50 percent.

(v) 2029 and thereafter: 75 percent.

(2) *Partial QP payment amount threshold.* The Partial QP payment amount thresholds are the following values for the indicated payment years:

(i) 2019 and 2020: 20 percent.

(ii) 2021 through 2026: 40 percent.

(iii) 2027: 50 percent.

(iv) 2028: 40 percent.

(v) 2029 and thereafter: 50 percent.

(3) *QP patient count threshold.* The QP patient count thresholds are the following values for the indicated payment years: (i) 2019 and 2020: 20 percent.

(ii) 2021 through 2026: 35 percent.
(iii) 2027: 50 percent.
(iv) 2028: 35 percent.
(v) 2029 and thereafter: 50 percent.
(4) *Partial QP patient count threshold.* The Partial QP patient count thresholds are the following values for the indicated payment years: (i) 2019 and 2020: 10 percent.
(ii) 2021 through 2026: 25 percent.
(iii) 2027: 35 percent.
(iv) 2028: 25 percent.
(v) 2029 and thereafter: 35 percent.
(b) * * *
(1) * * *
(i) * * *
(A) 2021 through 2026: 50 percent
(B) 2027: 75 percent.
(C) 2028: 50 percent.
(D) 2029 and thereafter: 75 percent.
(2) * * *
(i) * * *
(A) 2021 through 2026: 40 percent
(B) 2027: 50 percent.
(C) 2028: 40 percent.
(D) 2029 and thereafter: 75 percent.
* * * * *
(3) * * *
(i) * * *
(A) 2021 through 2026: 35 percent.
(B) 2027: 50 percent.
(C) 2028: 35 percent.
(D) 2029 and thereafter: 50 percent.
* * * * *
(4) * * *
(i) * * *
(A) 2021 through 2026: 25 percent
(B) 2027: 35 percent.
(C) 2028: 25 percent.
(D) 2029 and thereafter: 35 percent.
* * * * *

■ 47. Section § 414.1450 is amended by revising paragraphs (a)(1)(i) and (b)(1) to read as follows:

§ 414.1450 APM Incentive Payment.

(a) * * *
(1) * * *
(i) For payment years in which an APM incentive payment is authorized under section 1833(z)(1)(A) of the Act, CMS makes a lump sum payment to QPs in the amount described in paragraph (b) of this section for the applicable payment year and in the manner described in paragraphs (d) and (e) of this section.
(b) * * *
(1) The amount of the APM incentive payment is the applicable percentage established for the payment year of the estimated aggregate payments for covered professional services as defined in section 1848(k)(3)(A) of the Act furnished during the calendar year immediately preceding the payment year. CMS uses the paid amounts on claims for covered professional services to calculate the estimated aggregate payments on which CMS will calculate the APM Incentive Payment. The applicable percentage is the following value for the indicated payment years:
(i) 2019 through 2024: 5 percent.
(ii) 2025: 3.5 percent.
(iii) 2026: 1.88 percent.
(iv) 2028: 3.1 percent.
* * * * *

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ 48. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 49. Section 415.172 is amended by revising paragraphs (a) introductory text and (b)(2) to read as follows:

§ 415.172 Physician fee schedule payment for services of teaching physicians.

(a) *General rule.* If a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made only if a teaching physician is present during the key portion of any service or procedure for which payment is sought. For all teaching settings, if a resident participates in a service furnished in a teaching setting, physician fee schedule payment is made if a teaching physician is present during the key portion of the service including for Medicare telehealth services, through audio/video real-time communications technology for any service or procedure for which payment is sought, when either the teaching physician or resident is in the same physical location as the beneficiary or in instances when the service is a 3-way telehealth visit, with the teaching physician, resident, and patient in different locations.
* * * * *
(b) * * *
(2) For all teaching settings, except for services furnished as set forth in §§ 415.174 (concerning an exception for services furnished in hospital outpatient and certain other ambulatory settings), 415.176 (concerning renal dialysis services), and 415.184 (concerning psychiatric services), the medical records must document whether the teaching physician was physically present or present through audio/video real-time communications technology at the time the service (including a Medicare telehealth service) is furnished. The medical records must contain a notation describing the specific portion(s) of the service for which the teaching physician was present through audio/video real-time communications technology. The presence of the teaching physician during procedures and evaluation and management services may be demonstrated by the notes in the medical records made by the physician or as provided in § 410.20(e) of this chapter.

■ 50. Section 415.174 is amended by revising paragraph (a) introductory text to read as follows:

§ 415.174 Exception: Evaluation and management services furnished in certain centers.

(a) In the case of certain evaluation and management codes (as specified by CMS in program instructions), MACs may make physician fee schedule payment for a service furnished by a resident without the presence of a teaching physician. For the exception to apply, all of the following conditions must be met:
* * * * *

PART 417—HEALTH MAINTENANCE ORGANIZATIONS, COMPETITIVE MEDICAL PLANS, AND HEALTH CARE PREPAYMENT PLANS

■ 51. The authority for part 417 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh, and 300e, 300e–5, and 300e–9, and 31 U.S.C. 9701.

■ 52. Section 417.2 is amended by revising paragraph (b) to read as follows:

§ 417.2 Basis and scope.

* * * * *
(b) Subparts G through R of this part set forth the rules for Medicare contracts with, and payment to, HMOs and competitive medical plans (CMPs) under sections 1876 and 1899C of the Act and 8 U.S.C. 1611.
* * * * *

■ 53. Section 417.422 is amended by revising paragraph (h) to read as follows:

§ 417.422 Eligibility to enroll in an HMO or CMP.

* * * * *
(h) Effective July 4, 2025, is a United States citizen or national, or an eligible noncitizen as defined in 42 CFR 400.200.

■ 54. Section 417.460 is amended by revising paragraphs (b)(2)(iv) and (j) to read as follows:

§ 417.460 Disenrollment of beneficiaries by an HMO or CMP.

* * * * *
(b) * * *
(2) * * *

(iv) No longer meets the requirements of § 417.422(h); or

* * * * *

(j) *Enrollee is not a United States citizen or national, or an eligible noncitizen.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with § 417.422(h).

PART 422—MEDICARE ADVANTAGE PROGRAM

■ 55. The authority for part 422 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–21 through 1395w–28, and 1395hh.

■ 56. Section 422.1 is amended by adding paragraph (a)(1)(xii) and removing and reserving paragraph (a)(2) to read as follows:

§ 422.1 Basis and scope.

(a) * * *

(1) * * *

(xii) 1899C–Limiting Medicare coverage of certain individuals.

(2) [Reserved]

* * * * *

■ 57. Section 422.50 is amended by revising paragraph (a)(7) to read as follows:

§ 422.50 Eligibility to elect an MA plan.

* * * * *

(a) * * *

(7) Effective July 4, 2025, is a United States citizen or national, or an eligible noncitizen as defined in 42 CFR 400.200.

* * * * *

■ 58. Section 422.62 is amended by revising paragraph (b)(16) to read as follows:

§ 422.62 Election of coverage under an MA plan.

* * * * *

(b) * * *

(16) The individual becomes an eligible noncitizen.

(i) The SEP begins when the individual provides the Social Security Administration with sufficient information to demonstrate that the requirements of § 406.20(b)(2) and § 407.10(a)(2)(ii) have been met and is entitled to Medicare Part A and enrolled in Medicare Part B. The SEP continues for the first 2 months after the date that the individual is entitled to Medicare Part A and enrolled in Medicare Part B.

* * * * *

■ 59. Section 422.74 is amended by revising paragraphs (b)(2)(v) and (d)(9) to read as follows:

§ 422.74 Disenrollment by the MA organization.

* * * * *

(b) * * *

(2) * * *

(v) The individual no longer meets the requirements of § 422.50(a)(7).

* * * * *

(d) * * *

(9) *Enrollee loses U.S. citizenship, U.S. nationality, or eligible noncitizen status.* Disenrollment is effective the first day of the month following notice by CMS that the individual is ineligible in accordance with § 422.50(a)(7) of this chapter.

* * * * *

PART 423—VOLUNTARY MEDICARE PRESCRIPTION DRUG BENEFIT

■ 60. The authority for part 423 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395w–101 through 1395w–152, and 1395hh.

■ 61. Section 423.1 is amended by adding a section in numerical order in paragraph (a)(1) and removing and reserving paragraph (a)(3) to read as follows:

§ 423.1 Basis and scope.

(a) * * *

(1) * * *

1899C. Limiting Medicare coverage of certain individuals.

* * * * *

(3) [Reserved]

* * * * *

■ 62. Section 423.30 is amended by revising paragraph (a)(1)(iii) to read as follows:

§ 423.30 Eligibility and enrollment.

(a) * * *

(1) * * *

(iii) Effective July 4, 2025, is a United States citizen or national, or an eligible noncitizen as defined in 42 CFR 400.200.

* * * * *

■ 63. Section 423.38 is amended by revising paragraphs (c)(21)(i) and (ii) to read as follows:

§ 423.38 Enrollment periods.

* * * * *

(c) * * *

(21) * * *

(i) The individual becomes an eligible noncitizen.

(ii) The SEP begins when the individual provides the Social Security Administration with sufficient information to demonstrate that the requirements of § 406.20(b)(2) or § 407.10(a)(2)(ii) have been met and is entitled to, or enrolled for, either Medicare Part A or Part B. The SEP continues for the first 2 months after the Part A or Part B entitlement date, whichever is earlier.

* * * * *

■ 64. Section 423.44 is amended by revising paragraphs (b)(2)(vi) and (d)(8) heading to read as follows:

§ 423.44 Involuntary disenrollment from Part D coverage.

* * * * *

(b) * * *

(2) * * *

(vi) The individual no longer meets the requirements of § 423.30(a)(1)(iii).

* * * * *

(d) * * *

(8) *Individual loses U.S. citizenship, U.S. nationality, or eligible noncitizen status.* * * *

* * * * *

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 65. The authority for part 424 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 66. Section 424.516 is amended by adding paragraph (f)(4) to read as follows:

§ 424.516 Additional provider and supplier requirements for enrolling and maintaining active enrollment status in the Medicare program.

* * * * *

(f) * * *

(4) A provider or supplier that is a covered entity as defined at 42 CFR 10.3 is required to—

(i) Submit to CMS the documentation set forth at § 428.203(c)(1) and (2) relating to covered Part D drugs written or ordered by such provider or supplier.

(ii) Comply with the submission requirements set forth at § 428.203(c)(3) and (4).

* * * * *

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 67. The authority citation for part 425 continues to read as follows:

Authority: 42 U.S.C. 1302, 1306, 1395hh, and 1395jjj.

■ 68. Section 425.20 is amended by—

■ a. Revising and republishing the definition of ''Beneficiary eligible for Medicare CQMs'';

■ b. Adding the definition of ''Beneficiary eligible for Medicare eCQMs'' in alphabetical order;

■ c. Revising paragraph (2) in the definition of ''Experienced with performance-based risk Medicare ACO initiatives'';

■ d. Revising paragraph (2) in the definition of ''Inexperienced with performance-based risk Medicare ACO initiatives''; and
■ e. Adding the definition of ''Rural county status'' in alphabetical order.

The revisions, republication, and additions read as follows:

§ 425.20 Definitions.

* * * * *

Beneficiary eligible for Medicare CQMs means a beneficiary identified for purposes of reporting Medicare CQMs for ACOs participating in the Medicare Shared Savings Program (Medicare CQMs), who meets the following requirements (as applicable):

(1) For performance years 2024 through 2026, the beneficiary is either of the following:

(i) A Medicare fee-for-service beneficiary (as defined at § 425.20) who—

(A) Meets the criteria for a beneficiary to be assigned to an ACO described at § 425.401(a); and

(B)(*1*) For performance year 2024, had at least one claim with a date of service during the measurement period from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

(*2*) For performance years 2025 and 2026, had at least one primary care service with a date of service during the applicable performance year from an ACO professional who is a primary care physician or who has one of the specialty designations included in § 425.402(c), or who is a physician assistant, nurse practitioner, or clinical nurse specialist.

(ii) A Medicare fee-for-service beneficiary who is assigned to an ACO in accordance with § 425.402(e) because the beneficiary designated an ACO professional participating in an ACO as responsible for coordinating their overall care.

(2) For performance years 2027 and subsequent performance years, a beneficiary that is assigned to the ACO under subpart E of this part.

Beneficiary eligible for Medicare eCQMs means a beneficiary identified for purposes of reporting Medicare eCQMs for ACOs participating in the Medicare Shared Savings Program (Medicare eCQMs), who is a beneficiary that is assigned to the ACO under subpart E of this part.

* * * * *

Experienced with performance-based risk Medicare ACO initiatives * * *

(2) Forty percent or more of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in any of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years, unless the ACO participant TIN did not have a written agreement to participate in the performance-based risk Medicare ACO initiative.

* * * * *

Inexperienced with performance-based risk Medicare ACO initiatives

* * *

(2) Less than 40 percent of the ACO's ACO participants participated in a performance-based risk Medicare ACO initiative, or in an ACO that deferred its entry into a second Shared Savings Program agreement period under a two-sided model under § 425.200(e), in each of the 5 most recent performance years. An ACO participant is considered to have participated in a performance-based risk Medicare ACO initiative if the ACO participant TIN was or will be included in financial reconciliation for one or more performance years under such initiative during any of the 5 most recent performance years, unless the ACO participant TIN did not have a written agreement to participate in the performance-based risk Medicare ACO initiative.

* * * * *

Rural county status means a county that has a status of Micropolitan (population of 10,000 to 50,000 individuals) or Noncore (population less than 10,000 individuals) per the Federal Office of Rural Health Policy (FORHP) county designation using the most recently available version of the United States Census Bureau Delineation File.

* * * * *

■ 69. Section 425.304 is amended by—
■ a. In paragraph (a)(2), removing the phrase ''paragraph (b) or (c) of this section'' and adding in its place the phrase ''paragraph (b), (c), or (e) of this section''; and
■ b. Adding paragraph (e).The addition reads as follows:

§ 425.304 Beneficiary incentives.

* * * * *

(e) *Part B Cost Sharing Support.*

(1) *General.* ACOs, subject to certain conditions and safeguards, may enter into Part B cost sharing support arrangements with ACO participants, pursuant to which the ACO participants reduce or eliminate cost sharing for those categories of eligible Part B items and services and eligible beneficiaries identified by the ACO. This cost sharing support could include both or either of Medicare FFS deductible and coinsurance amounts.

(2) *Application of the CMS-sponsored model safe harbor.* CMS has determined that the Federal anti-kickback statute safe harbor for CMS-sponsored model arrangements and CMS-sponsored model patient incentives (§ 1001.952(ii)(1) and (2) of this title) is available to protect remuneration exchanged under Part B cost sharing support arrangements between ACOs and ACO participants, and patient incentives in the form of Part B cost sharing support furnished to eligible beneficiaries under the Shared Savings Program that meet all of the requirements of this section and the anti-kickback statute safe harbor requirements set forth at § 1001.952(ii) of this title.

(3) *Application procedures.*

(i) *General.* An ACO must submit a Part B cost sharing support implementation plan in the form and manner and by a deadline specified by CMS. The implementation plan must include the following:

(A) The categories of eligible beneficiaries for which the ACO plans to make Part B cost sharing support available.

(B) The categories of eligible Part B items and services for which the ACO plans to make Part B cost sharing support available.

(C) A description of how the ACO's planned Part B cost sharing support strategy meets at least one of the clinical goals in paragraph (e)(4)(iii) of this section.

(D) The procedures that the ACO will implement to ensure that ACO participants that have entered into a Part B cost sharing support arrangement with the ACO have access to the most current list of beneficiaries eligible to receive Part B cost sharing support.

(E) A requirement for the ACO to submit to CMS a complete and accurate list of ACO participants that have entered into a Part B cost sharing support arrangement with the ACO according to paragraph (e)(5)(i) of this section.

(F) An attestation that, in any marketing or communications regarding the availability of Part B cost-sharing support, the ACO and its ACO participants will not represent such support as a substitute for supplemental

insurance coverage or encourage beneficiaries to reduce or terminate such coverage.

(G) Such other information as may be specified by CMS.

(ii) *CMS review.* CMS evaluates an ACO's implementation plan and approves or denies the application. An ACO may only offer Part B cost sharing support to beneficiaries if CMS approves its application. CMS may reject the ACO's application on the basis of one or more of the following:

(A) The ACO's and the ACO participant's history of noncompliance in the Shared Savings Program.

(B) The ACO's history of noncompliance in CMMI ACO models.

(C) Whether the implementation plan complies with the requirements of § 425.304.

(D) Such other factors as CMS deems reasonable to protect the integrity of the Shared Savings Program, including concerns that the use of Part B cost sharing support may contribute to fraud, waste or abuse.

(iii) *Changes to the implementation plan.* If an ACO wants to make a change to its implementation plan, the ACO must submit a description of the change to CMS in a form and manner and by a deadline or deadlines specified by CMS. CMS evaluates the proposed change and either approves or rejects it.

(4) *Part B cost sharing support requirements.*

(i) *Beneficiary eligibility.* Beneficiaries are eligible to receive Part B cost sharing support if they meet the following criteria:

(A) The beneficiary is assigned to the applying ACO (as described at § 425.400(a)(1)(i)) if the ACO has selected prospective assignment or the beneficiary is an assignable beneficiary (as defined at § 425.20), if the applying ACO has selected preliminary prospective assignment with retrospective reconciliation.

(B) The beneficiary does not have secondary insurance that covers the associated Part B cost sharing obligation.

(C) The beneficiary's overall health is expected to be improved or maintained by receiving the associated Part B item or service.

(ii) *Eligible Part B items and services.* ACOs may reduce or eliminate beneficiary cost sharing for all Medicare FFS Part B items and services except durable medical equipment, prosthetics, orthotics, supplies, and prescription drugs.

(iii) *Clinical goals.* Cost sharing support must advance one or more of the following clinical goals:

(A) Adherence to a treatment regime.

(B) Adherence to a drug regime.

(C) Adherence to a follow-up care plan.

(D) Management of a chronic disease or condition.

(5) *Part B cost sharing support arrangements.*

(i) *ACO participant agreements.* The ACO must have a written agreement with each ACO participant that has agreed to reduce or eliminate Part B cost sharing for eligible ACO beneficiaries under a Part B cost sharing support arrangement with the ACO. The terms of the Part B cost sharing support agreement must include all of the following:

(A) The categories of eligible beneficiaries and eligible Part B items and services for which the ACO participant may reduce or eliminate Part B cost sharing.

(B) A requirement that the ACO participant reduce or eliminate cost sharing in accordance with the ACO's approved implementation plan.

(C) The amount and frequency with which the ACO will reimburse the ACO participant for the cost sharing amounts not collected.

(D) A requirement for ACO participants to maintain copies of records that identify each beneficiary who received a reduction or elimination of Part B cost sharing, the type and date of item or service for which cost sharing support was provided, and the dollar amount of the cost sharing support.

(E) The ability for the ACO or ACO participant to terminate the Part B cost sharing support agreement if the ACO or ACO participant fails to comply with the requirements of this section.

(F) A requirement that the ACO or ACO participants will not market to beneficiaries the availability of the Part B cost sharing support as a substitute for their supplemental insurance coverage.

(ii) *Other rules governing participation.*

(A) An ACO participant must not be required by an ACO to participate in a Part B cost sharing support arrangement.

(B) An ACO may participate in Part B cost sharing support in accordance with an approved implementation plan even if not all of its ACO participants agree to participate.

(iii) *Source of funding.* The ACO must finance all payments made to ACO participants in accordance with the Part B cost sharing support agreement from its own funds.

(6) *Record retention.*

(i) The ACO must maintain copies of the written Part B cost sharing support agreement with ACO participants, as well as the following records:

(A) Records that identify each beneficiary who received a reduction or elimination of Part B cost sharing.

(B) Records that document the type and date of the Part B item or service for which Part B cost sharing was reduced or eliminated.

(C) Records that document the dollar amount of Part B cost sharing that was reduced or eliminated.

(D) Records that document the ACO participant that furnished the item or service for which Part B cost sharing was reduced or eliminated.

(ii) The ACO must provide the records specified in paragraph (e)(6)(i) of this section to CMS upon request.

(7) *Addressing compliance problems.* At any time, CMS may suspend or prohibit the ACO or any ACO participant from participating in a Part B cost sharing support arrangement if CMS determines that the ACO or its ACO participants have failed to comply with any of the requirements of this part. This suspension or prohibition will be effective, in CMS' discretion, regardless of whether the ACO has corrected or otherwise resolved the noncompliance.

■ 70. Section 425.308 is amended by—

■ a. In paragraph (b)(9) introductory text, removing the phrase ''For performance year 2025 and subsequent performance years,'' and adding in its place the phrase ''For performance years 2025 and 2026,''; and

■ b. Adding paragraph (b)(11).The addition reads as follows:

§ 425.308 Public reporting and transparency.

* * * * *

(b) * * *

(11) For performance year 2027 and subsequent performance years, the CEHRT use activity selected by the ACO for the purpose of meeting the ACO CEHRT use requirement at § 425.507(c).

* * * * *

■ 71. Section 425.312 is amended by—

■ a. Revising the last sentence in paragraph (a)(2)(iii);

■ b. Adding a new sentence at the end of paragraph (a)(2)(iv); and

■ c. Removing paragraph (a)(2)(v).The revision and addition read as follows:

§ 425.312 Beneficiary notifications.

(a) * * *

(2) * * *

(iii) * * * The standardized written notice must be furnished to all of these beneficiaries by May 30, unless CMS specifies a later date during the performance year.

(iv) * * * The standardized written notice must be furnished to all of these beneficiaries by May 30, unless CMS

specifies a later date during the performance year.

* * * * *

■ 72. Section 425.400 is amended by revising paragraph (c)(1)(x) introductory text and adding paragraph (c)(1)(xi) to read as follows:

§ 425.400 General.

* * * * *

(c) * * *

(1) * * *

(x) For the performance year starting on January 1, 2026, as follows:

* * * * *

(xi) For the performance year starting on January 1, 2027, and subsequent performance years as follows:

(A) CPT codes:

(*1*) 96160 and 96161 (codes for administration of health risk assessment).

(*2*) 96202 and 96203 (codes for caregiver behavior management training).

(*3*) 97550, 97551, and 97552 (codes for caregiver training services).

(*4*) 98016 (code for virtual check-in).

(*5*) 99201 through 99215 (codes for office or other outpatient visit for the evaluation and management of a patient).

(*6*) 99304 through 99318 (codes for professional services furnished in a nursing facility; professional services or services reported on an FQHC or RHC claim identified by these codes are excluded when furnished in a skilled nursing facility (SNF)).

(*7*) 99319 through 99340 (codes for patient domiciliary, rest home, or custodial care visit).

(*8*) 99341 through 99350 (codes for evaluation and management services furnished in a patient's home).

(*9*) 99354 and 99355 (add-on codes, for prolonged evaluation and management or psychotherapy services beyond the typical service time of the primary procedure; when the base code is also a primary care service code under this paragraph (c)(1)(xi)).

(*10*) 99406 and 99407 (codes for smoking and tobacco-use cessation counseling services).

(*11*) 99421, 99422, and 99423 (codes for online digital evaluation and management).

(*12*) 99424, 99425, 99426, and 99427 (codes for principal care management services).

(*13*) 99437, 99487, 99489, 99490 and 99491 (codes for chronic care management).

(*14*) 99439 (code for non-complex chronic care management).

(*15*) 99452 (code for interprofessional consultation service).

(*16*) 99483 (code for assessment of and care planning for patients with cognitive impairment).

(*17*) 99484, 99492, 99493 and 99494 (codes for behavioral health integration services).

(*18*) 99495 and 99496 (codes for transitional care management services).

(*19*) 99497 and 99498 (codes for advance care planning; services identified by these codes furnished in an inpatient setting are excluded).

(B) HCPCS codes:

(*1*) G0019 and G0022 (codes for community health integration services).

(*2*) G0023 and G0024 (codes for principal illness navigation services).

(*3*) G0101 (code for cervical or vaginal cancer screening).

(*4*) G0136 (code for physical activity and nutritional assessment services).

(*5*) G0317, G0318, and G2212 (codes for prolonged office or other outpatient visit for the evaluation and management of a patient).

(*6*) G0402 (code for the Welcome to Medicare visit).

(*7*) G0438 and G0439 (codes for the annual wellness visits).

(*8*) G0442 (code for alcohol misuse screening service).

(*9*) G0443 (code for alcohol misuse counseling service).

(*10*) G0444 (code for annual depression screening service).

(*11*) G0463 (code for services furnished in electing teaching amendment (ETA) hospitals).

(*12*) G0506 (code for chronic care management).

(*13*) G0537 and G0538 (codes for cardiovascular risk assessment and risk management services).

(*14*) G0539 and G0540 (codes for individual behavior management/modification caregiver training services).

(*15*) G0541, G0542, and G0543 (codes for direct care caregiver training services).

(*16*) G0544 (code for post-discharge telephonic follow-up contacts intervention).

(*17*) G0556, G0557, and G0558 (codes for advanced primary care management services).

(*18*) G0560 (code for safety planning interventions).

(*19*) G0568 and G0569 (codes for behavioral health integration add-on when furnished with advanced primary care management services).

(*20*) G0570 (code for psychiatric collaborative care model add-on when furnished with advanced primary care management services).

(*21*) G2010 (code for the remote evaluation of patient video/images).

(*22*) G2011, G0396, G0397 (codes for screening, brief intervention, and referral to treatment).

(*23)* G2012 and G2252 (codes for virtual check-in).

(*24*) G2058 (code for non-complex chronic care management).

(*25*) G2064 and G2065 (codes for principal care management services).

(*26*) G2086, G2087, and G2088 (codes for office-based opioid use disorder services).

(*27*) G2211 (code for visit complexity inherent to evaluation and management services add-on).

(*28*) G2214 (code for psychiatric collaborative care model).

(*29*) G3002 and G3003 (codes for chronic pain management).

(*30*) GACP1 and GACP2 (codes for advance care planning).

(*31*) GADV1 (code for assessment and treatment of vaccine adverse effects).

(C) Primary care service codes include any CPT code identified by CMS that directly replaces a CPT code specified in paragraph (c)(1)(xi)(A) of this section or a HCPCS code specified in paragraph (c)(1)(xi)(B) of this section, when the assignment window or expanded window for assignment (as defined in § 425.20) for a benchmark or performance year includes any day on or after the effective date of the replacement code for payment purposes under FFS Medicare.

* * * * *

■ 73. Section 425.401 is revised and republished to read as follows:

§ 425.401 Criteria for a beneficiary to be assigned to an ACO.

(a) *Assignment eligibility criteria.* A beneficiary may be assigned to an ACO under the assignment methodology in §§ 425.402 and 425.404, for a performance or benchmark year, if the beneficiary meets all of the following criteria during the assignment window:

(1) For performance years starting prior to January 1, 2028 (as applicable):

(i)(A) Has at least 1 month of Part A and Part B enrollment; and

(B) Does not have any months of Part A only or Part B only enrollment.

(ii) Does not have any months of Medicare group (private) health plan enrollment.

(iii) Is not assigned to any other Medicare shared savings initiative.

(iv) Lives in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

(2) For the performance year starting on January 1, 2028, and subsequent performance years:

(i) Has at least 1 month of Part A and Part B enrollment and does not have Medicare group (private) health plan enrollment during that same month during the assignment window.

(ii) Is not assigned to any other Medicare shared savings initiative.

(iii) Lives in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residence at the end of the assignment window.

(b) *Prospective assignment exclusion criteria.* A beneficiary is excluded from the prospective assignment list of an ACO that is participating under prospective assignment under § 425.400(a)(3) at the end of a performance or benchmark year and quarterly during each performance year consistent with § 425.400(a)(3)(ii), or at the end of CY 2019 as specified in § 425.609(b)(1)(ii) and (c)(1)(ii) if the beneficiary meets any of the following criteria during the performance or benchmark year:

(1) For performance years starting prior to January 1, 2028 (as applicable):

(i)(A) Does not have at least 1 month of Part A and Part B enrollment; and

(B) Has any months of Part A only or Part B only enrollment.

(ii) Has any months of Medicare group (private) health plan enrollment.

(iii) Did not live in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residency at the end of the year.

(2) For the performance year starting on January 1, 2028, and subsequent performance years:

(i) Does not have at least 1 month of Part A and Part B enrollment without Medicare group (private) health plan enrollment during that same month during the assignment window.

(ii) Did not live in the United States or U.S. territories and possessions, based on the most recent available data in our beneficiary records regarding the beneficiary's residency at the end of the year.

■ 74. Section 425.402 is amended by revising and republishing paragraphs (b)(3), (b)(4) and (b)(5)(iv) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(b) * * *

(3)(i) Under the first step, a beneficiary identified in paragraph (b)(1) of this section is assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by primary care physicians who are ACO professionals and non-physician ACO professionals in the ACO are greater than the allowed charges for primary care services furnished by primary care physicians, nurse practitioners, physician assistants, and clinical nurse specialists who are—

(A) ACO professionals in any other ACO; or

(B) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(ii) For performance year 2028 and subsequent performance years, if an ACO professional for which CMS identifies a primary care service under paragraph (b)(2) of this section also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then CMS excludes from consideration in assignment under paragraph (b)(3)(i) of this section the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable assignment window.

(4)(i) The second step considers the remainder of the beneficiaries identified in paragraph (b)(1) of this section who have not had a primary care service rendered by any primary care physician, nurse practitioner, physician assistant, or clinical nurse specialist, either inside the ACO or outside the ACO. The beneficiary will be assigned to an ACO if the allowed charges for primary care services furnished to the beneficiary by physicians who are ACO professionals with specialty designations as specified in paragraph (c) of this section are greater than the allowed charges for primary care services furnished by physicians with specialty designations as specified in paragraph (c) of this section—

(A) Who are ACO professionals in any other ACO; or

(B) Who are unaffiliated with an ACO and are identified by a Medicare-enrolled billing TIN.

(ii) For performance year 2028 and subsequent performance years, if an ACO professional for which CMS identifies a primary care service under paragraph (b)(2) of this section also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then CMS excludes from consideration in assignment under paragraph (b)(4)(i) of this section the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable assignment window.

(5) * * *

(iv)(A) A beneficiary identified in paragraph (b)(5)(ii) of this section is assigned to the ACO if the allowed charges for primary care services furnished to the beneficiary by ACO professionals in the ACO who are primary care physicians, physicians with specialty designations included in paragraph (c) of this section, or non-physician ACO professionals during the applicable expanded window for assignment are greater than the allowed charges for primary care services furnished by primary care physicians, physicians with specialty designations as specified in paragraph (c) of this section, nurse practitioners, physician assistants, and clinical nurse specialists who are—

(*1*) ACO professionals in any other ACO; or

(*2*) Not affiliated with any ACO and identified by a Medicare-enrolled billing TIN.

(B) For performance year 2028 and subsequent performance years, if an ACO professional for which CMS identifies a primary care service under paragraph (b)(5)(iii) of this section also bills primary care services under a Medicare-enrolled billing TIN unaffiliated with any ACO, then CMS excludes from consideration in assignment under paragraph (b)(5)(iv)(A) of this section the allowed charges for primary care services billed by the ACO professional under the non-ACO TIN during the applicable expanded window for assignment.

* * * * *

■ 75. Section 425.507 is amended by—

■ a. In paragraph (a) introductory text, removing the phrase ''For performance years beginning on or after January 1, 2025,'' and adding in its place the phrase ''For performance years 2025 and 2026,'';

■ b. In paragraph (b) introductory text, by adding the words ''For performance years 2025 and 2026,'' to the beginning of the first sentence; and

■ c. Adding paragraph (c).The addition reads as follows:

§ 425.507 Incorporating Promoting Interoperability requirements related to the Quality Payment Program for performance years beginning on or after January 1, 2025.

* * * * *

(c) For performance years beginning on or after January 1, 2027, an ACO must demonstrate the use of CEHRT (as defined in paragraph (3) of the CEHRT definition at § 414.1305 of this chapter) in one of the following manners:

(1) The ACO uses CEHRT (as defined in paragraph (3) of the CEHRT definition at § 414.1305 of this chapter) that also supports the calculation and reporting of clinical quality measures by being certified to the ONC health IT certification criteria at 45 CFR 170.315(c)(2) and (c)(3), to completely

report at least one of the measures in the APP Plus quality measure set using the eCQMs or Medicare eCQMs collection types and meets the data completeness requirement at § 414.1340 of this chapter for the applicable performance year.

(2) The ACO completely reports at least one measure in the APP Plus quality measure set and meets the data completeness requirement at § 414.1340 of this chapter for the applicable performance year using EHR technology that meets paragraph (3) of the CEHRT definition at § 414.1305 of this chapter and attests that it used data collected from an HL7® Fast Healthcare Interoperable Resources (FHIR®)-based API to support quality measurement using a Health IT Module (as defined in 45 CFR 170.102) that has been certified to an unexpired criterion or criteria in 45 CFR 170.315 supporting standardized API access.

(3) The ACO attests to at least one of the Shared Savings Program CEHRT use metrics from the list of metrics established for the applicable performance year.

■ 76. Section 425.508 is amended by adding paragraphs (c)(1) through (4) to read as follows:

§ 425.508 Incorporating quality reporting requirements related to the Quality Payment Program.

* * * * *

(c) * * *

(1) For performance years beginning on or after January 1, 2026. ACOs may exclude one or more TINs of ACO participants from an ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure as required in this paragraph (c). Applicable exclusions may include:

(i) Unforeseen circumstance(s) that are outside of the control of the ACO, such as the unexpected closure of a group or individual's practice that bills under the ACO participant TIN.

(ii) An ACO participant TIN has a CEHRT that is intended for specialty use and does not support the measure(s) included in the APP Plus quality measure set.

(iii) Other circumstances as determined by CMS.

(2) ACOs may not exclude an ACO participant TIN from the ACO's quality data submission for each measure based on the following:

(i) The demographics of the beneficiaries who had an encounter during the performance year with an ACO participant TIN.

(ii) The health status of the beneficiaries who had an encounter during the performance year with an ACO participant TIN.

(iii) The estimated impact of the ACO participant TIN on the ACO's quality performance.

(3) The ACO's submission of eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data (as applicable) for each measure must include ACO participant TINs that represent at least 95 percent of the beneficiaries assigned to the ACO under subpart E of this part prior to the application of the measure specifications.

(4) CMS retains the right to audit and validate eCQM/MIPS CQM/Medicare CQM/Medicare eCQM data reported by an ACO and may request documentation from the ACO related to the exclusion of ACO participant TINs under paragraph (c)(1) of this section. Failure to report quality measure data accurately, completely, and timely may result in compliance actions as described in §§ 425.216 and 425.218.

* * * * *

■ 77. Section 425.512 is amended by—

■ a. In paragraph (a)(2)(iv), removing the phrase ''eCQMs/Medicare CQMs'' and adding in its place the phrase ''eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs'';

■ b. In paragraph (a)(5)(i)(B) introductory text, removing the phrase ''For performance years 2025 and 2026,'' and adding in its place the phrase ''For performance year 2025 and subsequent performance years,'';

■ c. Removing paragraph (a)(5)(i)(C);

■ d. In paragraph (a)(5)(iii)(C), removing the phrase ''eCQMs/Medicare CQMs'' and adding in its place the phrase ''eCQMs/MIPS CQMs/Medicare CQMs/Medicare eCQMs'';

■ e. In paragraph (a)(7)(ii), removing the phrase ''For performance year 2025 and subsequent performance years,'' and adding in its place the phrase ''For performance years 2025 and 2026''; and

■ f. Adding paragraph (a)(7)(iii).

The addition reads as follows:

§ 425.512 Determining the ACO quality performance standard for performance years beginning on or after January 1, 2021.

(a) * * *

(7) * * *

(iii) For performance year 2027 and subsequent performance years, if an ACO reports all of the required measures in the APP Plus quality measure set, meeting the data completeness requirement at § 414.1340 of this subchapter for each measure in the APP Plus quality measure set, and receiving a MIPS Quality performance category score as described at § 414.1380(b)(1) of this subchapter, for the relevant performance year, and the ACO meets the following—

(A) The ACO's MIPS Quality performance category score is calculated on less than five measures; and

(B) Any unscored measure(s) must meet all of the following:

(*1*) The ACO's total available measure achievement points used to calculate the ACO's MIPS Quality performance category score are reduced under § 414.1380(b)(1)(vii)(A) of this subchapter.

(*2*) The ACO's total measure achievement points used to calculate the ACO's MIPS Quality performance category score are not reduced under § 414.1380(b)(1)(iii) of this subchapter.

* * * * *

§ 425.600 [Amended]

■ 78. Section 425.600 is amended in paragraph (f)(4)(ii) by removing the references ''§§ 425.601(f), and 425.656(e)'' and adding in their place the references ''§ 425.601(f), and § 425.656(e) and (f)''.

■ 79. Section 425.605 is amended by—

■ a. Revising paragraph (d)(1)(v)(A)(*3*)(*ii*), the first sentence of paragraph (d)(1)(v)(A)(*4*) introductory text, and paragraph (d)(1)(v)(A)(*4*)(*ii*);

■ b. Adding paragraph (d)(1)(v)(A)(*5*);

■ c. In paragraph (h)(2), removing the references ''paragraph (d)(1)(i)(A)(*4*), (d)(1)(ii)(A)(*4*), (d)(1)(iii)(A)(*4*), (d)(1)(iv)(A)(*4*), or (d)(1)(v)(A)(*4*) of this section'' and adding in their place the references ''paragraph (d)(1)(i)(A)(*4*), (d)(1)(ii)(A)(*4*), (d)(1)(iii)(A)(*4*), (d)(1)(iv)(A)(*4*), (d)(1)(v)(A)(*4*) or (d)(1)(v)(A)(*5*) of this section'';

■ d. In paragraph (i)(2)(i) introductory text, removing the phrase ''paragraph (i)(2)(ii) of this section'' and adding in its place the phrase ''paragraph (i)(2)(ii) or (i)(2)(iii) of this section, as applicable''; and

■ e. Adding new paragraph (i)(2)(iii).

The revisions and additions read as follows:

§ 425.605 Calculation of shared savings and losses under the BASIC track.

* * * * *

(d) * * *

(1) * * *

(v) * * *

(A) * * *

(*3*) * * *

(*ii*) 50 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(4)(ii).

(*4*) *For ACOs in agreement periods beginning on July 1, 2019, through January 1, 2026, for performance years beginning on or after January 1, 2024.*

* * *

(*ii*) 50 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

(*5*) *For ACOs in agreement periods beginning on or after January 1, 2027, for performance years beginning on or after January 1, 2027.* An ACO that meets all the requirements for receiving shared savings payments under the BASIC track, Level E, receives a shared savings payment equal to a percentage of all the savings under the updated benchmark (up to the performance payment limit described in paragraph (d)(1)(v)(B) of this section). Except as provided in paragraph (h) of this section, the percentage is as follows:

(*i*) 60 percent for an ACO that that meets the quality performance standard by meeting the criteria specified in § 425.512(a)(2) or (a)(5)(i).

(*ii*) 60 percent multiplied by the ACO's quality score calculated according to § 425.512 for an ACO that meets the alternative quality performance standard by meeting the criteria specified in § 425.512(a)(5)(ii).

* * * * *

(i) * * *

(2) * * *

(iii) For agreement periods beginning on or after January 1, 2024, and before January 1, 2027, for performance year 2025 and subsequent performance years of the ACO's agreement period. CMS calculates the benchmark-based loss recoupment limit as follows:

(A) Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year prior to the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

(B) Calculates the value for total benchmark expenditures as the product of an ACO's per capita updated benchmark expenditures for the performance year after the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

(C) Calculates the product of the percentage specified in paragraph (d)(1)(iii)(D)(*2*), (d)(1)(iv)(D)(*2*), and (d)(1)(v)(D)(*2*) of this section, as applicable, and the lesser of the ACO's total benchmark expenditures calculated according to paragraphs (i)(2)(iii)(A) and (i)(2)(iii)(B) of this section.

■ 80. Section 425.610 is amended by—

■ a. In paragraph (l)(2) introductory text, removing the phrase ''paragraph (l)(3) of this section'' and adding in its place the phrase ''paragraph (l)(3) or (l)(4) of this section, as applicable''; and

■ b. Adding paragraph (l)(4).

The addition reads as follows:

§ 425.610 Calculation of shared savings and losses under the ENHANCED track.

* * * * *

(l) * * *

(4) For agreement periods beginning on or after January 1, 2024, and before January 1, 2027, for performance year 2025 and subsequent performance years of the ACO's agreement period. The amount of shared losses for which an eligible ACO is liable may not exceed 15 percent of the lesser of the following:

(i) Total benchmark expenditures calculated as the product of an ACO's per capita updated benchmark expenditures for the performance year prior to the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

(ii) Total benchmark expenditures calculated as the product of an ACO's per capita updated benchmark expenditures for the performance year after the recomputation of the ACPT as specified in § 425.660(c)(1) and an ACO's assigned beneficiary person years for the performance year.

§ 425.612 [Amended]

■ 81. Section 425.612(a)(1)(iv)(A)(*2*) is amended by removing the references ''§ 425.401(a)(1) and (2)'' and adding in its place the references ''§ 425.401(a)(1)(i)-(ii) and (a)(2)(i) (as applicable)''.

■ 82. Section 425.630 is amended by—

■ a. In paragraph (e)(1), removing the phrase ''social determinants of health'' and adding in its place the phrase ''upstream drivers of health'';

■ b. Revising paragraph (f)(2)(ii) introductory text to add a new first sentence; and

■ c. Revising and republishing paragraphs (f)(2)(iii) and (f)(2)(iv).

The revisions and republications read as follows:

§ 425.630 Option to receive advance investment payments.

* * * * *

(f) * * *

(2) * * *

(ii) For performance years 2023 through 2027.

* * * * *

(iii) Determines a beneficiary's payment amount.

(A) For performance years 2023 through 2027. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS determines the payment amount that corresponds to the beneficiary's risk factors-based score determined in paragraph (f)(2)(ii) of this section. The beneficiary payment amount is as follows:

TABLE 1 TO PARAGRAPH (f)(2)(iii)(A)

Rick factors-based score	1–24	25–34	35–44	45–54	55–64	65–74	75–84	85–100
Payment amount	$0	$20	$24	$28	$32	$36	$40	$45

(B) For performance year 2028 and subsequent performance years. For each beneficiary in the assigned population identified in paragraph (f)(2)(i) of this section, CMS determines the quarterly payment amount, as follows:

(*1*) An ACO will receive a quarterly payment of $45 for each beneficiary that meets any of the following criteria:

(*i*) Is enrolled in the LIS.

(*ii*) Is dually eligible for Medicare and Medicaid.

(*iii*) Is residing in a county with rural county status (as defined at § 425.20). CMS determines the county of residence for the beneficiary based on the beneficiary's mailing address.

(*2*) An ACO will receive a quarterly payment of $25 for each beneficiary that does not meet any of the criteria listed in paragraph (f)(2)(iii)(B)(*1*) of this section.

(iv) Calculates the ACO's quarterly payment amount.

(A) For performance years 2023 through 2027. The ACO's quarterly payment amount is the sum of the beneficiary payment amounts corresponding to each assigned beneficiary's risk factors-based score, specified in paragraph (f)(2)(iii)(A) of this section, capped at 10,000 beneficiaries. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, CMS will calculate the quarterly

payment amount based on the 10,000 assigned beneficiaries with the highest risk factors-based scores determined according to paragraph (f)(2)(ii) of this section.

(B) For performance year 2028 and subsequent performance years. The ACO's quarterly payment amount is the sum of the beneficiary payment amounts corresponding to the quarterly payments specified in paragraph (f)(2)(iii)(B) of this section. If the ACO has more than 10,000 assigned beneficiaries according to paragraph (f)(2)(i) of this section, CMS will calculate the quarterly payment amount based on the 10,000 assigned beneficiaries with the highest quarterly payment amount determined according to paragraph (f)(2)(iii)(B) of this section.

* * * * *

■ 83. Section 425.640 is amended by—

■ a. In paragraph (b)(1)(i), removing the phrase ''January 1, 2026, or in subsequent years'' and adding in its place the phrase ''January 1, 2026 or January 1, 2027'';

■ b. In paragraph (c)(1), removing the phrase ''January 1, 2026, or in subsequent years'' and adding in its place the phrase ''January 1, 2026 or January 1, 2027''; and

■ c. Revising paragraphs (f)(1)(i) and (ii).

The revisions read as follows:

§ 425.640 Option to receive prepaid shared savings.

* * * * *

(f) * * *

(1) * * *

(i) An eligible ACO entering an agreement period beginning on January 1, 2026 or January 1, 2027 will receive quarterly prepaid shared savings payments through December 31, 2027, unless the payment is withheld or terminated under paragraph (h) of this section.

(ii) An eligible ACO participating in an agreement period beginning on January 1, 2025, will receive quarterly prepaid shared savings payments starting with the performance year beginning on January 1, 2026 through December 31, 2027, unless the payment is withheld or terminated under paragraph (h) of this section. The ACO will not receive additional or catch-up payments for performance year 2025.

* * * * *

§ 425.650 [Amended]

■ 84. Section 425.650 is amended in paragraph (a) by removing the references ''§§ 425.652 through 425.662'' and adding in their place the references ''§§ 425.652 through 425.664''.

■ 85. Section 425.652 is amended by adding paragraph (a)(8)(iii) to read as follows:

§ 425.652 Establishing, adjusting, and updating the benchmark for agreement periods beginning on January 1, 2024, and in subsequent years.

(a) * * *

(8) * * *

(iii) For agreement periods beginning on January 1, 2027, and in subsequent years, in addition to any adjustment applied to the historical benchmark in accordance with paragraph (a)(8)(ii) of this section (either a regional adjustment, prior savings adjustment, or population adjustment, as applicable), the ACO will receive a growth adjustment (as calculated under § 425.664), if eligible. The sum of the adjustment amount (if any) applied in paragraph (a)(8)(ii) of this section and the growth adjustment (determined according to § 425.664(i)(1)) may not exceed an amount equal to the cap specified in § 425.664(i)(2).

* * * * *

■ 86. Section 425.656 is amended by—

■ a. Revising paragraph (a);

■ b. In paragraph (c)(2), removing the phrase ''paragraph (e) of this section'' and adding in its place the phrase ''paragraphs (e) or (f) of this section (as applicable)'';

■ c. Revising and republishing paragraph (c)(3);

■ d. Revising paragraph (e) introductory text;

■ e. Redesignating paragraph (f) as paragraph (g);

■ f. Adding new paragraph (f); and

■ g. In newly redesignated paragraph (g) introductory text, removing the phrase ''paragraphs (b) through (e) of this section'' and adding in its place the phrase ''paragraphs (b) through (f) of this section''.

The revisions, republications, and addition read as follows:

§ 425.656 Calculating the regional adjustment to the historical benchmark.

(a) *General.* This section describes the methodology for calculating the regional adjustment to the historical benchmark based on the ACO's regional service area expenditures, making separate calculations for the following populations of beneficiaries: ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries. This section applies to regional adjustment calculations for agreement periods beginning on January 1, 2024, and in subsequent years, except as specified otherwise.

* * * * *

(c) * * *

(3)(i) For agreement periods beginning on or after January 1, 2024 and before January 1, 2027. Caps the per capita dollar amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under paragraph (c)(2) of this section at a dollar amount equal to a percentage of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary. The cap is applied as follows:

(A) For positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(B) For negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at negative 1.5 percent of the national per capita expenditure amount for the enrollment type for BY3.

(ii) For agreement periods beginning on January 1, 2027, and in subsequent years. Caps the per capita dollar amount for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) calculated under paragraph (c)(2) of this section at a dollar amount, as follows:

(A) For positive adjustments, the per capita dollar amount for a Medicare enrollment type is capped at a dollar amount calculated as follows:

(*1*) Calculate the product of the following:

(*i*) The amount of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

(*ii*) The ACO's weighted average CMS–HCC risk score for the enrollment type for BY3.

(*2*) Calculate 5 percent of the enrollment type-specific product determined in paragraph (c)(3)(ii)(A)(*1*) of this section.

(B) For negative adjustments, the per capita dollar amount for a Medicare enrollment type is capped at a dollar amount equal to negative 1.5 percent of national per capita expenditures for Parts A and B services under the original Medicare fee-for-service

program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

* * * * *

(e) *Phase-in of weights used in the regional adjustment calculation for agreement periods beginning on or after January 1, 2024 and before January 1, 2027.*

* * * * *

(f) *Phase-in weights used in the regional adjustment calculation for agreement periods beginning on January 1, 2027, and in subsequent years.*

(1) The first time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have lower spending than the ACO's regional service area.

(ii) Using 15 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's initial or rebased historical benchmark, if the ACO is determined to have higher spending than the ACO's regional service area.

(2) The second time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) For an ACO participating under the BASIC track—

(A) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

(B) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(ii) For an ACO participating under the ENHANCED track—

(A) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

(B) Using 25 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(3) The third time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) For an ACO participating under the BASIC track—

(A) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

(B) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(ii) For an ACO participating under the ENHANCED track—

(A) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

(B) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(4) The fourth or subsequent time that an ACO's benchmark is adjusted based on the ACO's regional service area expenditures, CMS calculates the regional adjustment as follows:

(i) For an ACO participating under the BASIC track, using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark.

(ii) For an ACO participating under the ENHANCED track—

(A) Using 35 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have lower spending than the ACO's regional service area; or

(B) Using 50 percent of the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's rebased historical benchmark if the ACO is determined to have higher spending than the ACO's regional service area.

(5) To determine if an ACO has lower or higher spending compared to the ACO's regional service area, CMS does the following:

(i) Multiplies the difference between the average per capita amount of expenditures for the ACO's regional service area and the average per capita amount of the ACO's historical benchmark for each population of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) as calculated under paragraph (c)(1) of this section by the applicable proportion of the ACO's assigned beneficiary population (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries) for BY3 of the historical benchmark.

(ii) Sums the amounts determined in paragraph (f)(5)(i) of this section across the populations of beneficiaries (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries).

(iii) If the resulting sum is a net positive value, the ACO is considered to have lower spending compared to the ACO's regional service area. If the resulting sum is a net negative value, the ACO is considered to have higher spending compared to the ACO's regional service area.

(iv) If during the term of the agreement period CMS adjusts the ACO's benchmark, as specified in § 425.652(a)(9), CMS redetermines whether the ACO is considered to have lower spending or higher spending compared to the ACO's regional service area for purposes of determining the percentage in paragraphs (f)(1) through (4) of this section used in calculating the regional adjustment.

* * * * *

■ 87. Section 425.658 is amended by—

■ a. Revising paragraph (c)(1) introductory text and paragraph (c)(2); and

■ b. In paragraph (d), removing the phrase ''paragraph (c)(1) of this section'' and adding in its place the phrase ''paragraph (c) of this section''.

The revisions read as follows:

§ 425.658 Calculating the prior savings adjustment to the historical benchmark.

* * * * *

(c) * * *

(1) For agreement periods beginning on or after January 1, 2024 and before January 1, 2027. If an ACO is eligible for the prior savings adjustment as determined in paragraph (b)(3) of this section, the prior savings adjustment will equal the lesser of the following:

* * * * *

(2) For agreement periods beginning on January 1, 2027, and in subsequent years. If an ACO is eligible for the prior savings adjustment as determined in paragraph (b)(3) of this section, the prior savings adjustment will equal the lesser of the following:

(i) 75 percent of the pro-rated average per capita amount computed in paragraph (b)(3)(ii) of this section.

(ii) A single per capita value that is calculated as follows:

(A) Calculate the product of the following for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries)—

(*1*) The national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary; and

(*2*) The ACO's weighted average CMS–HCC risk score for that enrollment type for BY3.

(B) Calculate 5 percent of each enrollment type-specific product determined in paragraph (c)(2)(ii)(A) of this section.

(C) Calculate the single per capita value as a person-year weighted average by multiplying each of the enrollment type-specific values determined in accordance with paragraph (c)(2)(ii)(B) of this section by the proportion of the ACO's assigned beneficiaries within that particular enrollment type, and then summing the results.

* * * * *

■ 88. Section 425.660 is revised to read as follows:

§ 425.660 Accountable Care Prospective Trend (ACPT).

(a) *General.* The methodology by which CMS calculates and adjusts a projected growth rate called the Accountable Care Prospective Trend (ACPT) is described in this section. CMS incorporates the ACPT into the blended update factor described in § 425.652(b) when updating an ACO's benchmark for each performance year of the agreement period, for agreement periods beginning on January 1, 2024, and in subsequent years.

(b) *Determination of ACPT.* An ACPT is a flat dollar amount calculated using one or more annualized growth rates based on national fee-for-service Medicare expenditures projected by the CMS Office of the Actuary. In determining the ACPT for a Medicare enrollment type for each performance year, CMS does all of the following:

(1) *Calculate annualized projected growth rates.* The annualized projected growth rates are calculated as an annual rate of growth in projected expenditures relative to the prior year. CMS projects annualized per capita growth in Parts A and B fee-for-service expenditures for each performance year of the ACO's agreement period. In calculating the annualized projected growth rates, CMS does all of the following:

(i) Excludes IME and DSH payments, and the supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals.

(ii) Makes separate expenditure calculations for each of the following populations of beneficiaries:

(A) ESRD.

(B) Aged/Disabled.

(iii) Calculates one or more annualized projected growth rates for the ESRD population of beneficiaries described in paragraph (b)(1)(ii)(A) of this section, and one or more annualized growth rates for the Aged/Disabled population of beneficiaries described in paragraph (b)(1)(ii)(B) of this section, as follows:

(A) Using a uniform annualized projected rate of growth over each of the 5 performance years of the 5-year agreement period (for agreement periods beginning on or after January 1, 2024, and before January 1, 2027), or for each performance year (for agreement periods beginning on January 1, 2027, and in subsequent years), as applicable; or

(B) If annualization as specified in paragraph (b)(1)(iii)(A) of this section is determined not to reasonably fit the anticipated growth curve, CMS applies an alternative annualization technique using two or more annualized growth rates reflecting the projected rates of growth during the 5 performance years comprising the 5-year agreement period (for agreement periods beginning on or after January 1, 2024, and before January 1, 2027), or for each performance year (for agreement periods beginning on January 1, 2027, and in subsequent years), as applicable.

(2) *Calculate cumulative projected growth rate.* For each performance year, CMS calculates cumulative projected growth rates relative to the ACO's benchmark year (BY) 3, using the annualized projected growth rates, determined in accordance with paragraph (b)(1) of this section, for each population of beneficiaries: the ESRD population and the Aged/Disabled population.

(3) *Express cumulative projected growth rate as a flat dollar amount.* For each performance year, CMS multiplies the applicable cumulative projected growth rate described in paragraph (b)(2) of this section by BY3 truncated national per capita fee-for-service Medicare expenditures for assignable beneficiaries for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries) identified for the 12-month calendar year corresponding to BY3 to express the cumulative projected growth rate as a flat dollar amount as follows:

(i) The ESRD cumulative projected growth rate calculated in accordance with paragraph (b)(2) of this section is used for the ESRD population.

(ii) The Aged/Disabled cumulative projected growth rate calculated in accordance with paragraph (b)(2) of this section is used for the following populations: disabled, aged/dual eligible Medicare and Medicaid beneficiaries, and aged/non-dual eligible Medicare and Medicaid beneficiaries.

(4) *Risk adjust the flat dollar amount.* CMS adjusts the flat dollar amounts described in paragraph (b)(3) of this section for each performance year for differences in severity and case mix between the ACO's BY3 assigned beneficiary population and the national assignable FFS population for each Medicare enrollment type identified for the 12-month calendar year corresponding to BY3.

(5) *Calculate ACO-specific ACPT growth rates.* CMS divides the risk adjusted flat dollar amounts described in paragraph (b)(4) of this section by the ACO's historical benchmark expenditures described in § 425.652(a) for each Medicare enrollment type to calculate the percentage increase to be included in the blended update factor described in § 425.652(b)(4).

(6) *Timing of calculations.*

(i) For agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

(A) At the beginning of the ACO's agreement period, CMS calculates the annualized projected growth rates for all performance years of the ACO's

agreement period in accordance with paragraph (b)(1) of this section. These annualized projected growth rates will remain fixed over the ACO's agreement period.

(B) For a given performance year, CMS calculates an ACO-specific ACPT value, in accordance with paragraphs (b)(2) through (b)(5) of this section, using the annualized projected growth rates calculated at the beginning of the ACO's agreement period, as described in paragraph (b)(6)(i)(A) of this section.

(ii) For agreement periods beginning on January 1, 2027, and in subsequent years.

(A) In the calendar year preceding a given performance year, CMS calculates the annualized projected growth rates in accordance with paragraph (b)(1) of this section for that performance year.

(B) For a given performance year, CMS calculates an ACO-specific ACPT value, in accordance with paragraphs (b)(2) through (b)(5) of this section, using the annualized projected growth rates calculated in the preceding calendar year, as described in paragraph (b)(6)(ii)(A) of this section.

(c) *Recomputation of ACPT.* At financial reconciliation for a given performance year, CMS may recompute the ACO-specific ACPT value for a Medicare enrollment type initially determined at paragraph (b)(5) of this section for that performance year, to address under-projection or over-projection of the ACPT (as applicable), as follows:

(1) For agreement periods beginning on or after January 1, 2024, and before January 1, 2027.

(i) For performance year 2025 and subsequent performance years of the ACO's agreement period, CMS separately calculates for the ESRD and Aged/Disabled populations the difference between the cumulative projected growth rates calculated in paragraph (b)(2) of this section and the cumulative observed growth in per capita expenditures for the national assignable FFS population.

(ii) For the ESRD and Aged/Disabled populations separately, if the difference calculated in paragraph (c)(1)(i) of this section is less (more negative) than −1.0 percentage point, CMS will recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at paragraph (b)(5) of this section. CMS will calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with paragraphs (b)(3) through (b)(5) of this section, using the cumulative observed growth in expenditures for the national assignable FFS population minus 1.0 percentage point.

(iii) For the ESRD and Aged/Disabled populations separately, if the difference calculated in paragraph (c)(1)(i) of this section is greater than (less negative) or equal to −1.0 percentage point, CMS will not recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at paragraph (b)(5) of this section.

(2) For agreement periods beginning on January 1, 2027, and in subsequent years.

(i) CMS separately calculates for the ESRD and Aged/Disabled populations the difference between the cumulative projected growth rates calculated in paragraph (b)(2) of this section and the cumulative observed growth in per capita expenditures for the national assignable FFS population.

(ii) For the ESRD and Aged/Disabled populations separately, if the difference calculated in paragraph (c)(2)(i) of this section is less (more negative) than −1.0 percentage point, CMS will recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at paragraph (b)(5) of this section. CMS will calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with paragraphs (b)(3) through (b)(5) of this section, using the cumulative observed growth in expenditures for the national assignable FFS population minus 1.0 percentage point.

(iii) For the ESRD and Aged/Disabled populations separately, if the difference calculated in paragraph (c)(2)(i) of this section is greater than or equal to +1.5 percentage points, CMS will recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at paragraph (b)(5) of this section. CMS will calculate an ACO-specific ACPT value for the corresponding enrollment type(s), in accordance with paragraphs (b)(3) through (b)(5) of this section, using the cumulative observed growth in expenditures for the national assignable FFS population plus 1.5 percentage point.

(iv) For the ESRD and Aged/Disabled populations separately, if the difference calculated in paragraph (c)(2)(i) of this section is between −1.0 and +1.5 percentage points, inclusive, CMS will not recompute the ACO-specific ACPT value for the corresponding enrollment type(s) initially determined at paragraph (b)(5) of this section.

■ 89. Section 425.662 is amended by revising and republishing paragraph (b)(2) to read as follows:

§ 425.662 Calculating the population adjustment to the historical benchmark.

* * * * *

(b) * * *

(2)(i) For agreement periods beginning on January 1, 2025, or January 1, 2026. Calculates a scaler as the difference between 5 percent of the national per capita expenditure amount, expressed as single value as calculated in paragraph (b)(1) of this section, and the higher of: the regional adjustment, expressed as a single value as described in § 425.656(d); the per capita prior savings adjustment determined in § 425.658(c); or no adjustment, in the case where the regional adjustment is negative and the ACO is not eligible for the prior savings adjustment under § 425.658(b)(3)(i).

(ii) For agreement periods beginning on January 1, 2027, and in subsequent years. Calculates a scaler as the difference between the following:

(A) A single per capita value that is calculated as follows:

(*1*) Calculate the product of the following for each Medicare enrollment type (ESRD, disabled, aged/dual eligible Medicare and Medicaid beneficiaries, aged/non-dual eligible Medicare and Medicaid beneficiaries):

(*i*) The national per capita expenditures for Parts A and B services under the original Medicare fee-for-service program in BY3 for assignable beneficiaries in that enrollment type identified for the 12-month calendar year corresponding to BY3 using data from the CMS Office of the Actuary.

(*ii*) The ACO's weighted average CMS–HCC risk score for that enrollment type for BY3.

(*2*) Calculate 5 percent of each enrollment type-specific product determined in paragraph (b)(2)(ii)(A)(*1*) of this section.

(*3*) Calculate a single per capita value as a person-year weighted average by multiplying each of the enrollment type-specific values determined in accordance with paragraph (b)(2)(ii)(A)(*2*) of this section by the proportion of the ACO's assigned beneficiaries within that particular enrollment type, then summing the results.

(B) The highest among—

(*1*) The regional adjustment, expressed as a single value as described in § 425.656(d);

(*2*) The per capita prior savings adjustment determined in § 425.658(c); or

(*3*) No adjustment, in the case where the regional adjustment is negative and the ACO is not eligible for the prior

savings adjustment under § 425.658(b)(3)(i).

* * * * *

■ 90. Section 425.664 is added to read as follows:

§ 425.664 Calculating the growth adjustment to the historical benchmark .

(a) *General.* This section describes the methodology for calculating the growth adjustment to the historical benchmark for agreement periods beginning on January 1, 2027, and in subsequent years.

(b) *Determine an ACO's new growth share of assigned beneficiary person years.*

(1) *Identify shared savings initiatives for the growth adjustment.* CMS means, for purposes of this part, an initiative implemented by CMS, including the following options and initiatives—

(i) The Shared Savings Program;

(ii) The Innovation Center ACO models; or

(iii) Other initiatives that may be specified by CMS.

(2) *Identify ACO professionals who are inexperienced in shared savings initiatives.* CMS determines that an ACO professional is inexperienced in a shared savings initiative if the ACO professional has not billed primary care services through a participant in the Shared Savings Program, or participated in an Innovation Center ACO model, or other initiative specified by CMS in financial reconciliation for one or more performance years under such initiative during any of the 5 performance years directly preceding the start of the current agreement period.

(3) *Identify beneficiaries who are inexperienced with shared savings initiatives assigned to the ACO.* CMS determines that a beneficiary assigned to an ACO is inexperienced with shared savings initiatives if the beneficiary was not included in assignment in financial reconciliation to an ACO in the Shared Savings Program, Innovation Center ACO model, or other initiative specified by CMS in the performance year that corresponds to the ACO's BY3.

(4) *Calculate an ACO's new growth for the applicable performance year.* CMS calculates an ACO's new growth as follows:

(i) CMS determines the number of beneficiary person years for beneficiaries who are inexperienced with shared savings initiatives (as determined under paragraph (b)(3) of this section) with an ACO professional who is inexperienced with shared savings initiatives (as determined under paragraph (b)(2) of this section) as the ACO professional who provided the highest number of primary care services at the ACO within the assignment window, or to whom the beneficiary was voluntarily aligned, in the performance year as follows:

(A) Count the primary care services (as defined at § 425.20) each assigned beneficiary who is inexperienced with shared savings initiatives (as determined under paragraph (b)(3) of this section) has with each ACO professional participating in the ACO within the assignment window, or to whom the beneficiary was voluntarily aligned for the applicable performance year.

(B) For the purposes of this calculation, attribute the assigned beneficiary who is inexperienced with shared savings initiatives (as determined under paragraph (b)(3) of this section) to the ACO professional with whom the beneficiary had the highest number of primary care services (as defined at § 425.20) for the applicable performance year.

(C) CMS counts, as new growth for the performance year, the number of beneficiary person years for beneficiaries who are inexperienced with shared savings initiatives (as determined under paragraph (b)(3) of this section) and who received the highest number of primary care services (as defined at § 425.20) for the applicable performance year from an ACO professional who is inexperienced with shared savings initiatives (as determined under paragraph (b)(2) of this section).

(ii) [Reserved]

(c) *Determine an ACO's overall growth assigned beneficiary person years.* CMS calculates an ACO's overall growth as the number of assigned beneficiary person years in the performance year minus the number of assigned beneficiary person years in the performance year that corresponds to the ACO's BY3. If the ACO is a new entrant or re-entering ACO, the overall growth is equal to the number of assigned beneficiary person years in the performance year.

(d) *Determine an ACO's capped new growth for the performance year.* An ACO's new growth is the lesser of an ACO's new growth (as determined in paragraph (b) of this section) and an ACO's overall growth (as determined in paragraph (c) of this section).

(e) *Apply the minimum new growth thresholds for the performance year.* CMS applies the minimum new growth threshold for each performance year, expressed in absolute terms and relative terms. CMS determines the minimum new growth threshold that applies as the lesser of the relative minimum new growth threshold multiplied by the number of total assigned beneficiary person years and the absolute minimum new growth threshold. The absolute minimum new growth threshold and the relative minimum new growth threshold are as follows:

TABLE 1 TO PARAGRAPH (e)

	PY 1	PY 2	PY 3	PY 4	PY 5
Absolute Minimum New Growth Threshold	100	300	600	900	1,200
Relative Minimum New Growth Threshold	0.5%	1.5%	3.5%	5.5%	7.5%

(f) *Calculate the new growth above the minimum and below the cap for the performance year.* CMS calculates the new growth above the minimum and below the cap for each performance year as the difference between an ACO's capped new growth for the applicable performance year (as determined under paragraph (d) of this section) and the minimum new growth threshold applied for the performance year (as determined under paragraph (e) of this section), or zero, if negative. The ACO is eligible for a growth adjustment for the applicable performance year if the new growth above the minimum and below the cap is greater than zero.

(g) *Calculate the new growth share for the performance year.* CMS calculates the new growth share for the performance year as the new growth above the minimum and below the cap in the performance year (as determined under paragraph (f) of this section) divided by the total assigned beneficiary person years in the performance year.

(h) *Determine ACO's incentive factor.* The ACO's incentive factor is an ACO-specific per capita dollar amount calculated as 5 percent of the per capita historical benchmark expressed as a single value before the application of the adjustments to the historical

benchmark specified at § 425.652(a)(8)(ii) (as applicable).

(i) *Determine the ACO's growth adjustment to the historical benchmark.*

(1) CMS calculates the growth adjustment to the historical benchmark as the product of the ACO's new growth share (as determined under paragraph (g) of this section) and the ACO's incentive factor (as determined under paragraph (h) of this section).

(2) The per capita dollar amount for a Medicare enrollment type is capped at 5 percent of the product of the following—

(i) The national per capita expenditure amount for the enrollment type for BY3; and

(ii) The ACO's weighted average CMS–HCC risk score for the enrollment type for BY3.

§ 425.672 [Amended]

■ 91. Section 425.672 is amended in paragraph (c)(2)(iv) by removing the reference ''§ 425.658(c)(1)(ii)'' and adding in its place the references ''§ 425.658(c)(1)(ii) and (c)(2)(ii)''.

§ 425.702 [Amended]

■ 92. Section 425.702 is amended in paragraph (c)(1)(iii) introductory text by removing the phrase ''For performance year 2024 and subsequent performance years,'' and adding in its place the phrase ''For performance years 2024 through 2026,''.

PART 427—MEDICARE PART B DRUG INFLATION REBATE PROGRAM

■ 93. The authority citation for part 427 continues to read as follows:

Authority: 42 U.S.C. 1395w–3a(i), 1302, and 1395hh.

■ 94. Section 427.20 is amended by revising the definition of ''First marketed date'' to read as follows:

§ 427.20 Definitions.

* * * * *

First marketed date means the earliest date of first sale of any NDC–11 within a billing and payment code among all products and package sizes under the same FDA application. The first marketed date will be identified using ASP data reported by NDC–11 to CMS by a manufacturer as required under sections 1927(b)(3)(A)(iii)(I) and 1847A(f)(2) of the Act, if available. If ASP date are not available, the first marketed date will be identified using an alternative public source, such as the NDC Directory.

■ 95. Section 427.101 is amended by revising paragraph (b)(5) to read as follows.

§ 427.101 Identification of the Part B rebatable drugs.

(b) * * *

(5) *Skin substitutes.* A product included within the suite of cellular- and tissue-based products that aid wound healing, other than skin substitute products that are licensed as a drug or biological product under section 351 of the Public Health Service Act.

■ 96. Section 427.302 is amended by adding paragraph (e)(6) and revising paragraph (f) to read as follows.

§ 427.302 Calculation of the per unit Part B rebate.

* * * * *

(e) * * *

(6) For paragraphs (e)(2) through (e)(5) of this section, in the event CPI–U data are unavailable for the month described in such paragraph, CMS will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.

(f) *Identification of the rebate period CPI–U.* For each Part B rebatable drug by billing and payment code, CMS will identify and use the greater of the benchmark period CPI–U index level or the CPI–U index level for the first month of the calendar quarter that is 2 calendar quarters before the applicable calendar quarter in which the Part B rebatable drug is furnished.

(1) In the event CPI–U data are unavailable for the month described in such paragraph, CMS will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.

(2) [Reserved].

PART 428—MEDICARE PART D DRUG INFLATION REBATE PROGRAM

■ 97. The authority citation for part 428 continues to read as follows:

Authority: 42 U.S.C. 1395w–114b, 1302, and 1395hh.

■ 98. Section 428.20 is amended by revising the definition of ''Applicable period Consumer Price Index for All Urban Consumers (CPI–U)'' to read as follows.

§ 428.20 Definitions.

* * * * *

Applicable period Consumer Price Index for All Urban Consumers (CPI–U) means, with respect to an applicable period, the CPI–U for the first month of such applicable period (that is, October). In the case where the first month's CPI–U data are unavailable, CMS will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.

■ 99. Section 428.202(e) is amended by adding paragraph (e)(6) to read as follows.

§ 428.202 Calculation of the per unit Part D rebate amount.

* * * * *

(e) * * *

(6) For paragraphs (e)(2) through (e)(5) of this section, in the event CPI–U data are unavailable for the month described in such paragraph, CMS will use the first month for which CPI–U data are available following the month for which CPI–U data are unavailable.

■ 100. Section 428.203 is amended by adding paragraph (c) to read as follows.

§ 428.203 Determination of the total number of units dispensed under Part D.

* * * * *

(c) *Data reporting requirement.*

(1) Beginning with claims with a date of service on or after January 1, 2027, a provider or supplier that is a covered entity as defined at § 10.3 must submit the data elements associated with each claim for a covered Part D drug billed to Medicare Part D for which such covered entity or its contractor(s) (such as contract pharmacies) dispensed units of a drug for which a manufacturer provides a discount under the 340B Program to such covered entity:

(i) Date of service.

(ii) Prescription or service reference number.

(iii) Fill number.

(iv) Dispensing pharmacy NPI.

(v) NDC–11.

(2) In addition to submitting the data elements set forth in paragraph (c)(1) of this section, such provider or supplier must submit its 340B ID and name as designated in the 340B Office of Pharmacy Affairs Information System (OPAIS) database.

(3) The data elements and information set forth in paragraphs (c)(1) and (2) of this section must be submitted on a quarterly basis and in a form and manner specified by CMS in accordance with the following timelines:

(i) Data elements and information associated with claims with dates of service during the first calendar quarter must be submitted by the close of the second calendar quarter.

(ii) Data elements and information associated with claims with dates of service during the second calendar quarter must be submitted by the close of the third calendar quarter.

(iii) Data elements and information associated with claims with dates of service during the third calendar quarter must be submitted by the close of the fourth calendar quarter.

(iv) Data elements and information associated with claims with dates of

service during the fourth calendar quarter must be submitted by the close of the first calendar quarter of the immediately following calendar year.

(4) Data elements and information submitted in accordance with paragraph (c)(3) of this section that is either incomplete or contains invalid data must be resubmitted at a later time in a form and manner specified by CMS.

PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR CERTAIN MODELS

■ 101. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 102. Section 512.705 is amended by—
■ a. Revising the definition for ''ASM beneficiary'' and ''Dual eligible proportion''; and
■ b. Adding definitions for ''PECOS'' and ''Rural area'' in alphabetical order.

The revisions and additions read as follows:

§ 512.705 Definitions.

* * * * *

ASM beneficiary means a Medicare FFS beneficiary who is being treated by an ASM participant for an ASM targeted chronic condition.

* * * * *

Dual eligible proportion means the share of an ASM participant's beneficiaries who are dually eligible Medicare beneficiaries.

* * * * *

PECOS stands for the Provider Enrollment, Chain, and Ownership System.

* * * * *

Rural area has the same meaning as the term is defined at 42 CFR 414.1305 under MIPS.

* * * * *

■ 103. Section 512.710 is amended by—
■ a. Revising paragraph (a)(1) introductory text;
■ b. Revising paragraphs (a)(2) and (c);
■ c. Revising the introductory text of paragraphs (d)(1) and (d)(2); and
■ d. Adding paragraph (h).

The revisions and additions read as follows:

§ 512.710 Participant eligibility and selection.

(a) * * *

(1) A clinician selected by CMS as an ASM participant for any ASM performance year and who furnishes covered services during any applicable ASM performance year remains an ASM participant for the duration of the ASM test period unless CMS either terminates ASM in accordance with § 512.165 or the ASM participant receives notice of termination as described in paragraph (h) of this section.

* * * * *

(2) *Effect of not meeting ASM participant eligibility criteria for an ASM performance year.* For any ASM performance year within the ASM test period that an ASM participant does not meet the criteria for mandatory participation set forth in this section, the ASM participant is—

(i) Not subject to §§ 512.715, 512.720, and 512.745 for the applicable ASM performance year;

(ii) Not subject to § 512.750 for the corresponding ASM payment year;

(iii) Not eligible for the waivers described in § 512.775 for the applicable ASM performance year; and

(iv) Not eligible for the CMS-sponsored model arrangements and patient incentives safe harbor described in § 512.765 with respect to remuneration attributable to the applicable ASM performance year; and

* * * * *

(c) *Exceptions to specific ASM performance requirements.*

(1) *Exceptions.* CMS may in its sole discretion determine that an ASM participant who meets the requirements described in paragraph (c)(1)(i) or (c)(1)(ii) is excepted from model requirements as described in paragraph (c)(2) of this section for the duration specified in paragraph (c)(3) of this section.

(i) *Exception based on change in TIN.* An ASM participant stops reassigning billing rights to the TIN that CMS used to select the ASM participant for the applicable ASM performance year and satisfies the written notice requirements in paragraph (c)(1)(i)(A) or (c)(1)(i)(B) of this section.

(A) *Notification of change in TIN before an ASM performance year.* An ASM participant who stops reassigning billing rights to the TIN that CMS used to select the ASM participant before the applicable ASM performance year must provide written notice of the change to CMS in a form and manner determined by CMS no later than 60 days after the start of the applicable ASM performance year.

(B) *Notification of change in TIN during an ASM performance year.* An ASM participant who stops reassigning billing rights to the TIN that CMS used to select the ASM participant during an applicable ASM performance year must provide written notice of the change to CMS in a form and manner determined by CMS within 30 days of the effective date of the termination of reassignment to the ASM participant's TIN.

(ii) *Exception based on ASM heart failure participant specialty type redesignation.* An ASM heart failure participant redesignates their primary specialty type through the applicable paper CMS–855 form or internet-based PECOS before or during the applicable ASM performance year to a specialty type described in paragraph (c)(1)(ii)(A) and satisfies the written notice requirements in paragraph (c)(1)(ii)(B) of this section.

(A) *Specialty type redesignations for ASM heart failure participants.*

(*1*) Cardiac Electrophysiology.

(*2*) Cardiac Surgery.

(*3*) Interventional Cardiology.

(*4*) Advanced Heart Failure and Transplant Cardiology.

(*5*) Adult Congenital Heart Disease

(B) *Notification of specialty type redesignation.* An ASM heart failure participant who redesignates their primary specialty type through the applicable paper CMS–855 form or internet-based PECOS before or during the applicable ASM performance year as described in paragraph (c)(1)(ii) of this section must provide written notice of the CMS-approved redesignation together with verification of board certification in the newly designated primary specialty type to CMS in a form and manner determined by CMS within 30 days of the effective date of the CMS-approved redesignation.

(2) *Effect of exception.* If CMS determines an ASM participant meets an exception under paragraph (c)(1) of this section, the ASM participant is—

(i) Not subject to §§ 512.715, 512.720, and 512.745 for the applicable ASM performance year;

(ii) Not subject to § 512.750 for the corresponding ASM payment year;

(iii) Not eligible for the waivers described in § 512.775 for the applicable ASM performance year;

(iv) Not eligible for the CMS-sponsored model arrangements and patient incentives safe harbor described at § 512.765 with respect to remuneration attributable to the period beginning on the CMS-determined date of the exception described in paragraph (c)(3) of this section.

(3) *Duration of exception.*

(i) An exception under paragraph (c)(1)(i) of this section is effective on the CMS-determined date and applies for the ASM performance year specified by CMS.

(ii) An exception under paragraph (c)(1)(ii) of this section is effective on the CMS-determined date and applies for the ASM performance year specified by CMS and for the remainder of the ASM test period.

(d) * * *

(1) Heart failure specialty type—

* * * * *

(2) Low back pain specialty type—

* * * * *

(h) *Termination.*

(1) CMS may in its sole discretion terminate an ASM participant's participation in the model immediately or upon advance notice if CMS determines:

(i) One or more grounds for remedial action described in § 512.160(a) have occurred with respect to the ASM participant; or

(ii) The ASM participant's continued participation would be inconsistent with the purposes of ASM, the requirements of this part, or applicable law.

■ 104. Section 512.720 is amended by—

■ a. Revising paragraphs (a)(1)(i), (a)(ii)(B), and (e); and

■ b. Removing paragraph (f).

The revisions read as follows:

§ 512.720 Data submission requirements.

(a) * * *

(1) * * *

(i) * * *

(A) Include numerator and denominator data for at least one applicable quality measure described in § 512.725(b) or (c) that is not an administrative claims-based collection type and that meets the data completeness requirement as specified at § 512.725(f); and

(B) Except as provided in paragraph (a)(1)(i)(C) of this section, be submitted at the TIN/NPI level.

(C) An ASM participant who is in a small practice may submit quality ASM performance category data at either the TIN/NPI or the TIN level.

(ii) * * *

(B) Be submitted at either the TIN/NPI or TIN level;

* * * * *

(e) * * *

(1) *Quality ASM performance category.*

(i) If CMS receives multiple data submissions in the quality ASM performance category in accordance with paragraph (a)(1)(i) of this section from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor) for an individual ASM participant, CMS scores each submission and assigns the highest score.

(ii) If CMS receives multiple data submissions for the quality ASM performance category in accordance with paragraph (a)(1)(i) of this section from one or more submitters in the same organization for an individual ASM participant, CMS scores the most recent submission and assigns that score.

(iii) If CMS receives a TIN-level data submission in the quality ASM performance category in accordance with paragraph (a)(1)(i) of this section for an ASM participant in a small practice, CMS scores the TIN-level submission and assigns that score to all individual ASM participants in the small practice, regardless of any TIN/NPI-level submission(s) received for one or more of those ASM participants.

(2) *Improvement activities ASM performance category.*

(i) If CMS receives multiple data submissions in the improvement activities ASM performance category in accordance with paragraph (a)(1)(ii) of this section from submitters in multiple organizations (for example, qualified registry, practice administrator, or EHR vendor) for an individual ASM participant, CMS scores each submission and assigns the highest score.

(ii) If CMS receives multiple data submissions in the improvement activities ASM performance category in accordance with paragraph (a)(1)(ii) of this section from one or more submitters in the same organization for an individual ASM participant, CMS scores the most recent submission and assigns that score.

(3) *Promoting Interoperability ASM performance category.*

(i) For multiple data submissions received for the Promoting Interoperability ASM performance category in accordance with paragraph (a)(1)(iii) of this section, CMS calculates a score for each submission and assigns the highest of the scores.

* * * * *

■ 105. Section 512.725 is amended by—

■ a. Revising paragraph (c)(4);

■ b. Adding paragraphs (c)(5), (e)(3)(i), and adding and reserving paragraph (e)(3)(ii);

■ c. Revising paragraphs (f)(3), (h)(1)(i), (h)(2) introductory text, and (h)(2)(i) introductory text;

■ d. Removing paragraph (h)(2)(iii);

■ e. Redesignating paragraph (h)(2)(iv) as paragraph (h)(2)(iii); and

■ f. Adding new paragraphs (h)(2)(iv) and (i).

The revisions and additions read as follows:

§ 512.725 Quality ASM performance category.

* * * * *

(c) * * *

(4) Functional Outcome Assessment (MIPS Q182).

(5) Magnetic Resonance Imaging (MRI) Lumbar Spine for Low Back Pain (modified for ASM).

* * * * *

(e) * * *

(3) * * *

(i) For ASM participants in small practices, CMS scores all administrative claims-based quality measures at the TIN/NPI level according to the measure specifications for the applicable ASM performance year.

(ii) [Reserved].

* * * * *

(f) * * *

(3) CMS excludes from an ASM participant's total measure achievement points and total available measure achievement points any measure required under paragraph (b) or (c) of this section that meets the respective measure's data completeness requirement but does not have a benchmark.

* * * * *

(h) * * *

(1) * * *

(i) For each ASM performance year, an ASM participant receives between 1 and 10 measure achievement points (including partial points) for each measure specified in paragraph (b) or (c) of this section that satisfies the requirements described in paragraph (h)(1)(i)(A) or (h)(1)(i)(B) of this section, as applicable.

(A) For each measure other than an administrative claims-based quality measure under the quality ASM performance category on which data is submitted in accordance with paragraph (e) of this section, the measure must do all of the following:

(*1*) Have a benchmark specified in paragraph (h)(2) of this section.

(*2*) Meet the case minimum requirements specified in paragraph (g) of this section.

(*3*) Meet the data completeness criteria specified in paragraph (f) of this section.

(B) For each administrative claims-based quality measure calculated by CMS under the quality ASM performance category, the measure must have a benchmark as specified in paragraph (h)(2) of this section and meet the case minimum requirements specified in paragraph (g) of this section.

* * * * *

(2) *Benchmarks for quality ASM performance category.*

(i) CMS bases benchmarks on an ASM participant's performance by collection type, from one of the following data sources:

* * * * *

(iv) CMS excludes from an ASM participant's total measure achievement points and total available measure achievement points any measure required under paragraphs (b) or (c) of this section that does not have a benchmark.

* * * * *

(i) *Voluntary submission of patient-reported outcome data.* For any ASM cohort and ASM performance year for which CMS specifies that a voluntary patient-reported outcome data submission is available, CMS may add 5 additional points to the ASM participant's quality ASM performance category score for the ASM participant's voluntary submission of patient-reported outcome data that meets the applicable requirements set forth in paragraph (i)(1) of this section for any CMS-specified data collection period. Additional points awarded under this paragraph are added to the ASM participant's total measure achievement points calculated under paragraph (h)(4)(i) of this section, subject to the limitation set forth under paragraph (h)(4)(i)(B) of this section.

(1) *Requirements for successful voluntary submission of patient-reported outcome data.* To be eligible to receive the additional points for the quality ASM performance category for the applicable ASM performance year described in paragraph (i) of this section, an ASM participant must submit all of the following:

(i) Baseline assessment data for at least 20 ASM beneficiaries for a first CMS-specified data collection period or follow-up assessment data for at least 20 ASM beneficiaries who received a baseline assessment during the preceding data collection period.

(ii) All data elements for the applicable voluntary patient-reported outcome instrument for each required assessment, as specified and in a form and manner determined by CMS, for the applicable data collection period.

(iii) Data on all risk variables, as specified and in a form and manner determined by CMS, for each ASM beneficiary from whom an ASM participant voluntarily collects patient-reported outcome data during the applicable data collection period.

(iv) The voluntary patient-reported outcome data in a form and manner determined by CMS by the data submission deadline for the applicable ASM performance year as described at § 512.720(d).

(2) *Correction and resubmission of voluntary patient-reported outcome data.*

(i) An ASM participant may correct or resubmit any data needed to meet the voluntary data submission requirements described in paragraph (i)(1) of this section.

(ii) CMS does not accept new submissions, corrected submissions, or resubmissions of voluntary patient-reported outcome data after the applicable data submission deadline described in paragraph (i)(1)(iv) of this section.

(3) *Timely error notice for determination of quality ASM performance category scoring incentive.* An ASM participant may submit a written timely error notice as described at § 512.755 if the ASM participant believes an error occurred in CMS' determination of whether the ASM participant met the requirements described in paragraph (i)(1) of this section to receive the additional quality ASM performance category points described in paragraph (i) of this section for the applicable ASM performance year as provided to an ASM participant by CMS in an ASM performance report.

■ 106. Section 512.740 is amended by—

■ a. Revising paragraphs (b)(2)(ii), (b)(2)(iv), and (b)(3)(i)(C);

■ b. Removing paragraph (b)(3)(ii);

■ c. Redesignating paragraph (b)(3)(iii) as paragraph (b)(3)(ii);

■ d. Removing paragraph (b)(4)(i);

■ e. Redesignating paragraph (b)(4)(ii) as paragraph (b)(4)(i) and reserving paragraph (b)(4)(ii);

■ f. Revising newly redesignated paragraph (b)(4)(i);

■ g. Redesignating paragraph (c)(2) as paragraph (c)(3); and

■ h. Adding new paragraph (c)(2).

The revisions and addition read as follows:

§ 512.740 Promoting Interoperability ASM performance category.

* * * * *

(b) * * *

(2) * * *

(ii) An ASM participant must fulfill the Health Information Exchange objective through the following:

(A) For each ASM performance year, report one of the following options:

(1) Support Electronic Referral Loops by Sending Health Information (Measure ID # PI_HIE_1) and Support Electronic Referral Loops by Receiving and Reconciling Health Information (Measure ID # PI_HIE_4).

(2) Health Information Exchange (HIE) Bi-Directional Exchange (Measure ID # PI_HIE_5).

(3) Enabling Exchange Under the Trusted Exchange Framework and Common Agreement (TEFCA) (Measure ID # PI_HIE_6).

(B) For the 2027 ASM performance year, an ASM participant may, but is not required to, report the Electronic Prior Authorization measure (Measure ID # PI_HIE_7).

(C) Beginning with the 2028 ASM performance year, an ASM participant must report both measures described in paragraphs (b)(2)(ii)(C)*(1)* and (b)(2)(ii)(C)*(2)* of this section, report one measure and claim one exclusion, or claim exclusions to both measures:

(1) Electronic Prior Authorization (Measure ID # PI_HIE_7).

(2) Electronic Prior Authorization for Prescription Drugs (Measure ID # PI_HIE_8).

* * * * *

(iv) An ASM participant must fulfill the Public Health and Clinical Data Exchange objective by reporting both measures described in paragraphs (b)(2)(iv)(A) and (b)(2)(iv)(B) of this section, reporting one measure and claiming one exclusion, or claiming exclusions to both measures:

(A) Immunization Registry Reporting (Measure ID # PI_PHCDRR_1).

(B) Electronic Case Reporting (Measure ID # PI_PHCDRR_3).

* * * * *

(3) * * *

(i) * * *

(C) An exclusion for each measure that includes an option for an exclusion.

(ii) Submit an affirmative attestation regarding the ASM participant's completion of the annual self-assessment checklist under the MIPS Promoting Interoperability High Priority Practices Guide of the SAFER Guides measure (Measure ID# PI_PPHI_2) within the calendar year of the ASM performance year.

(4) * * *

(i) *Actions to limit or restrict the compatibility or interoperability of CEHRT.* To fulfill ASM requirements for activities related to limiting or restricting the compatibility or interoperability of CEHRT, an ASM participant must not knowingly and willfully take action, such as disabling functionality, to limit or restrict the compatibility or interoperability of CEHRT.

(ii) [Reserved].

* * * * *

(c) * * *

(2) *Promoting Interoperability measure suppression.* If certain circumstances occur that impact CMS' assessment of the performance of ASM participants on a measure specified for the Promoting Interoperability ASM performance category, CMS may in its sole discretion suppress the affected measure by excluding it from CMS' assessment of ASM participant performance while allocating the

maximum points available or providing full credit for the affected measure as long as the affected measure is reported, resulting in a suppressed measure contributing to the Promoting Interoperability ASM performance category objective score under paragraph (c)(3) of this section; or excluding it from the determination of a meaningful EHR user if the affected measure is not scored. CMS determines whether certain circumstances exist that warrant suppression of a measure based on CMS' consideration of one or more of the following factors:

(i) The nature, breadth, and duration of the circumstances' effect on ASM participants' ability to fulfill the measure requirement.

(ii) The availability of certified health IT modules to fulfill the measure.

(iii) The circumstance affects the measure such that calculating the measure score would lead to misleading or inaccurate results, which may include performance or compliance.

(iv) Out-of-date or conflicting technical standards.

(v) Technical and operational capacity of required partners.

(vi) Other factors as determined by CMS.

* * * * *

■ 107. Section 512.745 is amended by—

■ a. Revising paragraph (a) introductory text and paragraph (a)(2)(iii)(B);

■ b. Redesignating paragraph (a)(5) as paragraph (a)(6);

■ c. Adding new paragraph (a)(5);

■ d. Revising newly redesignated paragraph (a)(6);

■ e. Revising paragraphs (b)(2) through (b)(6); and

■ f. Adding paragraphs (b)(7) and (b)(8).

The revisions and additions read as follows:

§ 512.745 Final scoring.

(a) *Final score calculation.* CMS calculates a final score of zero to 100 points using the formula specified at paragraph (a)(6) of this section for each ASM participant that meets the requirements to receive a final score as specified in paragraph (a)(2) of this section.

* * * * *

(2) * * *

(iii) * * *

(B) Do not receive either a—

(*1*) Quality ASM performance category score under § 512.725(h)(4)(iii); or

(*2*) Cost ASM performance category score under § 512.730(e)(3)(i).

* * * * *

(5) *Rural scoring adjustment.*

(i) *Scoring adjustment for an ASM participant in a rural area.* CMS adds 5 points to the final score of an ASM participant who is in a rural area as defined at § 512.705 and meets the requirements to receive a final score greater than zero as described in paragraph (a)(2)(i) of this section for an applicable ASM performance year.

(6) *Final score formula.* Final score = [(quality ASM performance category score × quality ASM performance category weight) + (cost ASM performance category score × cost ASM performance category weight)] × 100 + improvement activities ASM performance category scoring adjustment + Promoting Interoperability ASM performance category scoring adjustment + complex patient scoring adjustment + small practice scoring adjustment + rural scoring adjustment. The final score cannot be below zero points or exceed 100 points.

(b) * * *

(2) The ASM participant's quality ASM performance category scoring incentive for voluntary reporting of patient-reported outcome data under § 512.725(i), as applicable.

(3) The ASM participant's complex patient scoring adjustment under paragraph (a)(3) of this section, as applicable.

(4) The ASM participant's small practice or solo practitioner scoring adjustment under paragraph (a)(4) of this section, as applicable.

(5) The ASM participant's rural scoring adjustment under paragraph (a)(5) of this section, as applicable.

(6) The ASM participant's final score, as applicable.

(7) The ASM payment adjustment factor under § 512.750(c)(1).

(8) The ASM payment multiplier under § 512.750(c).

* * * * *

■ 108. Section 512.750 is amended by revising paragraphs (f)(1) and (f)(2) to read as follows:

§ 512.750 Payment adjustment.

* * * * *

(f) * * *

(1) If an NPI submits Part B covered professional service claims during an ASM payment year under a different TIN than the TIN CMS selected them as an ASM participant for that same ASM performance year and to which the NPI began assigning billing rights after the applicable ASM performance year but before the end of the corresponding ASM payment year, CMS multiplies the amount otherwise paid under Part B for covered professional services to the different TIN by the ASM payment multiplier calculated for the ASM participant based on their performance in the corresponding ASM performance year.

(2) CMS multiplies the amount otherwise paid under Part B for covered professional services by the highest ASM payment multiplier calculated for an NPI who meets all the following:

(i) Is an ASM participant under multiple TINs for a given ASM performance year.

(ii) Submits Part B covered professional service claims during an ASM payment year under a TIN by which CMS did not select the NPI as an ASM participant and to which the ASM participant began reassigning billing rights after the applicable ASM performance year but before the end of the corresponding ASM payment year.

* * * * *

■ 109. Section 512.765 is amended by adding paragraph (c) to read as follows:

§ 512.765 Application of the CMS-sponsored model arrangements and patient incentives safe harbor.

* * * * *

(c) *Scope.* The CMS-sponsored model arrangements and patients incentives safe harbor described in paragraphs (a) and (b) of this section is available only with respect to remuneration exchanged or furnished in connection with an ASM participant's performance under the model and does not apply with respect to remuneration attributable to any period for which CMS determines the ASM participant does not meet ASM participant eligibility criteria under § 512.710(a)(2) or is excepted from specified ASM requirements under § 512.710(c).

■ 110. Section 512.771 is amended by—

■ a. Revising paragraphs (a)(1), (a)(2), (a)(5), and (a)(6);

■ b. Redesignating paragraphs (a)(7) and (a)(8) as paragraphs (d)(2) and (d)(3), respectively.

■ c. Redesignating paragraphs (a)(9) through (13) as (a)(7) through (11), respectively.

■ d. Revising newly redesignated paragraphs (a)(7) and (a)(9); and

■ e. Adding paragraph (d).

The revisions and additions read as follows:

§ 512.771 Collaborative care arrangements.

(a) * * *

(1) The collaborative care arrangement must be in writing, signed by all parties, specify the effective date, and be exclusively between one or more ASM participants who reassign billing rights through the same TIN and a primary care practice.

(2) The primary care practice party and an ASM participant party to the

collaborative care arrangement must share one or more patients who are ASM beneficiaries.

* * * * *

(5) All parties to the collaborative care arrangement must comply with the provisions of this section and all other applicable statutes, regulations, and guidance.

(6) Neither the opportunity to enter into a collaborative care arrangement nor remuneration given or received under a collaborative care arrangement may be conditioned directly or indirectly on the volume or value of past or anticipated referrals or business generated by, between, or among the parties to the collaborative care arrangement or any other person. A selection criterion that considers whether an ASM participant and primary care practice share one or more ASM beneficiaries for the purpose of satisfying the requirement set forth in paragraph (a)(2) of this section will be deemed not to violate the volume or value standard of this section if the purpose of the criterion is to further the purpose of the collaborative care arrangement.

(7) All parties to the collaborative care arrangement must retain the ability to make decisions in the best interests of ASM beneficiaries, including the selection of clinicians, devices, supplies, and treatments.

* * * * *

(9) An ASM participant must maintain contemporaneous documentation, in accordance with § 512.135, regarding all collaborative care arrangements entered into, including the following:

(i) The relevant written agreements.

(ii) Records of all remuneration exchanged, if any, for each ASM participant party to a collaborative care arrangement, including, at a minimum, all of the following:

(A) A description of the remuneration.

(B) The value of remuneration.

(C) The methodology for determining the value of any in-kind remuneration in accordance with paragraph (d)(2)(ii) of this section, if applicable.

(D) The date on which the remuneration was exchanged.

(iii) The identity of each ASM participant who is a party to the collaborative care arrangement.

* * * * *

(d) *Remuneration under a collaborative care arrangement.* If the parties to a collaborative care arrangement elect to include terms allowing for the exchange of remuneration under the collaborative care arrangement, the parties must also comply with all of the following:

(1) The purpose of the exchange of remuneration under the collaborative care arrangement must be reasonably related to the purpose of the collaborative care arrangement, consistent with the requirements of paragraph (a)(3) of this section.

(2) The total amount of any remuneration exchanged under a collaborative care arrangement in a given ASM performance year must not exceed an amount equal to the ASM participant's ASM payment adjustment factor for the applicable ASM performance year multiplied by the amount otherwise paid to the ASM participant by CMS under Part B for covered professional services during the applicable ASM performance year.

(i) The collaborative care arrangement must specify a methodology for the parties to identify and calculate the total amount of remuneration exchanged under such arrangement in the ASM performance year for each ASM participant and determine within a reasonable amount of time after the information necessary to make the calculation in paragraph (d)(2) of this section becomes available whether the total amount of remuneration exceeds the limitation in paragraph (d)(2) of this section.

(ii) For in-kind remuneration, the value of remuneration exchanged for the purpose of this section is determined based on the offeror's cost for the remuneration, using any reasonable accounting methodology, or the fair market value of the in-kind remuneration.

(iii) The collaborative care arrangement must require the parties to reconcile any remuneration exchanged by each ASM participant under the arrangement in the ASM performance year after the limitation in paragraph (d)(2) of this section is determined.

(iv) If the total amount of remuneration received by a party in the ASM performance year exceeds the limitation in paragraph (d)(2) of this section, the collaborative care arrangement must require the party that received the excess amount to repay the excess amount to the other party within a reasonable amount of time after the reconciliation.

(3) Any remuneration exchanged under a collaborative care arrangement must be solely between the parties to the arrangement. To the extent that remuneration exchanged is monetary, any payment between the parties must be made by check, electronic funds transfer, or another traceable cash transaction.

* * * * *

■ 111. Section 512.775 is amended in paragraph (a) by removing the reference ''§ 512.710(a)(2)'' and adding in its place the phrase ''§ 512.710(a)(2) or § 512.710(c)''.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

Note: The following Appendices will not appear in the Code of Federal Regulations.

Appendix 1: MIPS Quality Measures

Note: Except as otherwise noted in this proposed rule, previously finalized measures and specialty sets would continue to apply for the CY 2027 performance period/2029 MIPS payment year and future years. Previously finalized measures and specialty sets are in the CY 2017 through CY 2026 PFS final rules: 81 FR 77558 through 77816, 82 FR 53966 through 54174, 83 FR 60097 through 60285, 84 FR 63205 through 63513, 85 FR 85045 through 85369, 86 FR 65687 through 65968, 87 FR 70250 through 70633, 88 FR 79556 through 79964, 89 FR 98599 through 98957, and 90 FR 50036 through 50353. In addition, electronic clinical quality measures (eCQMs) that are endorsed by a Consensus-Based Entity (CBE) are shown in Table A of this Appendix as follows: CBE #/ eCQM CBE #.

Note: In section IV.A.4.d.(1)(c)(i) of this proposed rule, we are proposing to implement MIPS core measures for traditional MIPS and MVP reporting which are identified in the tables in this Appendix. In addition, in section IV.A.4.d.(1)(c)(ii) of this proposed rule, we are proposing to remove the high priority designation from MIPS quality measures and therefore, we have removed the high priority indicator across all tables in this Appendix.

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Table Group A: New MIPS Quality Measures Proposed for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

Note: Proposed specialty sets for new measures are indicated under Table Group A of this Appendix within the last row of each A table.

We request comments on these new measures and the applicable specialty sets.

A.1. Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 years and older with clinical atherosclerotic cardiovascular disease (ASCVD) who received a low-density lipoprotein cholesterol (LDL-C) test via lipid panel and achieved an LDL-C of <70mg/dL on the most recent test during the performance period.
Measure Steward:	American Heart Association
Numerator:	Numerator 1: Patients aged 18 years and older with clinical atherosclerotic cardiovascular disease (ASCVD) who had a low density lipoprotein cholesterol (LDL-C) test via a lipid panel. Numerator 2: Patients aged 18 years and older with clinical ASCVD and had a lipid panel completed during the 12-month measurement period who achieved an LDL-C of <70 mg/dL on the most recent test during the 12-month measurement period.
Denominator:	Denominator 1: All patients aged 18 years and older diagnosed with clinical atherosclerotic cardiovascular disease (ASCVD). Denominator 2: All patients aged 18 years and older with clinical ASCVD who had a low density lipoprotein cholesterol (LDL-C) test via a lipid panel during the measurement period.
Exclusions:	Pregnancy, ESRD, hospice, over age 66+ with advanced illness, frailty, or dementia medications
Measure Type:	Intermediate Outcome
MIPS Core Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We are proposing this intermediate outcome measure because it addresses appropriate care for adult patients with clinical atherosclerotic cardiovascular disease (ASCVD), ensuring patients diagnosed with this condition are annually tested for LDL-C and achieve a desired level. Studies support that elevated LDL-C levels contribute to ASCVD and once identified can be addressed via lipid management. Lowering LDL-C produces a marked reduction in clinical ASCVD and evidence shows that lower LDL-C levels are associated with better outcomes.[403] This measure ensures that patients receiving cholesterol lowering treatment, such as statin therapy, achieve a reduction in LDL-C, which in turn reduces risk of ASCVD and other patient outcomes, such as hospitalizations and cardiovascular death.[404] This measure is based on peer-reviewed evidence demonstrating that, for adults 20 years of age or older and not on lipid-lowering therapy, measurement of either a fasting or non-fasting plasma lipid profile is effective in estimating ASCVD risk and documenting baseline LDL-C.[405] This measure would expand on current MIPS measure Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease, which focuses on appropriate statin treatment of patients at high risk for cardiovascular events. While measure Q438 assesses for the prescribing of statin therapy, this new measure would build on measure Q438 by assessing the outcome of LDL-C treatment, through achievement of reaching a desired LDL-C level. The Pre-Rulemaking Measure Review (PRMR) Clinician Recommendation Committee reached consensus agreement to recommend the measure. Testing indicated good reliability based on signal to noise ratio and adequate face validity. Testing of measure performance indicated a gap in care with a mean performance rate of 46.8 percent for the first criteria and 64.9 percent for the second criteria. This demonstrates that there is room for improvement among clinicians treating this patient population. This measure is not currently CBE endorsed. Although CBE endorsement is preferred, it is still recommended this measure be added to MIPS because it is an evidence-based measure, satisfying the requirement set forth at section 1848(q)(2)(D)(v) of the Act, stating that any measure selected for inclusion in MIPS that is not endorsed by a CBE shall have a focus that is evidence-based. This measure could be added to multiple MVPs in the future, including the proposed Hypertension MVP, Advancing Care for Heart Disease MVP, and Value in Primary Care MVP. We are proposing to add this measure to applicable specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties. Note: Refer to the PRMR Clinician Recommendation Committee Spreadsheet of Final Recommendations to CMS and HHS at *https://p4qm.org/sites/default/files/2026-02/Final-2025-2026-MUC-Recommendations-Report-508.pdf.*
Measure Proposed for Addition to the Following Specialty Sets:	Cardiology, Endocrinology, Family Medicine, Geriatrics, Internal Medicine, Nephrology, Neurology, Obstetrics/Gynecology, Preventive Medicine, Vascular Surgery

[403] Grundy, S. M., Stone, N. J., Bailey, A. L., Beam, C., Birtcher, K. K., Blumenthal, R. S., Braun, L. T., de Ferranti, S., Faiella-Tommasino, J., Forman, D. E., Goldberg, R., Heidenreich, P. A., Hlatky, M. A., Jones, D. W., Lloyd-Jones, D., Lopez-Pajares, N., Ndumele, C. E., Orringer, C. E., Peralta, C. A., Saseen, J. J., … Yeboah, J. (2019). 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. Circulation, 139(25), e1082–e1143. https://doi.org/10.1161/CIR.0000000000000625.

[404] See footnote Grundy et al., 2019.

[405] See footnote Grundy et al., 2019.

A.2. Functional Improvement for Patients with Neck Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 years and older with a neck impairment that met the risk-adjusted Predicted Moderate Clinical Improvement (P-MCI) on the PROMIS Pain Interference (PPI) or the alternative (legacy) patient-reported outcome measure (PROM), the Neck Disability Index (NDI).
Measure Steward:	Limber Health, Inc. and Patient360, LLC
Numerator:	Patients whose most recent PPI score beyond the baseline score meets or exceeds the P-MCI at the time of the completed episode of care.
Denominator:	All patients aged 18 years or older at the start of the episode of care with a neck impairment who completed a baseline PPI.
Exclusions:	Pre-operative Care: Patients who are being seen for pre-operative care and/or have surgery for the neck impairment within 30 days after the initial assessment, documented in the medical record. Cognitive Deficit: A significant mental or cognitive impairment that compromises the patient's ability to complete the PROM, such as dementia or intellectual disabilities, documented in the medical record. Hospice: Patient is in hospice care or receiving palliative care for terminal illness, as documented in the medical record. Active Cancer Treatment: The patient is in active treatment for cancer (e.g., undergoing chemotherapy, radiation therapy, immunotherapy, or cancer-related surgery) AND the goal of musculoskeletal care is primarily to avoid or minimize decline in function, documented in the medical record. Maintenance Therapy: The patient meets Medicare requirements for maintenance therapy, such as the maintenance of functional status or prevention of a slow deterioration in function, as defined by the Medicare Benefits Policy Manual, Chapter 15,[406] as documented in the medical record.
Measure Type:	Patient-Reported Outcome-Based Performance Measure (PRO-PM)
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

[406] Medicare Benefit Policy Manual. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.

Category	Description
Rationale:	We are proposing this current QCDR patient-reported outcome-based performance measure to replace current MIPS quality measure Q478: Functional Status Change for Patients with Neck Impairments. This new measure would address the same clinical topic as measure Q478; however, it allows for broader implementation by including widely available, non-proprietary tools to assess physical function improvement. Additionally, this measure's analytic allows independent calculation of performance by the clinician, or easy and free collaboration with the steward, which supports clinicians reporting this important aspect of rehabilitative care. This measure utilizes the PROMIS® Pain Interference tool, which was developed using item response theory (IRT) methods. Evidence indicates that the PROMIS-PI items constitute a psychometrically sound item bank for assessing the negative effects of pain on functioning across the range commonly experienced by people who have pain.[407] It allows clinician flexibility in administration as it uses computer adaptive testing (CAT) or a fixed-length short form. This measure also allows utilization of the Neck Disability Index (NDI), which is a commonly used tool for neck pain with established reliability and validity.[408] [409] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Rehabilitative Support for Musculoskeletal Care MVP (currently proposed to be renamed as the Rehabilitative Support MVP under Appendix 3: MVP Inventory, Table B.24). We are proposing to add this measure to the Chiropractic Medicine and Physical Therapy/Occupational Therapy specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Chiropractic Medicine, Physical Therapy/Occupational Therapy

[407] Amtmann, D., Cook, K. F., Jensen, M. P., Chen, W. H., Choi, S., Revicki, D., Cella, D., Rothrock, N., Keefe, F., Callahan, L., & Lai, J. S. (2010). Development of a PROMIS Item Bank to Measure Pain Interference. *Pain*, *150*(1), 173–182. https://doi.org/10.1016/j.pain.2010.04.025.

[408] Young, I. A., Dunning, J., Butts, R., Mourad, F., & Cleland, J. A. (2019). Reliability, Construct Validity, and Responsiveness of the Neck Disability Index and Numeric Pain Rating Scale in Patients with Mechanical Neck Pain Without Upper Extremity Symptoms. *Physiotherapy Theory and Practice*, *35*(12), 1328–1335. https://doi.org/10.1080/09593985.2018.1471763.

[409] MacDermid, J. C., Walton, D. M., Avery, S., Blanchard, A., Etruw, E., McAlpine, C., & Goldsmith, C. H. (2009). Measurement Properties of the Neck Disability Index: A Systematic Review. *The Journal of Orthopaedic and Sports Physical Therapy*, *39*(5), 400–417. https://doi.org/10.2519/jospt.2009.2930.

A.3. Functional Improvement for Patients with Upper Extremity Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 years and older with an upper extremity impairment that met the risk-adjusted Predicted Moderate Clinical Improvement (P-MCI) on the PROMIS Upper Extremity (PUE) or the alternative (legacy) patient-reported outcome measure (PROM), the Quick Disabilities of the Arm, Shoulder, & Hand (QDASH).
Measure Steward:	Limber Health, Inc. and Patient360, LLC
Numerator:	Patients whose most recent PUE score beyond the baseline score meets or exceeds the P-MCI at the time of the completed episode of care.
Denominator:	All patients aged 18 years or older at the start of the episode of care with an upper extremity impairment who completed a baseline PUE.
Exclusions:	Pre-operative Care: Patients who are being seen for pre-operative care and/or have surgery for upper extremity impairment within 30 days after the initial assessment, documented in the medical record. Cognitive Deficit: A significant mental or cognitive impairment that compromises the patient's ability to complete the PROM, such as dementia or intellectual disabilities, documented in the medical record. Hospice: Patient is in hospice care or receiving palliative care for terminal illness, as documented in the medical record. Active Cancer Treatment: The patient is in active treatment for cancer (e.g., undergoing chemotherapy, radiation therapy, immunotherapy, or cancer-related surgery) AND the goal of musculoskeletal care is primarily to avoid or minimize decline in function, documented in the medical record. Maintenance Therapy: The patient meets Medicare requirements for maintenance therapy, such as the maintenance of functional status or prevention of a slow deterioration in function, as defined by the Medicare Benefits Policy Manual, Chapter 15,[410] as documented in the medical record.
Measure Type:	Patient-Reported Outcome-Based Performance Measure (PRO-PM)
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

[410] Medicare Benefit Policy Manual. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.

Category	Description
Rationale:	We are proposing this current QCDR patient-reported outcome-based performance measure to replace current MIPS quality measure Q221: Functional Status Change for Patients with Shoulder Impairments and Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments. This new measure would address the same clinical topics as measures Q221 and Q222; however, it allows for broader implementation by including widely available, non-proprietary tools to assess physical function improvement. Additionally, this measure's analytic allows independent calculation of performance by the clinician, or easy and free collaboration with the steward, which supports clinicians reporting this important aspect of rehabilitative care. This measure utilizes the PROMIS® Upper Extremity tool, which was developed using item response theory (IRT) methods and evidence supports high reliability and validity[411]. It allows clinician flexibility in administration as it uses computer adaptive testing (CAT) or a fixed-length short form. This measure also allows use of the Quick Disabilities of the Arm, Shoulder, and Hand (QuickDASH) tool, which has also shown to be highly reliable and valid for use in patients with upper extremity musculoskeletal disorders.[412] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Rehabilitative Support for Musculoskeletal Care MVP (currently proposed to be renamed as the Rehabilitative Support MVP under Appendix 3: MVP Inventory, Table B.24). We are proposing to add this measure to the Chiropractic Medicine and Physical Therapy/Occupational Therapy specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Chiropractic Medicine, Physical Therapy/Occupational Therapy

[411] Hung, M., Voss, M. W., Bounsanga, J., Crum, A. B., & Tyser, A. R. (2017). Examination of the PROMIS Upper Extremity Item Bank. *Journal of Hand Therapy: Official Journal of the American Society of Hand Therapists*, *30*(4), 485–490. https://doi.org/10.1016/j.jht.2016.10.008.

[412] Chao, Z., & Guo, H. (2023). Reliability and Validity of Quick Disabilities of the Arm, Shoulder, and Hand Questionnaire in Taiwan. *Archives of Physical Medicine and Rehabilitation*, *104*(3), e49. https://doi.org/10.1016/j.apmr.2022.12.142.

A.4. Functional Improvement for Patients with Back Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 years and older with a back impairment that met the risk-adjusted Predicted Moderate Clinical Improvement (P-MCI) on the PROMIS Pain Interference (PPI) or the alternative (legacy) patient-reported outcome measure (PROM), the Modified Low Back Disability Questionnaire (MDQ).
Measure Steward:	Limber Health, Inc. and Patient360, LLC
Numerator:	Patients whose most recent PPI score beyond the baseline score meets or exceeds the P-MCI at the time of the completed episode of care.
Denominator:	All patients aged 18 years or older at the start of the episode of care with a back impairment who completed a baseline PPI.
Exclusions:	Pre-operative Care: Patients who are being seen for pre-operative care and/or have surgery for the back impairment within 30 days after the initial assessment, documented in the medical record. Cognitive Deficit: A significant mental or cognitive impairment that compromises the patient's ability to complete the PROM, such as dementia or intellectual disabilities, documented in the medical record. Hospice: Patient is in hospice care or receiving palliative care for terminal illness, as documented in the medical record. Active Cancer Treatment: The patient is in active treatment for cancer (e.g., undergoing chemotherapy, radiation therapy, immunotherapy, or cancer-related surgery) AND the goal of musculoskeletal care is primarily to avoid or minimize decline in function, documented in the medical record. Maintenance Therapy: The patient meets Medicare requirements for maintenance therapy, such as the maintenance of functional status or prevention of a slow deterioration in function, as defined by the Medicare Benefits Policy Manual, Chapter 15,[413] as documented in the medical record.
Measure Type:	Patient-Reported Outcome-Based Performance Measure (PRO-PM)
MIPS Core Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

[413] Medicare Benefit Policy Manual. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.

Category	Description
Rationale:	We are proposing this current QCDR patient-reported outcome-based performance measure to replace current MIPS quality measure Q220: Functional Status Change for Patients with Low Back Impairments. This new measure would address the same clinical topic as measure Q220; however, it allows for broader implementation by including widely available, non-proprietary tools to assess physical function improvement. Additionally, this measure's analytic allows independent calculation of performance by the clinician, or easy and free collaboration with the steward, which supports clinicians reporting this important aspect of rehabilitative care. This measure utilizes the PROMIS® Pain Interference tool, which was developed using item response theory (IRT) methods. Evidence indicates that the PROMIS-PI items constitute a psychometrically sound item bank for assessing the negative effects of pain on functioning across the range commonly experienced by people who have pain.[414] It allows clinician flexibility in administration as it uses computer adaptive testing (CAT) or a fixed-length short form. This measure also allows utilization of the Modified Low Back Disability Questionnaire (MDQ), which has shown to be a valid, reliable, and responsive condition-specific assessment tool that is suited for use in clinical practice.[415] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Rehabilitative Support for Musculoskeletal Care MVP (currently proposed to be renamed as the Rehabilitative Support MVP under Appendix 3: MVP Inventory, Table B.24). We are proposing to add this measure to the Chiropractic Medicine and Physical Therapy/Occupational Therapy specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Chiropractic Medicine, Physical Therapy/Occupational Therapy

[414] See footnote Amtmann et al., 2010.

[415] Vianin M. (2008). Psychometric Properties and Clinical Usefulness of the Oswestry Disability Index. *Journal of Chiropractic Medicine*, 7(4), 161–163. https://doi.org/10.1016/j.jcm.2008.07.001.

A.5. Functional Improvement for Patients with Lower Extremity Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 years and older with a lower extremity impairment—not including knee impairments—that met the risk-adjusted Predicted Moderate Clinical Improvement (P-MCI) on the PROMIS Physical Function (PPF) or alternative (legacy) patient-reported outcome measure (PROM), the Lower Extremity Functional Scale (LEFS).
Measure Steward:	Limber Health, Inc. and Patient360, LLC
Numerator:	Patients whose most recent PPF score beyond the baseline score meets or exceeds the P-MCI at the time of the completed episode of care.
Denominator:	All patients aged 18 years or older at the start of the episode of care with a non-knee impairment who completed a baseline PPF.
Exclusions:	Pre-operative Care: Patients who are being seen for pre-operative care and/or have surgery for the non-knee lower extremity impairment within 30 days after the initial assessment, documented in the medical record. Cognitive Deficit: A significant mental or cognitive impairment that compromises the patient's ability to complete the PROM, such as dementia or intellectual disabilities, documented in the medical record. Hospice: Patient is in hospice care or receiving palliative care for terminal illness, as documented in the medical record. Active Cancer Treatment: The patient is in active treatment for cancer (e.g., undergoing chemotherapy, radiation therapy, immunotherapy, or cancer-related surgery) AND the goal of musculoskeletal care is primarily to avoid or minimize decline in function, documented in the medical record. Maintenance Therapy: The patient meets Medicare requirements for maintenance therapy, such as the maintenance of functional status or prevention of a slow deterioration in function, as defined by the Medicare Benefits Policy Manual, Chapter 15,[416] as documented in the medical record.
Measure Type:	Patient-Reported Outcome-Based Performance Measure (PRO-PM)
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

[416] Medicare Benefit Policy Manual. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.

Category	Description
Rationale:	We are proposing this current QCDR patient-reported outcome-based performance measure to replace current MIPS quality measures Q218: Functional Status Change for Patients with Hip Impairments and Q219: Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments. This new measure would address the same clinical topics as measures Q218 and Q219; however, it allows for broader implementation by including widely available, non-proprietary tools to assess physical function improvement. Additionally, this measure's analytic allows independent calculation of performance by the clinician, or easy and free collaboration with the steward, which supports clinicians reporting this important aspect of rehabilitative care. This measure utilizes the PROMIS® Physical Function (PPF) tool, which was developed using item response theory (IRT) methods and has demonstrated reliability, convergent and known-groups discriminant validity, and responsiveness in a sample of patients with a lower extremity orthopedic trauma injury.[417] This measure also allows utilization of the Lower Extremity Functional Scale (LEFS). Evidence supports the reliability, validity, and responsiveness of LEFS scores for assessing functional impairment in a wide array of patient groups with lower extremity musculoskeletal conditions.[418] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Rehabilitative Support for Musculoskeletal Care MVP (currently proposed to be renamed as the Rehabilitative Support MVP under Appendix 3: MVP Inventory, Table B.24). We are proposing to add this measure to the Chiropractic Medicine and Physical Therapy/Occupational Therapy specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Chiropractic Medicine, Physical Therapy/Occupational Therapy

[417] Rothrock, N. E., Kaat, A. J., Vrahas, M. S., O'Toole, R. V., Buono, S. K., Morrison, S., & Gershon, R. C. (2019). Validation of PROMIS Physical Function Instruments in Patients With an Orthopaedic Trauma to a Lower Extremity. *Journal of Orthopaedic Trauma*, *33*(8), 377–383. https://doi.org/10.1097/BOT.0000000000001493.

[418] Mehta, S. P., Fulton, A., Quach, C., Thistle, M., Toledo, C., & Evans, N. A. (2016). Measurement Properties of the Lower Extremity Functional Scale: A Systematic Review. *The Journal of Orthopaedic and Sports Physical Therapy*, *46*(3), 200–216. https://doi.org/10.2519/jospt.2016.6165.

A.6. Functional Improvement for Patients with Knee Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged 18 years and older with a knee impairment that met the risk-adjusted Predicted Moderate Clinical Improvement (P-MCI) on the PROMIS Physical Function (PPF) or the alternative (legacy) patient-reported outcome measure (PROM), the Knee Outcome Survey (KOS).
Measure Steward:	Limber Health, Inc. and Patient360, LLC
Numerator:	Patients whose most recent PPF score beyond the baseline score meets or exceeds the P-MCI at the time of the completed episode of care.
Denominator:	All patients aged 18 years or older at the start of the episode of care with a knee impairment who completed a baseline PPF.
Exclusions:	Pre-operative Care: Patients who are being seen for pre-operative care and/or have surgery for the knee impairment within 30 days after the initial assessment, documented in the medical record. Cognitive Deficit: A significant mental or cognitive impairment that compromises the patient's ability to complete the PROM, such as dementia or intellectual disabilities, documented in the medical record. Hospice: Patient is in hospice care or receiving palliative care for terminal illness, as documented in the medical record. Active Cancer Treatment: The patient is in active treatment for cancer (e.g., undergoing chemotherapy, radiation therapy, immunotherapy, or cancer-related surgery) AND the goal of musculoskeletal care is primarily to avoid or minimize decline in function, documented in the medical record. Maintenance Therapy: The patient meets Medicare requirements for maintenance therapy, such as the maintenance of functional status or prevention of a slow deterioration in function, as defined by the Medicare Benefits Policy Manual, Chapter 15,[419] as documented in the medical record.
Measure Type:	Patient-Reported Outcome-Based Performance Measure (PRO-PM)
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

[419] Medicare Benefit Policy Manual. https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/bp102c15.pdf.

Category	Description
Rationale:	We are proposing this current QCDR patient-reported outcome-based performance measure to replace current MIPS quality measure Q217: Functional Status Change for Patients with Knee Impairments. This new measure would address the same clinical topic as measure Q217; however, it allows for broader implementation by including widely available, non-proprietary tools to assess physical function improvement. Additionally, this measure's analytic allows independent calculation of performance by the clinician, or easy and free collaboration with the steward, which supports clinicians reporting this important aspect of rehabilitative care. This measure utilizes the PROMIS® Physical Function (PPF) tool, which was developed using item response theory (IRT) methods and has demonstrated reliability, convergent and known-groups discriminant validity, and responsiveness in a sample of patients with a lower extremity orthopedic trauma injury.[420] This measure also allows utilization of the Knee Outcome Survey (KOS). Evidence shows it is a reliable, valid, and responsive instrument for the assessment of functional limitations that result from a wide variety of pathological disorders and impairments of the knee.[421] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Rehabilitative Support for Musculoskeletal Care MVP (currently proposed to be renamed as the Rehabilitative Support MVP under Appendix 3: MVP Inventory, Table B.24). We are proposing to add this measure to the Chiropractic Medicine and Physical Therapy/Occupational Therapy specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Chiropractic Medicine, Physical Therapy/Occupational Therapy

[420] See footnote Rothrock et al., 2019.

[421] Irrgang, J. J., Snyder-Mackler, L., Wainner, R. S., Fu, F. H., & Harner, C. D. (1998). Development of a Patient-Reported Measure of Function of the Knee. *The Journal of Bone and Joint Surgery. American volume*, *80*(8), 1132–1145. https://doi.org/10.2106/00004623-199808000-00006.

A.7. Age-Related Hearing Loss: Comprehensive Audiometric Evaluation

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients aged 50 years and older who failed a hearing screening and/or who report suspected hearing loss or tinnitus who were ordered or referred for a comprehensive audiometric evaluation on the day of diagnosis/office visit OR received a comprehensive audiometric evaluation within 4 weeks of the office visit.
Measure Steward:	American Academy of Otolaryngology - Head and Neck Surgery Foundation
Numerator:	Patients were ordered or referred for a comprehensive audiometric evaluation on the day of diagnosis/office visit OR received a comprehensive audiometric evaluation within 4 weeks of the office visit.
Denominator:	All patients aged 50 years and older who failed a hearing screening and/or who report suspected hearing loss or tinnitus.
Exclusions:	None
Measure Type:	Process
MIPS Core Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We are proposing this current QCDR measure as it fills a gap in the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP. It is specific to audiology and ensures that patients suspected of having age-related hearing loss, either identified through a failed hearing screen or diagnosis, are referred for or receive a comprehensive audiometric evaluation. Implementation of this measure as a MIPS CQM would allow wider availability for reporting by MIPS eligible clinicians. The objective of auditory assessment is to diagnose the type and magnitude of hearing loss and the need for treatment, including candidacy for amplification. Age-related hearing loss (ARHL), despite being the most common sensory deficit seen in the older population, remains an underdiagnosed and undertreated condition among individuals aged 50 years and above.[422] Identifying ARHL in early stages could prevent its known adverse outcomes, such as lower quality of life and ability to function.[423] [424] Undertreatment may lead to associated health risks, including dementia, depression, cardiovascular disease, and falls.[425] This measure is based on clinical guidelines intended to inform the practice of hearing care professionals involved in the audiological management of adults with severe to profound hearing loss.[426] Additionally, the guidelines identify quality improvement opportunities and evidence-based recommendations regarding the identification and management of ARHL.[427] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. We are proposing to add this measure to the Audiology and Otolaryngology specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Audiology, Otolaryngology

[422] Tsai Do, B. S., Bush, M. L., Weinreich, H. M., Schwartz, S. R., Anne, S., Adunka, O. F., Bender, K., Bold, K. M., Brenner, M. J., Hashmi, A. Z., Keenan, T. A., Kim, A. H., Moore, D. J., Nieman, C. L., Palmer, C. V., Ross, E. J., Steenerson, K. K., Zhan, K. Y., Reyes, J., & Dhepyasuwan, N. (2024). Clinical Practice Guideline: Age-Related Hearing Loss. *Otolaryngology--Head and Neck Surgery: Official Journal of American Academy of Otolaryngology-Head and Neck Surgery*, *170 Suppl 2*, S1–S54. https://doi.org/10.1002/ohn.750.

[423] Zazove, P., Plegue, M. A., McKee, M. M., DeJonckheere, M., Kileny, P. R., Schleicher, L. S., Green, L. A., Sen, A., Rapai, M. E., & Mulhem, E. (2020). Effective Hearing Loss Screening in Primary Care: The Early Auditory Referral-Primary Care Study. *Annals of Family Medicine*, *18*(6), 520–527. https://doi.org/10.1370/afm.2590.

[424] Chou, R., Dana, T., Bougatsos, C., Fleming, C., & Beil, T. (2011). Screening Adults Aged 50 Years or Older for Hearing Loss: A Review of the Evidence for the U.S. Preventive Services Task Force. *Annals of Internal Medicine*, *154*(5), 347–355. https://doi.org/10.7326/0003-4819-154-5-201103010-00009.

[425] See footnote Zazove et al., 2020.

[426] Turton, L., Souza, P., Thibodeau, L., Hickson, L., Gifford, R., Bird, J., Stropahl, M., Gailey, L., Fulton, B., Scarinci, N., Ekberg, K., & Timmer, B. (2020). Guidelines for Best Practice in the Audiological Management of Adults with Severe and Profound Hearing Loss. *Seminars in Hearing*, *41*(3), 141–246. https://doi.org/10.1055/s-0040-1714744.

[427] See footnote Tsai et al., 2024.

A.8. Patient-Reported Experience with Anesthesia

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of patients, aged 18 and older, who were surveyed on their patient experience and satisfaction with anesthesia care and who reported a positive experience.
Measure Steward:	American Society of Anesthesiologists Anesthesia Quality Institute
Numerator:	Numerator 1. Patients who received a valid survey within 30 days of the procedure to assess their experience and satisfaction with anesthesia. Numerator 2. Patients who reported a positive experience with anesthesia care within 60 days of receipt of the survey.
Denominator:	Denominator 1. Patients aged 18 and older, who undergo a procedure under anesthesia during the denominator identification period. Denominator 2. All patients from Submission Criteria 1 who complete a survey on their patient experience and satisfaction with anesthesia care within 60 days of receipt of the survey.
Exclusions:	Organ Donors as designated by American Society of Anesthesiologists (ASA) Physical Status 6[428] Patient died within 30 days of the procedure Patients who did not complete the mandatory anesthesia satisfaction question within 60 days of receipt of the survey
Measure Type:	Patient-Reported Outcome-Based Performance Measure (PRO-PM)
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	A minimum of 20 completed surveys required to be eligible to report Denominator 2
Rationale:	We are proposing this current QCDR patient-reported outcome-based performance measure as it fills a gap in the Anesthesiology specialty set. It would be the only patient experience of care measure for that specialty and is reported for each procedure. The measure assesses for patients that receive a valid survey and report a positive experience with their anesthesia care. The assessment of patient satisfaction with anesthesia care provides important feedback allowing clinicians to improve the quality-of-care delivery.[429] There are a variety of surveys available for practices and clinicians to implement based upon local patient populations, such as the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS): Patients' Perspectives of Care Survey[430] and Outpatient and Ambulatory Surgery CAHPS.[431] However, the measure would not require the use of a specific survey to collect patient feedback. Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Patient Safety and Support of Positive Experiences with Anesthesia MVP. We are proposing to add this measure to the Anesthesiology specialty set based on available coding and because the clinical quality action is within the scope of care for anesthesiologists.
Measure Proposed for Addition to the Following Specialty Sets:	Anesthesiology

[428] American Society of Anesthesiologists (ASA) Physical Status 6 is defined as a declared brain-dead patient whose organs are being removed for donor purposes.
ASA. (2026). American Society of Anesthesiologists Statement on ASA Physical Status Classification System. *Anesthesiology Open, 1*(1), e0002. https://doi.org/10.1097/ao9.0000000000000002.
[429] Agency for Healthcare Research and Quality. (2013). Guide to Patient and Family Engagement in Hospital Quality and Safety. https://psnet.ahrq.gov/issue/guide-patient-and-family-engagement-hospital-quality-and-safety.
[430] CMS. (2025). HCAHPS: Patients' Perspectives of Care Survey. https://www.cms.gov/data-research/research/consumer-assessment-healthcare-providers-systems/hospital-cahps-hcahps.
[431] CMS. (2026). Outpatient and Ambulatory Surgery CAHPS (OAS CAHPS). https://www.cms.gov/data-research/research/consumer-assessment-healthcare-providers-systems/outpatient-and-ambulatory-surgery-cahps.

A.9. Intraoperative Hypotension (IOH) Among Non-Emergent Noncardiac Surgical Cases

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	Percentage of general, neuraxial, or regional anesthesia care cases performed during the performance period in which the mean arterial pressure (MAP) fell below 65 mmHg for a cumulative total of 15 minutes or more.
Measure Steward:	Anesthesia Quality Registry (AQR QCDR) in Collaboration with Anesthesia Quality Institute (AQI) and American Society of Anesthesiologists (ASA)
Numerator:	Patients who have a MAP below 65 mmHg that exceeds the cumulative length of 15 minutes during the performance period.
Denominator:	All cases in which adults (ages 18 and older) with non-cardiac, non-emergency surgery require general, neuraxial, or regional anesthesia care during the performance period.
Exclusions:	Patients with a baseline MAP below 65 mmHg Patients with surgeries where anesthesia is complicated by utilization of controlled hypotension during the primary anesthesia procedure American Society of Anesthesiologists (ASA) Physical Status Classification of 1, 5 or 6[432] Emergency cases Cardiac procedures Obstetric non-operative procedures Liver or lung transplant procedures Cataract procedures
Measure Type:	Intermediate Outcome
MIPS Core Measure:	Yes
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A
Rationale:	We are proposing this current QCDR measure as it fills a gap in the Anesthesiology specialty set. This inverse, intermediate outcome measure ensures mean arterial pressure (MAP) does not fall below 65mmHg for greater than 15 minutes during a procedure as it could be associated with adverse outcomes, such as acute kidney injury (AKI) or myocardial injury.[433] Evidence indicates a MAP below absolute thresholds of 65 mmHg or relative thresholds of 20 percent was progressively related to both myocardial and kidney injury. Prolonged exposure below the threshold was also associated with increased risk. Noncardiac surgery patients are at increased risk of AKI when their cumulative time below a MAP of 65 mmHg reaches or exceeds 13 minutes. When patients fall further below 65 mmHg, even shorter durations are associated with increased risk of AKI.[434] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. This measure may be added to the Patient Safety and Support of Positive Experiences with Anesthesia MVP. We are proposing to add this measure to the Anesthesiology specialty set based on available coding and because the clinical quality action is within the scope of care for anesthesiologists.

[432] ASA Physical Status 1 is defined as a normal healthy patient. Physical Status 5 is defined as a moribund patient who is not expected to survive without the operation. Physical Status 6 is defined as a declared brain-dead patient whose organs are being removed for donor purposes.
See footnote ASA, 2026.

[433] Walsh, M., Devereaux, P. J., Garg, A. X., Kurz, A., Turan, A., Rodseth, R. N., Cywinski, J., Thabane, L., & Sessler, D. I. (2013). *Relationship Between Intraoperative Mean Arterial Pressure and Clinical Outcomes After Noncardiac Surgery*. Anesthesiology, 119(3), 507–515. https://doi.org/10.1097/ALN.0b013e3182a10e26.

[434] Salmasi, V., Maheshwari, K., Yang, D., Mascha, E. J., Singh, A., Sessler, D. I., & Kurz, A. (2017). Relationship between Intraoperative Hypotension, Defined by Either Reduction from Baseline or Absolute Thresholds, and Acute Kidney and Myocardial Injury after Noncardiac Surgery: A Retrospective Cohort Analysis. *Anesthesiology*, *126*(1), 47–65. https://doi.org/10.1097/ALN.0000000000001432.

Category	Description
Measure Proposed for Addition to the Following Specialty Sets:	Anesthesiology

A.10. SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality #:	TBD
Description:	The percentage of patients aged 18 years and older with chronic kidney disease (CKD) stages 2 and 3 who are prescribed an SGLT2 inhibitor during the measurement period.
Measure Steward:	A Value-Based Care Registry
Numerator:	Patients who were prescribed or were currently taking an SGLT2 inhibitor during the performance period.
Denominator:	All patients aged 18 years and older diagnosed with chronic kidney disease (CKD) stages 2-3 during the measurement period.
Exclusions:	Patients with Type 1 Diabetes Mellitus Diabetic Ketoacidosis
Measure Type:	Process
MIPS Core Measure:	No
Collection Type:	MIPS CQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We are proposing this current QCDR measure as it fills a gap in the MIPS quality measure inventory, ensuring the appropriate, evidence-based treatment of patients diagnosed with CKD with SGLT2 inhibitors. Evidence demonstrates that SGLT2 inhibitors slow the progression of CKD and reduce cardiovascular events in this patient population.[435] [436] [437] As a result, SGLT2 inhibitors have become a key disease-modifying therapy to prevent CKD progression. These medications prevent decline in kidney function through reduction in glomerular hypertension, independent of their effect on glycemic control. This has expanded the approved clinical indications for these medications beyond patients with diabetes.[438] Current clinical and practice guidelines also recommend use of SGLT2 inhibitors to slow CKD progression in patients with or without type 2 diabetes.[439] [440] Under section 1848(q) of the Act, a QCDR measure may only become reportable as a MIPS quality measure if the Secretary formerly adopts it through rulemaking and includes it in the MIPS quality measure inventory. We have the authority to establish quality measures under MIPS. This authority is not dependent upon the pre-rulemaking process used to develop measures. Beginning with the CY 2024 performance period/2026 MIPS payment year, all QCDR measures are required to be fully developed and tested at the clinician level by their second year in MIPS, as finalized in the CY 2023 PFS final rule (87 FR 70104 through 70106) and codified at § 414.1400(b)(4)(iii)(A)(3). As a current QCDR measure, this measure has demonstrated feasibility, reliability, and validity in accordance with § 414.1400(b)(4)(iii)(A)(3). The measure is evidence-based and is fully developed and tested. We are proposing to add this measure to multiple applicable specialty sets based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Cardiology, Endocrinology, Family Medicine, Geriatrics, Internal Medicine, Nephrology

[435] Heerspink, H. J. L., Stefánsson, B. V., Correa-Rotter, R., Chertow, G. M., Greene, T., Hou, F. F., Mann, J. F. E., McMurray, J. J. V., Lindberg, M., Rossing, P., Sjöström, C. D., Toto, R. D., Langkilde, A. M., Wheeler, D. C., & DAPA-CKD Trial Committees and Investigators (2020). Dapagliflozin in Patients with Chronic Kidney Disease. *The New England Journal of Medicine*, *383*(15), 1436–1446. https://doi.org/10.1056/NEJMoa2024816.

[436] Perkovic, V., Jardine, M. J., Neal, B., Bompoint, S., Heerspink, H. J. L., Charytan, D. M., Edwards, R., Agarwal, R., Bakris, G., Bull, S., Cannon, C. P., Capuano, G., Chu, P. L., de Zeeuw, D., Greene, T., Levin, A., Pollock, C., Wheeler, D. C., Yavin, Y., Zhang, H., … CREDENCE Trial Investigators (2019). Canagliflozin and Renal Outcomes in Type 2 Diabetes and Nephropathy. *The New England Journal of Medicine*, *380*(24), 2295–2306. https://doi.org/10.1056/NEJMoa1811744.

[437] The EMPA-KIDNEY Collaborative Group, Herrington, W. G., Staplin, N., Wanner, C., Green, J. B., Hauske, S. J., Emberson, J. R., Preiss, D., Judge, P., Mayne, K. J., Ng, S. Y. A., Sammons, E., Zhu, D., Hill, M., Stevens, W., Wallendszus, K., Brenner, S., Cheung, A. K., Liu, Z. H., Li, J., … Haynes, R. (2023). Empagliflozin in Patients with Chronic Kidney Disease. *The New England Journal of Medicine*, *388*(2), 117–127. https://doi.org/10.1056/NEJMoa2204233.

[438] Yau, K., Dharia, A., Alrowiyti, I., & Cherney, D. Z. I. (2022). Prescribing SGLT2 Inhibitors in Patients With CKD: Expanding Indications and Practical Considerations. *Kidney International Reports*, *7*(7), 1463–1476. https://doi.org/10.1016/j.ekir.2022.04.094.

[439] Kidney Disease: Improving Global Outcomes (KDIGO) Diabetes Work Group. (2022). *KDIGO 2022 Clinical Practice Guideline for Diabetes Management in Chronic Kidney Disease. Kidney International, 102*(5S), S1–S127. https://doi.org/10.1016/j.kint.2022.06.008.

[440] American Diabetes Association Professional Practice Committee. (2024). *11. Chronic Kidney Disease and Risk Management: Standards of Care in Diabetes—2024. Diabetes Care, 47*(Suppl. 1), S219–S230. https://doi.org/10.2337/dc24-S011.

Table Group AA: New MIPS Quality Measures Proposed for the CY 2028 Performance Period/2030 MIPS Payment Year and Future Years

In addition to the new quality measures proposed in Table Group A of this Appendix, we are proposing to add one eCQM measure for the 2028 performance period/2030 MIPS payment year and future years to allow clinicians sufficient time to adapt their workflows prior to implementation within MIPS. We request comments on this new measure.

AA.1. Rate of Timely Follow-up on Abnormal Screening Mammograms for Breast Cancer Detection

Category	Description
CBE # / eCQM CBE #:	N/A / 4700e
Quality #:	TBD
Description:	This electronic clinical quality measure (eCQM) reports the percentage of female patients aged 40 to 75 years with at least one abnormal screening (BI-RADS 0) or screening-to-diagnostic (BI-RADS 4, 5) mammogram during the measurement period (i.e., calendar year) who received timely diagnostic resolution defined as either follow-up imaging with negative/benign/probably benign results or a breast biopsy within 60 days after their index (i.e., first) abnormal screening mammogram.
Measure Steward:	Brigham and Women's Hospital
Numerator:	Patients in the denominator population who received timely diagnostic resolution defined as negative/benign/probably benign follow-up imaging (BI-RADS 1, 2, 3) or breast biopsy within 60 days after the date of their index (i.e., first) abnormal screening (BI-RADS 0) or screening-to-diagnostic (BI-RADS 4, 5) mammogram.
Denominator:	Female patients aged 40 to 75 years with an abnormal screening (BI-RADS 0) or screening-to-diagnostic (BI-RADS 4, 5) mammogram during the measurement period (i.e., calendar year). Only the first abnormal screening or screening-to-diagnostic mammogram (i.e., index screening test) is included in the measure calculation.
Exclusions:	N/A
Measure Type:	Process
MIPS Core Measure	No
Collection Type:	eCQM
Measure-Specific Case Minimum/Performance Period:	N/A

Category	Description
Rationale:	We are proposing this eCQM because it addresses timely follow up of diagnostic testing for patients with an abnormal mammogram. Additionally, it fills a gap in the Diagnostic Radiology specialty set with potential for inclusion in an MVP. Breast cancer is the second most common cause of cancer deaths among women in the United States[441] and survival is dependent upon cancer stage at diagnosis. Breast cancer mainly occurs in middle-aged and older women, with the median age at the time of diagnosis being 62 years.[442] Noninvasive mammographic screening is the primary screening modality used to detect breast cancer. Studies show that between 27 to 72 percent of women did not receive appropriate follow-up within 6 months of an abnormal mammogram.[443] Delays in diagnostic follow-up after abnormal mammographic screening results increase the risk of diagnosing cancer at a more advanced stage.[444] Timely follow-up is essential to facilitate early-stage detection and improve overall survival outcomes. The Pre-Rulemaking Measure Review (PRMR) Clinician Recommendation Committee did not reach consensus on this measure; however, the majority (71 percent) of the committee expressed support for use of the measure. The measure is CBE endorsed with conditions of continued monitoring of performance and additional data element validity testing of other electronic health records (EHRs). We are proposing this measure with a one-year delay in implementation to allow time for clinicians to adapt their workflows and therefore ensure greater feasibility of reporting within MIPS. If finalized as proposed, this measure would be available for reporting for the CY 2028 performance period/2030 MIPS payment year. We are proposing to add this measure to the Diagnostic Radiology specialty set for the CY 2028 performance period/2030 MIPS payment year based on available coding and because the clinical quality action is within the scope of care for clinicians in these specialties.
Measure Proposed for Addition to the Following Specialty Sets:	Diagnostic Radiology

[441] American Cancer Society (ACS). (2024). Key Statistics for Breast Cancer. https://www.cancer.org/cancer/types/breast-cancer/about/how-common-is-breast-cancer.html.

[442] See footnote ACS, 2024.

[443] Reece, J. C., Neal, E. F. G., Nguyen, P., et al. (2021). Delayed or Failure To Follow-up Abnormal Breast Cancer Screening Mammograms in Primary Care: A Systematic Review. *BMC Cancer, 21*, 373. https://doi.org/10.1186/s12885-021-08100-3.

[444] McCarthy, A. M., Kim, J. J., Beaber, E. F., Zheng, Y., Burnett-Hartman, A., Chubak, J., Ghai, N. R., McLerran, D., Breen, N., Conant, E. F., Geller, B. M., Green, B. B., Klabunde, C. N., Inrig, S., Skinner, C. S., Quinn, V. P., Haas, J. S., Schnall, M., Rutter, C. M., Barlow, W. E., … PROSPR consortium (2016). Follow-Up of Abnormal Breast and Colorectal Cancer Screening by Race/Ethnicity. *American Journal of Preventive Medicine*, *51*(4), 507–512. https://doi.org/10.1016/j.amepre.2016.03.017.

Table Group B: Modifications to Previously Finalized Specialty Sets Proposed for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

We are proposing to modify the previously finalized specialty sets based upon review of updates made to existing quality measure specifications, the proposed addition of new measures for inclusion in MIPS, and feedback provided by specialty societies and other interested parties. There may be instances where the quality measures within a specialty set remain static, but the individual measures have proposed substantive changes in Table Group D of this Appendix.

We use the following symbols in the Indicator column in the Table Group B tables below:

- Existing quality measures with substantive changes described in Table Group D of this Appendix are identified with an asterisk (*).
- Quality measures designated as MIPS core measures are identified with an exclamation point (!). As discussed in section IV.A.4.d.(1)(c)(i) of this proposed rule, we are proposing to implement the MIPS core measure designation for traditional MIPS and MVP reporting.
- Quality measures proposed for addition to a proposed specialty set are identified with a plus sign (+).

Additionally, measures that are endorsed by a CBE are shown in Table Group B of this Appendix as follows: CBE # / eCQM CBE #.

Note: We updated the format of the specialty set tables to reflect what the specialty set would be for the CY 2027 performance period, if finalized as proposed. Measures proposed for addition to the specialty sets have been added to applicable tables and are noted with a plus sign (+) in the Indicator column. See Table Group A of this Appendix for rationales for proposed new measures. Existing measures proposed for addition to a specific specialty set are also indicated with a plus sign (+) and are included in the introductory paragraphs of the specialty set, as applicable.

Measures proposed for removal have been removed from each specialty set, as applicable. See Table Group C of this Appendix for rationales for proposed measure removals from MIPS. Specialty-specific measure additions and/or removals would be noted under applicable specialty sets. If a measure is not finalized for addition, it would be removed from the specialty set(s) in the final rule. If a measure is not finalized for removal, it would be added back to the specialty set(s) in the final rule.

We request comments on proposed measure additions and/or proposed measure removals under applicable specialty sets in Table Group B of this Appendix. New measures proposed for addition to applicable specialty sets are open for comment under Table Group A of this Appendix. Measures proposed for removal from MIPS are open for comment under Table Group C of this Appendix. Previously finalized measures that have proposed substantive changes are open for comment under Table Group D of this Appendix. Previously finalized measures that have no substantive changes are not open for comment under this proposed rule.

The following specialty set is not open for comment as it has no proposed modifications for the CY 2027 performance period/2029 MIPS payment year: Diagnostic Radiology.

B.1. Allergy/Immunology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Allergy/Immunology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.1. Allergy/Immunology

PROPOSED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology – Head and Neck Surgery Foundation
!	N/A / N/A	338	CMS31 4v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration
	N/A / N/A	340	CMS11 57v3	eCQM, MIPS CQM	Process	HIV Annual Retention in Care	Health Resources and Services Administration
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance

B.1. Allergy/Immunology

PROPOSED MEASURES IN THE ALLERGY/IMMUNOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.2. Anesthesiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Anesthesiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.2. Anesthesiology

PROPOSED MEASURES IN THE ANESTHESIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	404	N/A	MIPS CQM	Intermediate Outcome	Anesthesiology Smoking Abstinence	American Society of Anesthesiologists
!	N/A / N/A	477	N/A	MIPS CQM	Process	Multimodal Pain Management	American Society of Anesthesiologists
+	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Patient-Reported Experience with Anesthesia	American Society of Anesthesiologists Anesthesia Quality Institute
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediate Outcome	Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases	Anesthesia Quality Registry (AQR QCDR) in Collaboration with Anesthesia Quality Institute (AQI) and American Society of Anesthesiologists (ASA)

B.3. Audiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Audiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.3. Audiology

PROPOSED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	NA / NA	261	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness	Audiology Quality Consortium
* !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS139v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
	2152/ N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use	National Committee for Quality Assurance

B.3. Audiology

PROPOSED MEASURES IN THE AUDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Process	Age-Related Hearing Loss: Comprehensive Audiometric Evaluation	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.4a. Cardiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Cardiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.4a. Cardiology

PROPOSED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0081 / 0081e	005	CMS13 5v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0083 / 0083e	008	CMS14 4v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	0066 / N/A	118	N/A	MIPS CQM	Process	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)	American Heart Association
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
	N/A / N/A	187	N/A	MIPS CQM	Process	Stroke and Stroke Rehabilitation: Thrombolytic Therapy	American Heart Association
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	236	CMS16 5v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Inter-mediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance

B.4a. Cardiology

PROPOSED MEASURES IN THE CARDIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	0643 / N/A	243	N/A	MIPS CQM	Process	Cardiac Rehabilitation Patient Referral from an Outpatient Setting	American Heart Association
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	344	N/A	MIPS CQM	Outcome	Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)	Society for Vascular Surgery
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	N/A / N/A	438	CMS347v10	eCQM, MIPS CQM	Process	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Centers for Medicare & Medicaid Services
* !	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)	Wisconsin Collaborative for Healthcare Quality
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665/ N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	TBD	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.4b. Electrophysiology Cardiac Specialist

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Electrophysiology Cardiac Specialist specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.4b. Electrophysiology Cardiac Specialist

PROPOSED MEASURES IN THE ELECTROPHYSIOLOGY CARDIAC SPECIALIST SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	2474 / N/A	392	N/A	MIPS CQM	Outcome	Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation	American College of Cardiology Foundation
*	N/A / N/A	393	N/A	MIPS CQM	Outcome	Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision	American College of Cardiology Foundation

B.5. Certified Nurse Midwife

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Certified Nurse Midwife specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We are also proposing to add one existing MIPS quality measure to this specialty set:

- **Q493:** Adult Immunization Status: This MIPS quality measure assesses whether adult patients are up-to-date with recommended routine immunizations. We agree with interested parties' feedback that this measure is clinically relevant to this clinician type. Certified Nurse Midwives are advanced practice clinicians uniquely qualified to deliver comprehensive primary care, pregnancy care, and gynecological care. Their scope of practice often includes primary care services such as immunizations, especially in alignment with their focus on preventive care and wellness for women.[445] [446] Adding this measure would align the Certified Nurse Midwife specialty set with the Obstetrics and Gynecology specialty set, recognizing the similarities in care delivery between these specialties and ensuring consistency across specialty sets. Including this measure in the Certified Nursing Midwife specialty set acknowledges the important role they play in preventive care and primary health maintenance, as well as promoting consistent, high quality care delivery across patient populations. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.5. Certified Nurse Midwife

PROPOSED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / N/A	335	N/A	MIPS CQM	Outcome	Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse)	Centers for Medicare & Medicaid Services
*	N/A / N/A	336	N/A	MIPS CQM	Process	Maternity Care: Postpartum Follow-up and Care Coordination	Centers for Medicare & Medicaid Services

[445] American College of Nurse-Midwives. (2024). Discover Midwives: Certified Nurse-Midwives and Certified Midwives. https://midwife.org/wp-content/uploads/2024/11/2022_Discover-Midwives.pdf.

[446] American College of Nurse-Midwives. (2025). American College of Nurse-Midwives Statement on Maternal Immunization: Updated July 2025. https://midwife.org/american-college-of-nurse-midwives-statement-on-maternal-immunization-updated-july-2025/.

B.5. Certified Nurse Midwife

PROPOSED MEASURES IN THE CERTIFIED NURSE MIDWIFE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	N/A / N/A	475	CMS349v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
+	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
	N/A / N/A	496	N/A	MIPS CQM	Process	Cardiovascular Disease (CVD) Risk Assessment Measure – Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument	University of California, Irvine
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
*	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Reduction in Suicidal Ideation or Behavior Symptoms	American Psychiatric Association

B.6. Chiropractic Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Chiropractic Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.6. Chiropractic Medicine

PROPOSED MEASURES IN THE CHIROPRACTIC MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
+	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Neck Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Upper Extremity Impairments	Limber Health, Inc. and Patient360, LLC
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Back Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Lower Extremity Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Knee Impairments	Limber Health, Inc. and Patient360, LLC

B.7. Clinical Social Work

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Clinical Social Work specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.7. Clinical Social Work

PROPOSED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v15	eCQM	Process	Dementia: Cognitive Assessment	American Academy of Neurology
!	N/A / N/A	282	N/A	MIPS CQM	Process	Dementia: Functional Status Assessment	American Academy of Neurology
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Academy of Neurology/ American Psychiatric Association
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
!	N/A / N/A	305	CMS13 7v15	eCQM	Process	Initiation and Engagement of Substance Use Disorder Treatment	National Committee for Quality Assurance
!	0710 / 0710e	370	CMS15 9v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Minnesota Community Measurement

B.7. Clinical Social Work

PROPOSED MEASURES IN THE CLINICAL SOCIAL WORK SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	382	CMS177v15	eCQM	Process	Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment	Centers for Medicare & Medicaid Services
* !	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	Adherence to Antipsychotic Medications For Individuals with Schizophrenia	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder	American Psychiatric Association
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
*	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Reduction in Suicidal Ideation or Behavior Symptoms	American Psychiatric Association

B.8. Dentistry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Dentistry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.8. Dentistry

PROPOSED MEASURES IN THE DENTISTRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	379	CMS 74v16	eCQM	Process	Primary Caries Prevention Intervention as Offered by Dentists	Centers for Medicare & Medicaid Services

B.9. Dermatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Dermatology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.9. Dermatology

PROPOSED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A/ N/A	176	N/A	MIPS CQM	Process	Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy	American College of Rheumatology
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
!	N/A / N/A	410	N/A	MIPS CQM	Intermediate Outcome	Psoriasis: Clinical Response to Systemic Medications	American Academy of Dermatology
* !	N/A / N/A	440	N/A	MIPS CQM	Process	Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician	American Academy of Dermatology
	N/A / N/A	485	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Psoriasis – Improvement in Patient-Reported Itch Severity	American Academy of Dermatology
!	N/A / N/A	486	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Dermatitis – Improvement in Patient-Reported Itch Severity	American Academy of Dermatology

B.9. Dermatology

PROPOSED MEASURES IN THE DERMATOLOGY SPECIALTY SET							
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title	Measure Steward
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
*	N/A / N/A	509	N/A	MIPS CQM	Process	Melanoma: Tracking and Evaluation of Recurrence	American Academy of Dermatology

B.10. Diagnostic Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Diagnostic Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set. This specialty set has no proposed changes and is not open for comment.

B.10. Diagnostic Radiology

PREVIOUSLY FINALIZED MEASURES IN THE DIAGNOSTIC RADIOLOGY SPECIALTY SET							
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title	Measure Steward
!	N/A / N/A	145	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy	American College of Radiology
!	N/A / N/A	360	N/A	MIPS CQM	Process	Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies	American College of Radiology
	N/A / N/A	364	N/A	MIPS CQM	Process	Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines	American College of Radiology
!	N/A / N/A	405	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Appropriate Follow-up Imaging for Incidental Abdominal Lesions	American College of Radiology
	N/A / N/A	406	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Appropriate Follow-up Imaging for Incidental Thyroid Nodules	American College of Radiology
	3633e, 3662e / 3633e, 3662e	494	CMS1056v4	eCQM	Intermediate Outcome	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Clinician Level)	Alara Imaging, Inc. in collaboration with the University of California, San Francisco (UCSF)

B.11. Emergency Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Emergency Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.11. Emergency Medicine

PROPOSED MEASURES IN THE EMERGENCY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	0069/ N/A	065	CMS15 4v15	eCQM, MIPS CQM	Process	Appropriate Treatment for Upper Respiratory Infection (URI)	National Committee for Quality Assurance
	N/A / N/A	066	CMS14 6v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
	N/A / N/A	187	N/A	MIPS CQM	Process	Stroke and Stroke Rehabilitation: Thrombolytic Therapy	American Heart Association
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology – Head and Neck Surgery Foundation
!	N/A / N/A	416	N/A	MIPS CQM	Efficiency	Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years	American College of Emergency Physicians

B.12. Endocrinology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Endocrinology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.12. Endocrinology

PROPOSED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	0059 / N/A	001	CMS122v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
	0055 / N/A	117	CMS131v15	eCQM, MIPS CQM	Process	Diabetes: Eye Exam	National Committee for Quality Assurance
	0066 / N/A	118	N/A	MIPS CQM	Process	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy – Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)	American Heart Association
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	236	CMS165v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
*	N/A / N/A	374	CMS50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services

B.12. Endocrinology

PROPOSED MEASURES IN THE ENDOCRINOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance
*	N/A / N/A	438	CMS347v10	eCQM, MIPS CQM	Process	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease Disease	Centers for Medicare & Medicaid Services
!	N/A / N/A	462	CMS645v10	eCQM	Process	Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy	Oregon Urology Institute
!	N/A / N/A	488	CMS951v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	TBD	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.13. Family Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Family Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We are also proposing to add two existing MIPS quality measures to this specialty set:

- **Q205**: Sexually Transmitted Infection (STI) Testing for People with HIV: This MIPS quality measure assesses appropriate screening of STIs for patients with HIV. We agree with interested parties' feedback that this measure is clinically relevant to this clinician type and propose adding this measure to the Family Medicine specialty set. Clinical guidelines, such as those from the Centers for Disease Control and Prevention (CDC), recommend regular screening for STIs in individuals with HIV.[447] Despite the high incidence of STIs among people with HIV, screening rates remain suboptimal.[448] Including this measure emphasizes adherence to established best practices in care provision within family medicine. This measure would allow clinicians and health systems to track and benchmark their performance in meeting preventive care goals for patients with HIV. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.
- **Q340**: HIV Annual Retention in Care: This MIPS quality measure promotes routine monitoring to track patient progress and ensure treatment efficacy. We agree with interested parties' feedback that this measure is clinically relevant to this clinician type and propose adding this measure to the Family Medicine specialty set. Incorporating this measure aligns with national goals such as the Ending the HIV Epidemic initiative, led by the CDC, which highlights retention and viral suppression as cornerstones for reducing transmission and new infections.[449] A study from the Centers for AIDS Research Network of Integrated Clinical Systems revealed that patients who missed more than two clinic visits over a two-year period had significantly higher mortality risks, even if they otherwise met institutional retention metrics.[450] These findings underscore the life-saving importance of retention in improving survival rates. By measuring and promoting retention in HIV care, the addition of this measure could drive system-wide improvements, support better patient outcomes, reduce preventable mortality, and contribute to public health efforts to end the HIV epidemic. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

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[448] Gass, S. J., Chen, S., Zhang, J., Elliott, A. S., Wagner, K. D., White, K. P., & Magnus, M. (2025). Sexually Transmitted Infection (STI) Incidence and Risk Factors Among People with HIV (PWH): Insights From a 13-Year Cohort Study in South Carolina. *AIDS and Behavior, 29*, 2882–2890. https://doi.org/10.1007/s10461-025-04744-5.

[449] CDC. (2024b). About Ending the HIV Epidemic in the US. https://www.cdc.gov/ehe/php/about/index.html.

[450] Mugavero, M. J., Westfall, A. O., Cole, S. R., Geng, E. H., Crane, H. M., Kitahata, M. M., Mathews, W. C., Napravnik, S., Eron, J. J., Moore, R. D., Keruly, J. C., Mayer, K. H., Giordano, T. P., Raper, J. L., & Centers for AIDS Research Network of Integrated Clinical Systems (CNICS) (2014). Beyond Core Indicators of Retention in HIV Care: Missed Clinic Visits are Independently Associated with All-Cause Mortality. *Clinical Infectious Diseases: An Official Publication of the Infectious Diseases Society of America*, *59*(10), 1471–1479. https://doi.org/10.1093/cid/ciu603.

B.13. Family Medicine

PROPOSED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title	Measure Steward
* !	0059 / N/A	001	CMS1 22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
!	0081 / 0081e	005	CMS1 35v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0083 / 0083e	008	CMS1 44v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
	N/A / N/A	009	CMS1 28v15	eCQM	Process	Antidepressant Medication Management	National Committee for Quality Assurance
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
	0069 / N/A	065	CMS1 54v15	eCQM, MIPS CQM	Process	Appropriate Treatment for Upper Respiratory Infection (URI)	National Committee for Quality Assurance
	N/A / N/A	066	CMS1 46v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
	0055 / N/A	117	CMS1 31v15	eCQM, MIPS CQM	Process	Diabetes: Eye Exam	National Committee for Quality Assurance
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association

B.13. Family Medicine

PROPOSED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2 v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
* !	N/A / N/A	176	N/A	MIPS CQM	Process	Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy	American College of Rheumatology
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
+ !	N/A / 3755e	205	CMS1188v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
* !	N/A / N/A	236	CMS165v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
!	0022 / N/A	238	CMS156v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	0643 / N/A	243	N/A	MIPS CQM	Process	Cardiac Rehabilitation Patient Referral from an Outpatient Setting	American Heart Association
!	N/A / N/A	305	CMS137v15	eCQM	Process	Initiation and Engagement of Substance Use Disorder Treatment	National Committee for Quality Assurance
	N/A / N/A	309	CMS124v15	eCQM	Process	Cervical Cancer Screening	National Committee for Quality Assurance
	0101 / N/A	318	CMS139v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement /Experience	CAHPS for MIPS Clinician/Group Survey	Centers for Medicare & Medicaid Services
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology – Head and Neck Surgery Foundation
!	N/A / N/A	338	CMS314v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration

B.13. Family Medicine

PROPOSED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
+	N/A / N/A	340	CMS1 157v3	eCQM, MIPS CQM	Process	HIV Annual Retention in Care	Health Resources and Services Administration
!	0710 / 0710e	370	CMS1 59v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Minnesota Community Measurement
*	N/A / N/A	374	CMS5 0v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	N/A / N/A	377	CMS9 0v16	eCQM	Process	Functional Status Assessments for Heart Failure	Centers for Medicare & Medicaid Services
* !	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	Adherence to Antipsychotic Medications For Individuals with Schizophrenia	Centers for Medicare & Medicaid Services
	N/A / N/A	387	N/A	MIPS CQM	Process	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users	American Gastroenterological Association
	N/A / N/A	394	N/A	MIPS CQM	Process	Immunizations for Adolescents	National Committee for Quality Assurance
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
	N/A / N/A	400	N/A	MIPS CQM	Process	One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation	American Gastroenterological Association
	N/A / N/A	401	N/A	MIPS CQM	Process	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis	American Gastroenterological Association
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	N/A / N/A	438	CMS3 47v10	eCQM, MIPS CQM	Process	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Centers for Medicare & Medicaid Services
* !	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)	Wisconsin Collaborative for Healthcare Quality
*	0657 / N/A	464	N/A	MIPS CQM	Process	Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	N/A / N/A	468	N/A	MIPS CQM	Process	Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)	University of Southern California

B.13. Family Medicine

PROPOSED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
*	N/A / N/A	475	CMS349v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
*	N/A / N/A	476	CMS771v8	eCQM	Patient-Reported Outcome-Based Performance Measure	Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia	Large Urology Group Practice Association and Oregon Urology Institute
!	N/A / N/A	488	CMS951v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665/ N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
*	N/A / N/A	497	N/A	MIPS CQM	Process	Preventive Care and Wellness (composite)	Centers for Medicare & Medicaid Services
	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder	American Psychiatric Association
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
*	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Reduction in Suicidal Ideation or Behavior Symptoms	American Psychiatric Association
	N/A / 3749e	514	CMS1173v2	eCQM	Intermediate Outcome	Diagnostic Delay of Venous Thromboembolism in Primary Care	Brigham and Women's Hospital
	N/A / N/A	515	CMS1154v2	eCQM	Process	Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes	American Medical Association
!	N/A / N/A	516	N/A	MIPS CQM	Outcome	Hepatitis C Virus (HCV): Sustained Virological Response (SVR)	American Gastroenterological Association

B.13. Family Medicine

PROPOSED MEASURES IN THE FAMILY MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	TBD	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.14. Gastroenterology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Gastroenterology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.14. Gastroenterology

PROPOSED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	NA / N/A	275	N/A	MIPS CQM	Process	Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy	American Gastroenterological Association
* !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	N/A / N/A	401	N/A	MIPS CQM	Process	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis	American Gastroenterological Association
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.14. Gastroenterology

PROPOSED MEASURES IN THE GASTROENTEROLOGY SPECIALTY SET							
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title	Measure Steward
!	N/A / N/A	516	N/A	MIPS CQM	Outcome	Hepatitis C Virus (HCV): Sustained Virological Response (SVR)	American Gastroenterological Association

B.15. General Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the General Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.15. General Surgery

PROPOSED MEASURES IN THE GENERAL SURGERY SPECIALTY SET							
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title	Measure Steward
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	354	N/A	MIPS CQM	Outcome	Anastomotic Leak Intervention	American College of Surgeons
	N/A / N/A	355	N/A	MIPS CQM	Outcome	Unplanned Reoperation within the 30-Day Postoperative Period	American College of Surgeons
!	N/A / N/A	356	N/A	MIPS CQM	Outcome	Unplanned Hospital Readmission within 30 Days of Principal Procedure	American College of Surgeons
!	N/A / N/A	357	N/A	MIPS CQM	Outcome	Surgical Site Infection (SSI)	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services

B.16. Geriatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Geriatrics specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.16. Geriatrics

PROPOSED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138 v15	Medicare Part B Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS156 v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	N/A / 2872e	281	CMS149 v15	eCQM	Process	Dementia: Cognitive Assessment	American Academy of Neurology

B.16. Geriatrics

PROPOSED MEASURES IN THE GERIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	282	N/A	MIPS CQM	Process	Dementia: Functional Status Assessment	American Academy of Neurology/ American Psychiatric Association
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
	0101 / N/A	318	CMS139 v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
!	0710 / 0710e	370	CMS159 v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Minnesota Community Measurement
*	N/A / N/A	476	CMS771 v8	eCQM	Patient-Reported Outcome-Based Performance Measure	Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia	Large Urology Group Practice Association and Oregon Urology Institute
!	N/A / N/A	488	CMS951 v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
!	1662/ N/A	489	N/A	MIPS CQM	Process	Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy	Renal Physicians Association
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	TBD	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.17. Hospitalists

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Hospitalists specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.17. Hospitalists

PROPOSED MEASURES IN THE HOSPITALISTS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0081 / 0081e	005	CMS13 5v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0083 / 0083e	008	CMS14 4v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services

B.18. Infectious Disease

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Infectious Disease specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.18. Infectious Disease

PROPOSED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	0069 / N/A	065	CMS154v15	eCQM, MIPS CQM	Process	Appropriate Treatment for Upper Respiratory Infection (URI)	National Committee for Quality Assurance
	N/A / N/A	066	CMS146v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	176	N/A	MIPS CQM	Process	Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy	American College of Rheumatology
!	N/A / 3755e	205	CMS1188v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / N/A	240	CMS117v15	eCQM	Process	Childhood Immunization Status	National Committee for Quality Assurance
!	NA / N/A	338	CMS314v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration
	N/A / N/A	340	CMS1157v3	eCQM, MIPS CQM	Process	HIV Annual Retention in Care	Health Resources and Services Administration
	N/A / N/A	387	N/A	MIPS CQM	Process	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users	American Gastroenterological Association
	N/A / N/A	394	N/A	MIPS CQM	Process	Immunizations for Adolescents	National Committee for Quality Assurance
*	N/A / N/A	475	CMS349v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance

B.18. Infectious Disease

PROPOSED MEASURES IN THE INFECTIOUS DISEASE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
!	N/A / N/A	516	N/A	MIPS CQM	Outcome	Hepatitis C Virus (HCV): Sustained Virological Response (SVR)	American Gastroenterological Association

B.19. Internal Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Internal Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We are also proposing to add two existing MIPS quality measures to this specialty set:

- **Q205**: Sexually Transmitted Infection (STI) Testing for People with HIV: This MIPS quality measure assesses appropriate screening of STIs for patients with HIV. We agree with interested parties' feedback that this measure is clinically relevant to this clinician type and propose adding this measure to the Internal Medicine specialty set. Clinical guidelines, such as those from the CDC, recommend regular screening for STIs in individuals with HIV.[451] Despite the high incidence of STIs among people with HIV, screening rates remain suboptimal.[452] Including this measure emphasizes adherence to established best practices in care provision within family medicine. This measure would allow clinicians and health systems to track and benchmark their performance in meeting preventive care goals for patients with HIV. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.
- **Q340**: HIV Annual Retention in Care: This MIPS quality measure promotes routine monitoring to track patient progress and ensure treatment efficacy. We agree with interested parties' feedback that this measure is clinically relevant to this clinician type and propose adding this measure to the Internal Medicine specialty set. Incorporating this measure aligns with national goals such as the Ending the HIV Epidemic initiative, led by the CDC, which highlights retention and viral suppression as cornerstones for reducing transmission and new infections.[453] A study from the Centers for AIDS Research Network of Integrated Clinical Systems revealed that patients who missed more than two clinic visits over a two-year period had significantly higher mortality risks, even if they otherwise met institutional retention metrics.[454] These findings underscore the life-saving importance of retention in improving survival rates. By measuring and promoting retention in HIV care, the addition of this measure could drive system-wide improvements, support better patient outcomes, reduce preventable mortality, and contribute to public health efforts to end the HIV epidemic. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.19. Internal Medicine

PROPOSED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	0059 / N/A	001	CMS122v 15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance

[451] See footnote CDC, 2024a.
[452] See footnote Gass et al., 2025.
[453] See footnote CDC, 2024b.
[454] See footnote Mugavero et al., 2014.

B.19. Internal Medicine

PROPOSED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	0081 / 0081e	005	CMS135v 15	eCQM, MIPS CQM	Process	Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0083 / 0083e	008	CMS144 v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
	N/A / N/A	009	CMS128 v15	eCQM	Process	Antidepressant Medication Management	National Committee for Quality Assurance
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
	0055 / N/A	117	CMS131 v15	eCQM, MIPS CQM	Process	Diabetes: Eye Exam	National Committee for Quality Assurance
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
*	N/A / N/A	130	CMS68v 16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v1 6	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
* !	N/A / N/A	176	N/A	MIPS CQM	Process	Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy	American College of Rheumatology

B.19. Internal Medicine

PROPOSED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
+ !	N/A / 3755e	205	CMS118 8v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
* !	N/A / N/A	236	CMS165 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
!	0022 / N/A	238	CMS156 v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	0643 / N/A	243	N/A	MIPS CQM	Process	Cardiac Rehabilitation Patient Referral from an Outpatient Setting	American Heart Association
	N/A / N/A	277	N/A	MIPS CQM	Process	Sleep Apnea: Severity Assessment at Initial Diagnosis	American Academy of Sleep Medicine
!	N/A / N/A	279	N/A	MIPS CQM	Process	Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy	American Academy of Sleep Medicine
!	N/A / N/A	305	CMS137 v15	eCQM	Process	Initiation and Engagement of Substance Use Disorder Treatment	National Committee for Quality Assurance
	N/A / N/A	309	CMS124 v15	eCQM	Process	Cervical Cancer Screening	National Committee for Quality Assurance
	0101 / N/A	318	CMS139 v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	CAHPS for MIPS Clinician/Group Survey	Centers for Medicare & Medicaid Services
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology – Head and Neck Surgery Foundation
!	N/A / N/A	338	CMS314 v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration
+	N/A / N/A	340	CMS115 7v3	eCQM, MIPS CQM	Process	HIV Annual Retention in Care	Health Resources and Services Administration
!	0710 / 0710e	370	CMS159 v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Minnesota Community Measurement
*	N/A / N/A	374	CMS50v 15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	N/A / N/A	377	CMS90v 16	eCQM	Process	Functional Status Assessments for Heart Failure	Centers for Medicare & Medicaid Services
* !	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	Adherence to Antipsychotic Medications For Individuals with Schizophrenia	Centers for Medicare & Medicaid Services

B.19. Internal Medicine

PROPOSED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	387	N/A	MIPS CQM	Process	Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users	American Gastroenterological Association
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
	N/A / N/A	400	N/A	MIPS CQM	Process	One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation	American Gastroenterological Association
	N/A / N/A	401	N/A	MIPS CQM	Process	Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis	American Gastroenterological Association
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	N/A / N/A	438	CMS347 v10	eCQM, MIPS CQM	Process	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Centers for Medicare & Medicaid Services
* !	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)	Wisconsin Collaborative for Healthcare Quality
	N/A / N/A	468	N/A	MIPS CQM	Process	Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)	University of Southern California
*	N/A / N/A	475	CMS349 v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
*	N/A / N/A	476	CMS771 v8	eCQM	Patient-Reported Outcome-Based Performance Measure	Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia	Large Urology Group Practice Association and Oregon Urology Institute
!	N/A / N/A	488	CMS951 v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
*	N/A / N/A	497	N/A	MIPS CQM	Process	Preventive Care and Wellness (composite)	Centers for Medicare & Medicaid Services
	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder	American Psychiatric Association

B.19. Internal Medicine

PROPOSED MEASURES IN THE INTERNAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
	N/A / N/A	515	CMS115 4v2	eCQM	Process	Screening for Abnormal Glucose Metabolism in Patients at Risk of Developing Diabetes	American Medical Association
!	N/A / N/A	516	N/A	MIPS CQM	Outcome	Hepatitis C Virus (HCV): Sustained Virological Response (SVR)	American Gastroenterological Association
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	TBD	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.20. Interventional Radiology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Interventional Radiology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.20. Interventional Radiology

PROPOSED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
*	N/A / N/A	130	CMS 68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	145	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy	American College of Radiology
	N/A / N/A	355	N/A	MIPS CQM	Outcome	Unplanned Reoperation within the 30-Day Postoperative Period	American College of Surgeons
!	N/A / N/A	356	N/A	MIPS CQM	Outcome	Unplanned Hospital Readmission within 30 Days of Principal Procedure	American College of Surgeons
!	N/A / N/A	357	N/A	MIPS CQM	Outcome	Surgical Site Infection (SSI)	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS 50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
!	N/A / N/A	413	N/A	MIPS CQM	Intermediate Outcome	Door to Puncture Time for Endovascular Stroke Treatment	Society of Interventional Radiology
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance

B.20. Interventional Radiology

PROPOSED MEASURES IN THE INTERVENTIONAL RADIOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	420	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Varicose Vein Treatment with Saphenous Ablation: Outcome Survey	Society of Interventional Radiology
	N/A / N/A	421	N/A	MIPS CQM	Process	Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal	Society of Interventional Radiology
	N/A / N/A	465	N/A	MIPS CQM	Process	Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries	Society of Interventional Radiology

B.21. Mental/Behavioral Health and Psychiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Mental/Behavioral Health and Psychiatry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.21. Mental/Behavioral Health and Psychiatry

PROPOSED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	009	CMS12 8v15	eCQM	Process	Antidepressant Medication Management	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v15	eCQM	Process	Dementia: Cognitive Assessment	American Academy of Neurology
!	N/A / N/A	282	N/A	MIPS CQM	Process	Dementia: Functional Status Assessment	American Academy of Neurology/ American Psychiatric Association
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
!	N/A / N/A	305	CMS13 7v15	eCQM	Process	Initiation and Engagement of Substance Use Disorder Treatment	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services

B.21. Mental/Behavioral Health and Psychiatry

PROPOSED MEASURES IN THE MENTAL/BEHAVIORAL HEALTH AND PSYCHIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	366	CMS13 6v16	eCQM	Process	Follow-Up Care for Children Prescribed ADHD Medication	National Committee for Quality Assurance
!	0710 / 0710e	370	CMS15 9v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Minnesota Community Measurement
	N/A / N/A	382	CMS17 7v15	eCQM	Process	Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment	Centers for Medicare & Medicaid Services
* !	1879 / N/A	383	N/A	MIPS CQM	Intermediate Outcome	Adherence to Antipsychotic Medications For Individuals with Schizophrenia	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
	N/A / N/A	468	N/A	MIPS CQM	Process	Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)	University of Southern California
	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder	American Psychiatric Association
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
*	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Reduction in Suicidal Ideation or Behavior Symptoms	American Psychiatric Association

B.22. Nephrology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Nephrology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.22. Nephrology

PROPOSED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	0059 / N/A	001	CMS122v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS139v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
	N/A / N/A	400	N/A	MIPS CQM	Process	One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation	American Gastroenterological Association
!	N/A/ N/A	482	N/A	MIPS CQM	Intermediate Outcome	Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate	Centers for Medicare & Medicaid Services
!	N/A / N/A	488	CMS951v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
!	1662/ N/A	489	N/A	MIPS CQM	Process	Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy	Renal Physicians Association
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance

B.22. Nephrology

PROPOSED MEASURES IN THE NEPHROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performanc e Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	510	N/A	MIPS CQM	Process	First Year Standardized Kidney Transplant Waitlist Ratio (FYSWR)	Centers for Medicare & Medicaid Services
	N/A / N/A	511	N/A	MIPS CQM	Process	Percentage of Prevalent Patients Waitlisted for Kidney Transplant (PPPW) and Percentage of Prevalent Patients Waitlisted for Kidney Transplant in Active Status (aPPPW)	Centers for Medicare & Medicaid Services
	N/A / N/A	512	N/A	MIPS CQM	Process	Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR)	Centers for Medicare & Medicaid Services
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediat e Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association
+	N/A / N/A	TBD	N/A	MIPS CQM	Process	SGLT2 Inhibitors for Patients with Chronic Kidney Disease (CKD) With or Without Type 2 Diabetes Mellitus	A Value-Based Care Registry

B.23. Neurology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Neurology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.23. Neurology

PROPOSED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / N/A	268	N/A	MIPS CQM	Process	Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy	American Academy of Neurology
	N/A / N/A	277	N/A	MIPS CQM	Process	Sleep Apnea: Severity Assessment at Initial Diagnosis	American Academy of Sleep Medicine
!	N/A / N/A	279	N/A	MIPS CQM	Process	Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy	American Academy of Sleep Medicine

B.23. Neurology

PROPOSED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / 2872e	281	CMS149v15	eCQM	Process	Dementia: Cognitive Assessment	American Academy of Neurology
!	N/A / N/A	282	N/A	MIPS CQM	Process	Dementia: Functional Status Assessment	American Academy of Neurology/ American Psychiatric Association
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Psychiatric Association/ American Academy of Neurology
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQM	Process	Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease	American Academy of Neurology
	N/A / N/A	293	N/A	MIPS CQM	Process	Rehabilitative Therapy Referral for Patients with Parkinson's Disease	American Academy of Neurology
* !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	N/A / N/A	386	N/A	MIPS CQM	Process	Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences	American Academy of Neurology
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
*	N/A / N/A	513	N/A	MIPS CQM	Process	Patient Reported Falls and Plan of Care	American Academy of Neurology

B.23. Neurology

PROPOSED MEASURES IN THE NEUROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association

B.24. Neurosurgical

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Neurosurgical specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.24. Neurosurgical

PROPOSED MEASURES IN THE NEUROSURGICAL SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
	N/A / N/A	187	N/A	MIPS CQM	Process	Stroke and Stroke Rehabilitation: Thrombolytic Therapy	American Heart Association
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	N/A / N/A	344	N/A	MIPS CQM	Outcome	Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)	Society for Vascular Surgery
!	N/A / N/A	413	N/A	MIPS CQM	Intermediate Outcome	Door to Puncture Time for Endovascular Stroke Treatment	Society of Interventional Radiology
!	N/A / N/A	459	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Back Pain After Lumbar Surgery	Minnesota Community Measurement
	N/A / N/A	461	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Leg Pain After Lumbar Surgery	Minnesota Community Measurement
	N/A / N/A	471	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Status After Lumbar Surgery	Minnesota Community Measurement

B.25. Nutrition/Dietician

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Nutrition/Dietician specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure

table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We are also proposing to add one existing MIPS quality measure to this specialty set:

- **Q317**: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: This MIPS quality measure supports screening for high blood pressure. We agree with interested parties' feedback that adding this measure to this specialty set would help empower registered dietician nutritionists (RDNs) to meaningfully participate in quality programs and value-based care, ensuring patients receive high-value nutritional care. Hypertension (HTN) is among the leading global preventable risk factors for cardiovascular disease and premature mortality.[455] Early detection and effective management of HTN have demonstrated significant reductions in mortality, morbidity, and health care costs.[456] RDNs provide medical nutrition therapy, which has demonstrated effectiveness in improving outcomes such as blood pressure control and reducing cardiovascular risks.[457] Including this measure within the Nutrition/Dietician specialty set recognizes the critical role of RDNs in managing HTN and promotes team-based, whole-person care. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.25. Nutrition/Dietician

PROPOSED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* !	0059 / N/A	001	CMS122v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	NA / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance

[455] Severin, R., Sabbahi, A., Albarrati, A., Phillips, S. A., & Arena, S. (2020). Blood Pressure Screening by Outpatient Physical Therapists: A Call to Action and Clinical Recommendations. Physical Therapy, 100(6), 1008–1019. https://doi.org/10.1093/ptj/pzaa034.

[456] See footnote Severin et al., 2020.

[457] Senkus, K. E., Dudzik, J. M., Lennon, S. L., DellaValle, D. M., Moloney, L. M., Handu, D., & Rozga, M. (2024). *Medical Nutrition Therapy Provided by a Dietitian Improves Outcomes in Adults With Prehypertension or Hypertension: A Systematic Review and Meta-Analysis. The American Journal of Clinical Nutrition, 119*(6), 1417–1442. https://doi.org/10.1016/j.ajcnut.2024.04.012.

B.25. Nutrition/Dietician

PROPOSED MEASURES IN THE NUTRITION/DIETICIAN SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	239	CMS155v15	eCQM	Process	Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents	National Committee for Quality Assurance
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
+ * !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Obstetrics/Gynecology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We are also proposing to add two existing MIPS quality measures to this specialty set:

- **Q205**: Sexually Transmitted Infection (STI) Testing for People with HIV: This MIPS quality measure assesses appropriate screening of STIs for patients with HIV. We agree with interested parties' feedback that this measure is clinically relevant to this clinician type and propose adding this measure to the Obstetrics/Gynecology specialty set. Clinical guidelines, such as those from the CDC, recommend regular screening for STIs in individuals with HIV.[458] Despite the high incidence of STIs among people with HIV, screening rates remain suboptimal.[459] Adding measure Q205 to this specialty set would help address critical screening gaps, ensuring sexual health services are consistently delivered in settings managing patients' reproductive health. This measure would allow clinicians and health systems to track and benchmark their performance in meeting preventive care goals for patients with HIV. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.
- **Q338**: HIV Viral Suppression: This MIPS quality measure promotes effective management of HIV viral load for patients diagnosed with HIV. We agree with interested parties' feedback that this measure is clinically relevant to this clinician type and are proposing to add this measure to the Obstetrics/Gynecology specialty set. This specialty plays an essential role in ensuring patients remain actively engaged in HIV care while accessing comprehensive prevention services that improve health outcomes. Viral suppression is widely recognized as the clinical goal of HIV treatment, reflecting successful management of the condition.[460] [461] Measuring viral suppression ensures clinicians are accountable for achieving this outcome across their patient population, which is directly linked to measurable preventive outcomes, such as reducing HIV transmission rates and decreasing HIV-related morbidity and mortality.[462] [463] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.26. Obstetrics/Gynecology

PROPOSED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance

[458] See footnote CDC, 2024a.

[459] See footnote Gass et al., 2025.

[460] Panel on Antiretroviral Guidelines for Adults and Adolescents. (2025). Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. U.S. Department of Health and Human Services. https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-arv/whats-new.

[461] CDC. (2023). Treating HIV. https://www.cdc.gov/hiv/treatment/?CDC_AAref_Val=https://www.cdc.gov/hiv/basics/livingwithhiv/treatment.html.

[462] Crawford, T. N., & Thornton, A. (2017). Retention in Continuous Care and Sustained Viral Suppression. *Journal of the International Association of Providers of AIDS Care*, *16*(1), 42–47. https://doi.org/10.1177/2325957416678929.

[463] CDC. (2024c). Effectiveness of HIV Treatment in Preventing HIV Transmission. https://www.cdc.gov/hivpartners/php/hiv-treatment/?CDC_AAref_Val=https://www.cdc.gov/hiv/risk/art/index.html.

B.26. Obstetrics/Gynecology

PROPOSED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
+ !	N/A / 3755e	205	CMS1188v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
* !	N/A / N/A	236	CMS165v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
	N/A / N/A	309	CMS124v15	eCQM	Process	Cervical Cancer Screening	National Committee for Quality Assurance
	N/A / N/A	310	CMS153v15	eCQM	Process	Chlamydia Screening in Women	National Committee for Quality Assurance
	N/A / N/A	335	N/A	MIPS CQM	Outcome	Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse)	Centers for Medicare & Medicaid Services
*	N/A / N/A	336	N/A	MIPS CQM	Process	Maternity Care: Postpartum Follow-up and Care Coordination	Centers for Medicare & Medicaid Services
+ !	N/A / N/A	338	CMS314v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration
*	N/A / N/A	374	CMS50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance
	2063 / N/A	422	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury	American Urogynecologic Society
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance

B.26. Obstetrics/Gynecology

PROPOSED MEASURES IN THE OBSTETRICS/GYNECOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / N/A	432	N/A	MIPS CQM	Outcome	Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair	American Urogynecologic Society
	N/A / N/A	448	N/A	MIPS CQM	Process	Appropriate Workup Prior to Endometrial Ablation	Centers for Medicare & Medicaid Services
*	N/A / N/A	475	CMS349v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
	N/A / N/A	496	N/A	MIPS CQM	Process	Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument	University of California, Irvine
*	N/A / N/A	497	N/A	MIPS CQM	Process	Preventive Care and Wellness (composite)	Centers for Medicare & Medicaid Services
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
	N/A / N/A	504	N/A	MIPS CQM	Process	Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk	American Psychiatric Association
*	N/A / N/A	505	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Reduction in Suicidal Ideation or Behavior Symptoms	American Psychiatric Association
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association

B.27a. Oncology/Hematology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Oncology/Hematology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.27a. Oncology/Hematology

PROPOSED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
* !	N/A / N/A	102	CMS1 29v16	eCQM, MIPS CQM	Process	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Centers for Medicare & Medicaid Services
*	N/A / N/A	130	CMS6 8v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2 v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
* !	0383 / N/A	144	N/A	MIPS CQM	Process	Oncology: Medical and Radiation – Plan of Care for Pain	American Society of Clinical Oncology
!	N/A / N/A	226	CMS1 38v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS1 56v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
*	N/A / N/A	250	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Radical Prostatectomy Pathology Reporting	College of American Pathologists
* !	N/A / N/A	317	CMS2 2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0005 / N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/Experience	CAHPS for MIPS Clinician/Group Survey	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS5 0v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services

B.27a. Oncology/Hematology

PROPOSED MEASURES IN THE ONCOLOGY/HEMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
	1858 / N/A	450	N/A	MIPS CQM	Process	Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer	American Society of Clinical Oncology
!	1859 / N/A	451	N/A	MIPS CQM	Process	RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who Receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy	American Society of Clinical Oncology
*	0210 / N/A	453	N/A	MIPS CQM	Process	Percentage of Patients who Died with Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)	American Society of Clinical Oncology
* !	0216 / N/A	457	N/A	MIPS CQM	Process	Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better)	American Society of Clinical Oncology
!	N/A / N/A	462	CMS645v10	eCQM	Process	Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy	Oregon Urology Institute
	N/A / N/A	490	N/A	MIPS CQM	Process	Appropriate Intervention of Immune-Related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors	Society for Immunotherapy of Cancer (SITC)
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
!	N/A / N/A	506	N/A	MIPS CQM	Process	Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy	Society for Immunotherapy of Cancer (SITC)
*	N/A / N/A	507	N/A	MIPS CQM	Process	Appropriate Germline Testing for Ovarian Cancer Patients	American Society of Clinical Oncology

B.27b. Radiation Oncology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Radiation Oncology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.27b. Radiation Oncology

PROPOSED MEASURES IN THE RADIATION ONCOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* !	N/A / N/A	102	CMS 129v16	eCQM, MIPS CQM	Process	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Centers for Medicare & Medicaid Services
* !	0383 / N/A	144	N/A	MIPS CQM	Process	Oncology: Medical and Radiation – Plan of Care for Pain	American Society of Clinical Oncology
!	N/A / N/A	226	CMS 138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance

B.28. Ophthalmology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Ophthalmology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.28. Ophthalmology

PROPOSED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / 0086e	012	CMS14 3v15	eCQM	Process	Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation	American Academy of Ophthalmology
	N/A / N/A	019	CMS14 2v15	eCQM	Process	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care	American Academy of Ophthalmology
	0055 / N/A	117	CMS13 1v15	eCQM, MIPS CQM	Process	Diabetes: Eye Exam	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	0563 / N/A	141	N/A	Medicare Part B Claims Measure, MIPS CQM	Outcome	Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care	American Academy of Ophthalmology
*	0565 / 0565e	191	CMS13 3v15	eCQM, MIPS CQM	Outcome	Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery	American Academy of Ophthalmology
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	N/A / N/A	303	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	American Academy of Ophthalmology
!	N/A / N/A	304	N/A	MIPS CQM	Patient Engagement/ Experience	Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery	American Academy of Ophthalmology

B.28. Ophthalmology

PROPOSED MEASURES IN THE OPHTHALMOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
!	N/A / N/A	385	N/A	MIPS CQM	Outcome	Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery	American Academy of Ophthalmology
	N/A / N/A	389	N/A	MIPS CQM	Outcome	Cataract Surgery: Difference Between Planned and Final Refraction	American Academy of Ophthalmology
	N/A / N/A	499	N/A	MIPS CQM	Process	Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy	American Society of Retina Specialists
	N/A / N/A	500	N/A	MIPS CQM	Process	Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up	American Society of Retina Specialists
!	N/A / N/A	501	N/A	MIPS CQM	Process	Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up	American Society of Retina Specialists

B.29. Optometry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Optometry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.29. Optometry

PROPOSED MEASURES IN THE OPTOMETRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	019	CMS14 2v15	eCQM	Process	Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care	American Academy of Ophthalmology
	0055 / N/A	117	CMS13 1v15	eCQM, MIPS CQM	Process	Diabetes: Eye Exam	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services

B.30. Orthopedic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Orthopedic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.30. Orthopedic Surgery

PROPOSED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
* !	N/A / N/A	178	N/A	MIPS CQM	Process	Rheumatoid Arthritis (RA): Functional Status Assessment	American College of Rheumatology
!	N/A / N/A	180	N/A	MIPS CQM	Process	Rheumatoid Arthritis (RA): Glucocorticoid Management	American College of Rheumatology
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS13 9v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance

B.30. Orthopedic Surgery

PROPOSED MEASURES IN THE ORTHOPEDIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
!	N/A / N/A	351	N/A	MIPS CQM	Process	Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation	American Association of Hip and Knee Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	N/A / N/A	376	CMS56 v15	eCQM	Process	Functional Status Assessments for Total Hip Replacement	Centers for Medicare & Medicaid Services
	0053 / N/A	418	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Osteoporosis Management in Women Who Had a Fracture	National Committee for Quality Assurance
!	N/A / N/A	459	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Back Pain After Lumbar Surgery	Minnesota Community Measurement
	N/A / N/A	461	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Leg Pain After Lumbar Surgery	Minnesota Community Measurement
!	N/A / N/A	470	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Status After Primary Total Knee Replacement	Minnesota Community Measurement
	N/A / N/A	471	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Status After Lumbar Surgery	Minnesota Community Measurement
!	3493 / N/A	480	N/A	Administrative Claims	Outcome	Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)	Centers for Medicare & Medicaid Services

B.31. Otolaryngology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Otolaryngology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.31. Otolaryngology

PROPOSED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	066	CMS14 6v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQM	Process	Sleep Apnea: Severity Assessment at Initial Diagnosis	American Academy of Sleep Medicine
!	N/A / N/A	279	N/A	MIPS CQM	Process	Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy	American Academy of Sleep Medicine
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS13 9v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology-Head and Neck Surgery Foundation

B.31. Otolaryngology

PROPOSED MEASURES IN THE OTOLARYNGOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	355	N/A	MIPS CQM	Outcome	Unplanned Reoperation within the 30-Day Postoperative Period	American College of Surgeons
!	N/A / N/A	357	N/A	MIPS CQM	Outcome	Surgical Site Infection (SSI)	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	0657 / N/A	464	N/A	MIPS CQM	Process	Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Process	Age-Related Hearing Loss: Comprehensive Audiometric Evaluation	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.32. Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.32. Pathology

PROPOSED MEASURES IN THE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	249	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Barrett's Esophagus	College of American Pathologists
*	N/A / N/A	250	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Radical Prostatectomy Pathology Reporting	College of American Pathologists
*	N/A / N/A	395	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Lung Cancer Reporting (Biopsy/Cytology Specimens)	College of American Pathologists
* !	N/A / N/A	396	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Lung Cancer Reporting (Resection Specimens)	College of American Pathologists
*	N/A / N/A	397	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Melanoma Reporting	College of American Pathologists
* !	N/A / N/A	440	N/A	MIPS CQM	Process	Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician	American Academy of Dermatology
* !	3661 / N/A	491	N/A	MIPS CQM	Process	Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status	College of American Pathologists

B.33. Pediatrics

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Pediatrics specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.33. Pediatrics

PROPOSED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0069 / N/A	065	CMS154v15	eCQM, MIPS CQM	Process	Appropriate Treatment for Upper Respiratory Infection (URI)	National Committee for Quality Assurance
	N/A / N/A	066	CMS146v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / 3755e	205	CMS1188v4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / N/A	239	CMS155v15	eCQM	Process	Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents	National Committee for Quality Assurance
	N/A / N/A	240	CMS117v15	eCQM	Process	Childhood Immunization Status	National Committee for Quality Assurance
!	N/A / N/A	305	CMS137v15	eCQM	Process	Initiation and Engagement of Substance Use Disorder Treatment	National Committee for Quality Assurance
	N/A / N/A	310	CMS153v15	eCQM	Process	Chlamydia Screening in Women	National Committee for Quality Assurance
	N/A / N/A	366	CMS136v16	eCQM	Process	Follow-Up Care for Children Prescribed ADHD Medication	National Committee for Quality Assurance
!	0710 / 0710e	370	CMS159v15	eCQM, MIPS CQM	Outcome	Depression Remission at Twelve Months	Minnesota Community Measurement
	N/A / N/A	382	CMS177v15	eCQM	Process	Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment	Centers for Medicare & Medicaid Services
	N/A / N/A	394	N/A	MIPS CQM	Process	Immunizations for Adolescents	National Committee for Quality Assurance

B.33. Pediatrics

PROPOSED MEASURES IN THE PEDIATRICS SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
*	0657 / N/A	464	N/A	MIPS CQM	Process	Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use	American Academy of Otolaryngology – Head and Neck Surgery Foundation

B.34. Physical Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Physical Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.34. Physical Medicine

PROPOSED MEASURES IN THE PHYSICAL MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS 68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS 138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS 22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS 50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
	N/A / N/A	468	N/A	MIPS CQM	Process	Continuity of Pharmacotherapy for Opioid Use Disorder (OUD)	University of Southern California

B.35. Physical Therapy/Occupational Therapy

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Physical Therapy/Occupational Therapy specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.35. Physical Therapy/Occupational Therapy

PROPOSED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear	American Podiatric Medical Association
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
	N/A / 2872e	281	CMS14 9v15	eCQM	Process	Dementia: Cognitive Assessment	American Academy of Neurology

B.35. Physical Therapy/Occupational Therapy

PROPOSED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Academy of Neurology/ American Psychiatric Association
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQM	Process	Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease	American Academy of Neurology
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS13 9v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
	N/A / N/A	502	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder	American Psychiatric Association
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
+	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Neck Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Upper Extremity Impairments	Limber Health, Inc. and Patient360, LLC
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Back Impairments	Limber Health, Inc. and Patient360, LLC
+	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Lower Extremity Impairments	Limber Health, Inc. and Patient360, LLC

B.35. Physical Therapy/Occupational Therapy

PROPOSED MEASURES IN THE PHYSICAL THERAPY/OCCUPATIONAL THERAPY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
+	N/A / N/A	TBD	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Functional Improvement for Patients with Knee Impairments	Limber Health, Inc. and Patient360, LLC

B.36. Plastic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Plastic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.36. Plastic Surgery

PROPOSED MEASURES IN THE PLASTIC SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	N/A / N/A	355	N/A	MIPS CQM	Outcome	Unplanned Reoperation within the 30-Day Postoperative Period	American College of Surgeons
!	N/A / N/A	356	N/A	MIPS CQM	Outcome	Unplanned Hospital Readmission within 30 Days of Principal Procedure	American College of Surgeons
!	N/A / N/A	357	N/A	MIPS CQM	Outcome	Surgical Site Infection (SSI)	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons

B.37. Podiatry

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Podiatry specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.37. Podiatry

PROPOSED MEASURES IN THE PODIATRY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
	N/A / N/A	127	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear	American Podiatric Medical Association
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	226	CMS 138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS 22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0101 / N/A	318	CMS 139v15	eCQM	Process	Falls: Screening for Future Fall Risk	National Committee for Quality Assurance
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.38. Preventive Medicine

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Preventive Medicine specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable.

We are also proposing to add two existing MIPS quality measures to this specialty set:

- **Q205**: Sexually Transmitted Infection (STI) Testing for People with HIV: This MIPS quality measure assesses appropriate screening of STIs for patients with HIV. We agree with interested parties' feedback that this measure is clinically relevant to this clinician type and propose adding this measure to the Preventive Medicine specialty set. Clinical guidelines, such as those from the CDC, recommend regular screening for STIs in individuals with HIV.[464] Despite the high incidence of STIs among people with HIV, screening rates remain suboptimal.[465] Including this measure emphasizes adherence to established best practices in care provision within preventive medicine. This measure would allow clinicians and health systems to track and benchmark their performance in meeting preventive care goals for patients with HIV. The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.
- **Q338**: HIV Viral Suppression: This MIPS quality measure promotes effective management of HIV viral load for patients diagnosed with HIV. We agree with interested parties' feedback that this measure is clinically relevant to this clinician type and are proposing to add this measure to the Preventive Medicine specialty set. This specialty plays an essential role in ensuring patients remain actively engaged in HIV care while accessing comprehensive prevention services that improve health outcomes. Viral suppression is widely recognized as the clinical goal of HIV treatment, reflecting successful management of the condition.[466] [467] Measuring viral suppression ensures clinicians are accountable for achieving this outcome across their patient populations, which is directly linked to measurable preventive outcomes, such as reducing HIV transmission rates and decreasing HIV-related morbidity and mortality.[468] [469] The measure being added to this specialty set would be contingent on the inclusion of applicable coding by the time of the CY 2027 PFS final rule publication. In the event appropriate coding is not included in the final specification, this measure would not be finalized for inclusion within this specialty measure set.

Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.38. Preventive Medicine

PROPOSED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
* !	0059 / N/A	001	CMS 122v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Diabetes: Glycemic Status Assessment Greater Than 9%	National Committee for Quality Assurance
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance

[464] See footnote CDC, 2024a.
[465] See footnote Gass et al., 2025.
[466] See footnote Panel on Antiretroviral Guidelines for Adults and Adolescents, 2025.
[467] See footnote CDC, 2023.
[468] See footnote Crawford & Thornton, 2017.
[469] See footnote CDC, 2024c.

B.38. Preventive Medicine

PROPOSED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
!	N/A / N/A	126	N/A	MIPS CQM	Process	Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation	American Podiatric Medical Association
*	N/A / N/A	130	CMS 68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS 2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
+ !	N/A / 3755e	205	CMS 1188v 4	eCQM, MIPS CQM	Process	Sexually Transmitted Infection (STI) Testing for People with HIV	Health Resources and Services Administration
	0643 / N/A	243	N/A	MIPS CQM	Process	Cardiac Rehabilitation Patient Referral from an Outpatient Setting	American Heart Association
+ !	N/A / N/A	338	CMS 314v4	eCQM, MIPS CQM	Outcome	HIV Viral Suppression	Health Resources and Services Administration
*	N/A / N/A	374	CMS 50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance

B.38. Preventive Medicine

PROPOSED MEASURES IN THE PREVENTIVE MEDICINE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	N/A / N/A	438	CMS 347v10	eCQM, MIPS CQM	Process	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease	Centers for Medicare & Medicaid Services
*	N/A / N/A	475	CMS 349v9	eCQM	Process	HIV Screening	Centers for Disease Control and Prevention
!	N/A / N/A	488	CMS 951v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
*	N/A / N/A	497	N/A	MIPS CQM	Process	Preventive Care and Wellness (composite)	Centers for Medicare & Medicaid Services
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association

B.39. Pulmonology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Pulmonology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.39. Pulmonology

PROPOSED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
!	0102 / N/A	052	N/A	MIPS CQM	Process	Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy	American Thoracic Society
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	236	CMS16 5v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
	N/A / N/A	277	N/A	MIPS CQM	Process	Sleep Apnea: Severity Assessment at Initial Diagnosis	American Academy of Sleep Medicine
!	N/A / N/A	279	N/A	MIPS CQM	Process	Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy	American Academy of Sleep Medicine
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
* !	N/A / N/A	398	N/A	MIPS CQM	Outcome	Optimal Asthma Control	Minnesota Community Measurement
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance

B.39. Pulmonology

PROPOSED MEASURES IN THE PULMONOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.40. Rheumatology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Rheumatology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.40. Rheumatology

PROPOSED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
	N/A / N/A	024	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older	National Committee for Quality Assurance
!	0046 / N/A	039	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Screening for Osteoporosis for Women Aged 65-85 Years of Age	National Committee for Quality Assurance
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	176	N/A	MIPS CQM	Process	Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy	American College of Rheumatology
	2523 / N/A	177	N/A	MIPS CQM	Process	Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity	American College of Rheumatology
* !	N/A / N/A	178	N/A	MIPS CQM	Process	Rheumatoid Arthritis (RA): Functional Status Assessment	American College of Rheumatology
!	N/A / N/A	180	N/A	MIPS CQM	Process	Rheumatoid Arthritis (RA): Glucocorticoid Management	American College of Rheumatology
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	236	CMS16 5v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
!	0022 / N/A	238	CMS15 6v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance

B.40. Rheumatology

PROPOSED MEASURES IN THE RHEUMATOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title**	**Measure Steward**
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
*	N/A / N/A	374	CMS50 v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee Quality Assurance
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.41. Skilled Nursing Facility

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Skilled Nursing Facility specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.41. Skilled Nursing Facility

PROPOSED MEASURES IN THE SKILLED NURSING FACILITY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0083 / 0083e	008	CMS1 44v15	eCQM, MIPS CQM	Process	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)	American Heart Association
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	0066 / N/A	118	N/A	MIPS CQM	Process	Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)	American Heart Association
!	0101 / N/A	155	N/A	MIPS CQM	Process	Falls: Plan of Care	National Committee for Quality Assurance
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	0022 / N/A	238	CMS1 56v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS2 2v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	3620 / N/A	493	N/A	MIPS CQM	Process	Adult Immunization Status	National Committee for Quality Assurance
!	3665 / N/A	495	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood	American Academy of Hospice and Palliative Medicine (AAHPM)

B.42. Speech Language Pathology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Speech Language Pathology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set.

The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.42. Speech Language Pathology

PROPOSED MEASURES IN THE SPEECH LANGUAGE PATHOLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v 16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	181	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Elder Maltreatment Screen and Follow-Up Plan	Centers for Medicare & Medicaid Services
	N/A / N/A	182	N/A	MIPS CQM	Process	Functional Outcome Assessment	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	N/A / N/A	282	N/A	MIPS CQM	Process	Dementia: Functional Status Assessment	American Academy of Neurology/ American Psychiatric Association
	N/A / N/A	286	N/A	MIPS CQM	Process	Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia	American Academy of Neurology/ American Psychiatric Association
*	N/A / N/A	288	N/A	MIPS CQM	Process	Dementia: Education and Support of Caregivers for Patients with Dementia	American Academy of Neurology
*	N/A / N/A	291	N/A	MIPS CQM	Process	Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease	American Academy of Neurology
	N/A / N/A	386	N/A	MIPS CQM	Process	Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences	American Academy of Neurology

B.43. Thoracic Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Thoracic Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.43. Thoracic Surgery

PROPOSED MEASURES IN THE THORACIC SURGERY SPECIALTY SET							
Indicator	CBE # / eCQM CBE #	Quality #	CMS eCQM ID	Collection Type	Measure Type	Measure Title and Description	Measure Steward
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS 68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	0129 / N/A	164	N/A	MIPS CQM	Outcome	Coronary Artery Bypass Graft (CABG): Prolonged Intubation	Society of Thoracic Surgeons
*	0114 / N/A	167	N/A	MIPS CQM	Outcome	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure	Society of Thoracic Surgeons
*	0115 / N/A	168	N/A	MIPS CQM	Outcome	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration	Society of Thoracic Surgeons
!	N/A / N/A	226	CMS 138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	N/A / N/A	356	N/A	MIPS CQM	Outcome	Unplanned Hospital Readmission within 30 Days of Principal Procedure	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS 50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	0119 / N/A	445	N/A	MIPS CQM	Outcome	Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG)	Society of Thoracic Surgeons

B.44. Urgent Care

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Urgent Care specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.44. Urgent Care

PROPOSED MEASURES IN THE URGENT CARE SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
	0069 / N/A	065	CMS15 4v15	eCQM, MIPS CQM	Process	Appropriate Treatment for Upper Respiratory Infection (URI)	National Committee for Quality Assurance
	N/A / N/A	066	CMS14 6v15	eCQM, MIPS CQM	Process	Appropriate Testing for Pharyngitis	National Committee for Quality Assurance
!	0058 / N/A	116	N/A	MIPS CQM	Process	Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis	National Committee for Quality Assurance
*	N/A / N/A	130	CMS68 v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS13 8v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22 v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	331	N/A	MIPS CQM	Process	Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)	American Academy of Otolaryngology – Head and Neck Surgery Foundation
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
*	0657 / N/A	464	N/A	MIPS CQM	Process	Otitis Media with Effusion: Systemic Antimicrobials – Avoidance of Inappropriate Use	American Academy of Otolaryngology – Head and Neck Surgery Foundation
!	N/A / N/A	488	CMS95 1v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation

B.45. Urology

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Urology specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.45. Urology

PROPOSED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
	N/A / N/A	048	N/A	MIPS CQM	Process	Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
!	N/A / N/A	050	N/A	MIPS CQM	Process	Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older	National Committee for Quality Assurance
* !	N/A / N/A	102	CMS129v16	eCQM, MIPS CQM	Process	Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients	Centers for Medicare & Medicaid Services
*	N/A / N/A	130	CMS68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
* !	N/A / N/A	134	CMS2v16	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for Depression and Follow-Up Plan	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
!	0022/ N/A	238	CMS156v15	eCQM, MIPS CQM	Process	Use of High-Risk Medications in Older Adults	National Committee for Quality Assurance
* !	N/A / N/A	317	CMS22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
	0005/ N/A	321	N/A	CMS-approved Survey Vendor	Patient Engagement/ Experience	CAHPS for MIPS Clinician/Group Survey	Centers for Medicare & Medicaid Services

B.45. Urology

PROPOSED MEASURES IN THE UROLOGY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services
	2152 / N/A	431	N/A	MIPS CQM	Process	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling	National Committee for Quality Assurance
!	N/A / N/A	432	N/A	MIPS CQM	Outcome	Proportion of Patients Sustaining a Bladder or Bowel Injury at the time of any Pelvic Organ Prolapse Repair	American Urogyneco-logic Society
*	0210/ N/A	453	N/A	MIPS CQM	Process	Percentage of Patients who Died with Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)	American Society of Clinical Oncology
* !	0216/ N/A	457	N/A	MIPS CQM	Process	Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better)	American Society of Clinical Oncology
!	N/A / N/A	462	CMS645v10	eCQM	Process	Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy	Oregon Urology Institute
*	N/A / N/A	476	CMS771v8	eCQM	Patient-Reported Outcome-Based Performance Measure	Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia	Large Urology Group Practice Association and Oregon Urology Institute
*	N/A/ N/A	481	CMS646v7	eCQM	Process	Intravesical Bacillus-Calmette -Guerin for Non-Muscle Invasive Bladder Cancer	Oregon Urology
!	N/A / N/A	488	CMS951v5	eCQM, MIPS CQM	Process	Kidney Health Evaluation	National Kidney Foundation
	2483 / N/A	503	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Gains in Patient Activation Measure (PAM®) Scores at 12 Months	Insignia Health, LLC, a wholly owned subsidiary of Phreesia

B.46. Vascular Surgery

In addition to the considerations discussed in the introductory language of Table Group B of this Appendix to this proposed rule, the Vascular Surgery specialty set takes additional criteria into consideration, which includes, but is not limited to, whether a measure reflects current clinical guidelines and the coding of the measure includes relevant clinician types. We may reassess the appropriateness of individual measures, on a case-by-case basis, to ensure appropriate inclusion in the specialty set. The measure table for this specialty set includes previously finalized measures we are maintaining within the set and modifications proposed for the CY 2027 performance period/2029 MIPS payment year.

Measures proposed for addition to this specialty set under Table Group A of this Appendix, or previously finalized measures proposed for addition, are indicated by a + in the Indicator column, as applicable. Measures proposed for removal under Table Group C of this Appendix have been removed from this specialty set, as applicable. Measures with proposed substantive changes under Table Group D of this Appendix are indicated with a * in the Indicator column, as applicable. Below would be the specialty set for this specialty for the CY 2027 performance period if everything is finalized as proposed. We request comments on these proposals.

B.46. Vascular Surgery

PROPOSED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	0326 / N/A	047	N/A	Medicare Part B Claims Measure, MIPS CQM	Process	Advance Care Plan	National Committee for Quality Assurance
*	N/A / N/A	130	CMS 68v16	eCQM, MIPS CQM	Process	Documentation of Current Medications in the Medical Record	Centers for Medicare & Medicaid Services
!	N/A / N/A	226	CMS 138v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention	National Committee for Quality Assurance
* !	N/A / N/A	236	CMS 165v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Intermediate Outcome	Controlling High Blood Pressure	National Committee for Quality Assurance
	N/A / N/A	259	N/A	MIPS CQM	Outcome	Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post Operative Day #2)	Society for Vascular Surgery
* !	N/A / N/A	317	CMS 22v15	Medicare Part B Claims Measure, eCQM, MIPS CQM	Process	Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented	Centers for Medicare & Medicaid Services
!	N/A / N/A	344	N/A	MIPS CQM	Outcome	Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)	Society for Vascular Surgery
!	N/A / N/A	357	N/A	MIPS CQM	Outcome	Surgical Site Infection (SSI)	American College of Surgeons
!	N/A / N/A	358	N/A	MIPS CQM	Process	Patient-Centered Surgical Risk Assessment and Communication	American College of Surgeons
*	N/A / N/A	374	CMS 50v15	eCQM, MIPS CQM	Process	Closing the Referral Loop: Receipt of Specialist Report	Centers for Medicare & Medicaid Services

B.46. Vascular Surgery

PROPOSED MEASURES IN THE VASCULAR SURGERY SPECIALTY SET							
Indicator	**CBE # / eCQM CBE #**	**Quality #**	**CMS eCQM ID**	**Collection Type**	**Measure Type**	**Measure Title and Description**	**Measure Steward**
!	N/A / N/A	420	N/A	MIPS CQM	Patient-Reported Outcome-Based Performance Measure	Varicose Vein Treatment with Saphenous Ablation: Outcome Survey	Society of Interventional Radiology
* !	N/A / N/A	441	N/A	MIPS CQM	Intermediate Outcome	Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)	Wisconsin Collaborative for Healthcare Quality
+ !	N/A / N/A	TBD	N/A	MIPS CQM	Intermediate Outcome	Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	American Heart Association

Table Group C: Previously Finalized Quality Measures Proposed for Removal for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

In this proposed rule, we are proposing to remove 20 previously finalized MIPS quality measures for the CY 2027 performance period/2029 MIPS payment year and future years. These measures are discussed in detail in the removal tables below. Note: Specialty sets impacted by each measure removal are indicated under Table Group C of this Appendix within the last row of each C table.

The CY 2019 PFS final rule (83 FR 59763 through 59765) and CY 2020 PFS final rule (84 FR 62957 through 62959) discuss our incremental approach to removing process measures. Further considerations are given in the evaluation of a measure's performance data to determine whether there is or no longer is variation in performance. As discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763), an additional criterion we use for the removal of measures includes extremely topped-out measures, which refers to measures topped out with an average (mean) performance rate between 98-100 percent. For a measure proposed for removal due to criteria relating to the benchmark and performance data, further information regarding 2025 MIPS benchmarking data can be located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks.*

As codified in the CY 2025 PFS final rule (89 FR 98561) at § 414.1330(c)(1), we list 12 criteria used to determine the removal of a quality measure.

(i) If the Secretary determines that the quality measure is no longer meaningful, such as measures that are topped out.
(ii) If a measure steward is no longer able to maintain the quality measure.
(iii) If the quality measure reached extremely topped out status.
(iv) If the quality measure does not meet case minimum and reporting volumes required for benchmarking after being in the program for 2 consecutive CY performance periods.
(v) If the quality measure is duplicative.
(vi) If the quality measure is not updated to reflect current clinical guidelines, which are not reflective of a clinician's scope of practice.
(vii) If the quality measure is a process measure.
(viii) If the quality measure addresses a measurement gap.
(ix) If the quality measure is a patient-reported outcome.
(x) If the quality measure is not available for MIPS quality reporting by or on behalf of all MIPS eligible clinicians.
(xi) The robustness of the quality measure.
(xii) Consideration of the quality measure in developing MIPS Value Pathways (MVPs).

Additionally, we codified at § 414.1330(c)(2) 6 instances when a quality measure that otherwise meets the criteria for removal in § 414.1330(c)(1) may nonetheless be retained based on the following considerations:

(i) Whether the removal of the process measure impacts the number of measures available for a specific specialty.
(ii) Whether the quality measure addresses a priority area.
(iii) Whether the quality measure promotes positive outcomes in patients.
(iv) Whether the quality measure is designated as high priority or not.
(v) Whether the quality measure has reached extremely topped out status.
(vi) Evaluation of the quality measure's performance data.

However, we would like to note that in section IV.A.4.d.(1)(c)(ii) of this proposed rule we are proposing to update the existing quality measure retention consideration at § 414.1330(c)(1)(iv) to state that we would consider whether the quality measure is designated as high priority or not through the CY 2026 performance period/CY 2028 MIPS payment year.

We request comments on these measure removals and the impacted specialty sets.

C.1 Coronary Artery Disease (CAD): Antiplatelet Therapy

Category	Description
CBE # / eCQM CBE #:	0067 / N/A
Quality#:	006
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12-month period who were prescribed aspirin or clopidogrel.
Measure Steward:	American Heart Association
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), at the measure steward's request because it would no longer be maintained for inclusion.
In the Circumstance the Measure Is Retained:	There are no substantive changes for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

C.2 Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF ≤ 40%)

Category	Description
CBE # / eCQM CBE #:	0070 / 0070e
Quality#:	007
CMS eCQM ID:	CMS145v15
Collection Type:	eCQM / MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12-month period who also have a prior MI or a current or prior LVEF ≤ 40% who were prescribed beta-blocker therapy.
Measure Steward:	American Heart Association
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), at the measure steward's request because it would no longer be maintained for inclusion.
In the Circumstance the Measure Is Retained:	There are no substantive changes for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

C.3 Oncology: Medical and Radiation – Pain Intensity Quantified

Category	Description
CBE # / eCQM CBE #:	0384 / 0384e
Quality#:	143
CMS eCQM ID:	CMS157v15
Collection Type:	eCQM / MIPS CQM
Measure Description:	Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified.
Measure Steward:	American Society of Clinical Oncology
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. Topped-out process measures are those with a median performance rate of 95 percent or higher (81 FR 77286). This measure's continued topped-out status is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf*.
In the Circumstance the Measure Is Retained:	There are no substantive changes for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Oncology/Hematology, Radiation Oncology

C.4 Functional Status Change for Patients with Knee Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	217
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with knee impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Knee Impairments measure being proposed in Table A.6 of this Appendix. Measure Q217 is specific to knee impairments and restricts clinicians to using the proprietary tool FOTO LEPF PROM or a manual crosswalk for numerator assessment. The new measure proposed in Table A.6 of this Appendix is a more comprehensive patient-reported outcome-based performance measure. The new measure allows the use of various validated assessments tools, including the Knee Outcome Survey, Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the Predicted Moderate Clinical Improvement (P-MCI), a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that would improve feasibility of reporting as all information to calculate performance would be provided by the measure steward.
In the Circumstance the Measure Is Retained:	There are no substantive changes for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

C.5 Functional Status Change for Patients with Hip Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	218
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with hip impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Lower Extremity Impairments measure being proposed in Table A.5 of this Appendix. Measure Q218 is specific to hip impairments and restricts clinicians to using the proprietary tool FOTO LEPF PROM or a manual crosswalk for numerator assessment. The new measure proposed in Table A.5 of this Appendix is a more comprehensive patient-reported outcome-based performance measure that includes all lower extremity injuries. The new measure allows the use of various validated assessments tools, including the Lower Extremity Functional Scale (LEFS), PROMIS Physical Function, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that would improve feasibility of reporting as all information to calculate performance would be provided by the measure steward.
In the Circumstance the Measure Is Retained:	There are no substantive changes for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

C.6 Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	219
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with foot, ankle or lower leg impairments. The change in FS is assessed using the FOTO Lower Extremity Physical Function (LEPF) PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Lower Extremity Impairments measure being proposed in Table A.5 of this Appendix. Measure Q219 is specific to lower leg, foot and ankle impairments and restricts clinicians to the use of the proprietary tool FOTO LEPF PROM or a manual crosswalk for numerator assessment. The new measure proposed in Table A.5 of this Appendix is a more comprehensive patient-reported outcome-based performance measure that includes all lower extremity injuries. The new measure allows the use of various validated assessments tools, including the LEFS, PROMIS Physical Function, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that would improve feasibility of reporting as all information to calculate performance would be provided by the measure steward.
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy, Podiatry

C.7 Functional Status Change for Patients with Low Back Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	220
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with low back impairments. The change in FS is assessed using the FOTO Low Back FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Back Impairments measure being proposed in Table A.4 of this Appendix. Measure Q220 is specific to low back impairments and restricts clinicians to the use of the proprietary tool FOTO Low Back FS PROM or a manual crosswalk for numerator assessment. The new measure proposed in Table A.4 of this Appendix is a more comprehensive patient-reported outcome-based performance measure that includes all back impairments. The new measure allows the use of various validated assessment tools, such as the Modified Low Back Disability Questionnaire, PROMIS Pain Interference, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that would improve feasibility of reporting as all information to calculate performance would be provided by the measure steward.
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

C.8 Functional Status Change for Patients with Shoulder Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	221
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with shoulder impairments. The change in FS is assessed using the FOTO Shoulder FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Upper Extremity Impairments measure being proposed in Table A.3 of this Appendix. Measure Q221 is specific to shoulder impairments and restricts clinicians to the use of the proprietary tool FOTO Shoulder FS PROM or a manual crosswalk for numerator assessment. The new measure proposed in Table A.3 of this Appendix is a more comprehensive patient-reported outcome-based performance measure that includes all upper extremity injuries. The new measure allows the use of various validated assessment tools, such as the Quick Disabilities of the Arm, Shoulder, & Hand (QDASH) and PROMIS Upper Extremity, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that would improve feasibility of reporting as all information to calculate performance would be provided by the measure steward.
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

C.9 Functional Status Change for Patients with Elbow, Wrist or Hand Impairments

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	222
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with elbow, wrist, or hand impairments. The change in FS is assessed using the FOTO Elbow/Wrist/Hand FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative of the Functional Improvement for Patients with Upper Extremity Impairments measure being proposed in Table A.3 of this Appendix. Measure Q222 is specific to elbow, wrist and hand impairments and restricts clinicians to the use of the proprietary tool FOTO Elbow/Wrist/Hand FS PROM or a manual crosswalk for numerator assessment. The new measure proposed in Table A.3 of this Appendix is a more comprehensive patient-reported outcome-based performance measure that includes all upper extremity injuries. The new measure allows the use of various validated assessment tools, such as QDASH and PROMIS Upper Extremity, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that would improve feasibility of reporting as all information to calculate performance would be provided by the measure steward.
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

C.10 Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients

Category	Description
CBE # / eCQM CBE #:	0658 / N/A
Quality#:	320
CMS eCQM ID:	N/A
Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Measure Description:	Percentage of patients aged 45 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of 10 years for repeat colonoscopy documented in their colonoscopy report.
Measure Steward	American Gastroenterological Association
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. Topped-out process measures are those with a median performance rate of 95 percent or higher (81 FR 77286). This measure's continued topped-out status is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf.*
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Gastroenterology

C.11 Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	326
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM

Category	Description
Measure Description:	Percentage of patients aged 18 years and older with atrial fibrillation (AF) or atrial flutter who were prescribed an FDA-approved oral anticoagulant drug for the prevention of thromboembolism during the measurement period.
Measure Steward	American Heart Association
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), at the measure steward's request because it would no longer be maintained for inclusion.
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Cardiology, Family Medicine, Internal Medicine, Skilled Nursing Facility

C.12 Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	332
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulanate, as a first line antibiotic at the time of diagnosis.
Measure Steward	American Academy of Otolaryngology – Head and Neck Surgery Foundation
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure is duplicative in clinical topic of measure Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse). Measure Q331 assesses patients with a diagnosis of acute viral sinusitis for receipt of antibiotics within 10 days of symptoms onset, highlighting inappropriate use of antibiotics in eligible patients. Measure Q331 is broader than measure Q332 as it encourages avoidance of prescribing any antibiotic for viral illnesses, capturing the patient populations found in both measures. Measure Q332 is narrower in scope, focusing only on patients with bacterial sinusitis appropriately receiving an antibiotic, impacting a smaller proportion of sinusitis cases.
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Allergy/Immunology, Emergency Medicine, Family Medicine, Internal Medicine, Otolaryngology, Urgent Care

C.13 Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	350
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients regardless of age undergoing a total knee or total hip replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g., non-steroidal anti-inflammatory drug (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure.
Measure Steward	American Association of Hip and Knee Surgeons
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because it is a process measure. Removing this process measure would support the goal of prioritizing measures that improve patient outcomes and have meaningful impact. Additionally, this measure is not prescriptive to conservative therapy utilization; therefore, it only assesses for informed consent, which is a standard of care for any clinician. In the CY 2019 (83 FR 59763 through 59765) and CY 2020 (84 FR 62957) PFS final rules, we communicated to interested parties our desire to reduce the number of process measures within the MIPS quality measure set. In the CY 2017 QPP final rule (81 FR 77101), we explained that outcome measures are more valuable than clinical process measures and are instrumental to improving the quality-of-care patients receive. In the CY 2025 PFS final rule (89 FR 98561), we codified under § 414.1330(c)(1)(vii) that CMS uses the following criteria to determine the removal of a quality measure: If the quality measure is a process measure.
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Orthopedic Surgery

C.14 Children Who Have Dental Decay or Cavities

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	378
CMS eCQM ID:	CMS75v15
Collection Type:	eCQM
Measure Description:	Percentage of children, 1 - 20 years of age at the start of the measurement period, who have had tooth decay or cavities during the measurement period as determined by a dentist.
Measure Steward:	Centers for Medicare & Medicaid Services
Measure Type:	Outcome
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), due to the robustness of the measure. This measure lacks a quality action that can be attributed to the clinicians reporting it, and as a result, the current scoring methodology for determination of measure achievement points for this measure is not a reflection of the quality of care provided. This measure focuses on incidence of tooth decay or cavities rather than the quality of care delivered, as patients would be attributed to clinicians based on encounter and not whether they have been involved in the patient's care. Therefore, it would be likely they would have had no impact on the outcome being assessed. While tracking the incidence of tooth decay or cavities identifies the prevalence of the issue, it is not a reflection of the quality of care given, as currently specified, and does not promote meaningful dental care interventions that would drive improvements in oral health outcomes. The lack of an actionable quality assessment reduces the overall robustness of the measure.
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Dentistry

C.15 Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery

Category	Description
CBE # / eCQM CBE #:	N/A / N/A

Category	Description
Quality#:	384
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery.
Measure Steward:	American Academy of Ophthalmology
Measure Type:	Outcome
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. This measure's continued topped-out status is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf.*
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Ophthalmology

C.16 Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	415
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of emergency department visits for patients aged 18 years and older who presented with a minor blunt head trauma who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.
Measure Steward:	American College of Emergency Physicians
Measure Type:	Efficiency
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because this measure has reached the end of the topped-out lifecycle (82 FR 53640) and has a limited opportunity to improve clinical outcomes. This measure's continued topped-out status is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks*, in addition to previous years MIPS benchmarking data. For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf.*
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Emergency Medicine

C.17 Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy

Category	Description
CBE # / eCQM CBE #:	N/A /N/A
Quality#:	430
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively and/or intraoperatively.
Measure Steward:	American Society of Anesthesiologists
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2017 Quality Payment Program final rule (81 FR 77558 through 77675), because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. The average performance for this measure, 99.34 percent, is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance rate is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks.* For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf.*
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Anesthesiology

C.18 Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	463
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	Percentage of patients aged 3 through 17 years, who undergo a procedure under general anesthesia in which an inhalational anesthetic is used for maintenance AND who have two or more risk factors for post-operative vomiting (POV), who receive combination therapy consisting of at least two prophylactic pharmacologic anti-emetic agents of different classes preoperatively and/or intraoperatively.
Measure Steward:	American Society of Anesthesiologists
Measure Type:	Process
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2018 Quality Payment Program final rule (82 FR 53966 through 53975), because the quality action being measured has become a standard of care, based upon MIPS performance data, and thus has limited opportunity to improve clinical outcomes. The average performance for this measure, 98.99 percent, is extremely high and unvarying, making this measure extremely topped out as discussed in the CY 2019 PFS final rule (83 FR 59761 through 59763). The average performance rate is based on the current 2026 MIPS benchmarking data located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks.* For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf.*
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Anesthesiology

C.19 Functional Status Change for Patients with Neck Impairments

Category	Description
CBE # / eCQM CBE #:	3461 / N/A
Quality#:	478
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	A patient-reported outcome measure (PROM) of risk-adjusted change in functional status (FS) for patients 14 years+ with neck impairments. The change in FS is assessed using the FOTO Neck FS PROM. The measure is adjusted to patient characteristics known to be associated with FS outcomes (risk-adjusted) and used as a performance measure at the patient, individual clinician, and clinic levels to assess quality.
Measure Steward:	Focus on Therapeutic Outcomes, Inc.
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2020 Quality Payment Program final rule (84 FR 63205 through 63213), because this measure is duplicative of the Functional Improvement for Patients with Neck Impairments measure being proposed in Table A.2 of this Appendix. Measure Q478 is specific to neck impairments and restricts clinicians to the use of the proprietary tool FOTO Neck FS PROM or a manual crosswalk for numerator assessment. The new measure proposed in Table A.2 of this Appendix is a more comprehensive patient-reported outcome-based performance measure. The new measure allows the use of various validated assessment tools, such as the Neck Disability Index, PROMIS Pain Interference, or equivalent tools. The new measure focuses on clinically meaningful outcomes by assessing improvement against the P-MCI, a patient-specific, risk-adjusted threshold. This measure incorporates a risk adjustment model that would improve feasibility of reporting as all information to calculate performance would be provided by the measure steward.
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Chiropractic Medicine, Orthopedic Surgery, Physical Therapy/Occupational Therapy

C.20 Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM)

Category	Description
CBE # / eCQM CBE #:	3568 / N/A
Quality#:	483
CMS eCQM ID:	N/A
Collection Type:	MIPS CQM
Measure Description:	The Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM) uses the PCPCM Patient Reported Outcome Measure (PROM) a comprehensive and parsimonious set of 11 patient-reported items - to assess the broad scope of primary care. Unlike other primary care measures, the PCPCM PRO-PM measures the high value aspects of primary care based on a patient's relationship with the clinician or practice.
Measure Steward:	The American Board of Family Medicine
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale for Removal:	We are proposing the removal of this quality measure from MIPS, finalized in the CY 2020 Quality Payment Program final rule (84 FR 63205 through 63213), because the limited adoption of this quality measure does not allow for the creation of a benchmark after being in the program for two consecutive CY performance periods. For more information on benchmarks, see the MIPS 2026 Quality Benchmarks User Guide at *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3611/2026-Quality-Benchmarks-User-Guide.pdf*. The current 2026 MIPS benchmarking data is located at *https://qpp.cms.gov/reporting-requirements/measures-activities/benchmarks*.
In the Circumstance the Measure Is Retained:	There are no substantive changes proposed for this measure. If the measure is not finalized for removal in the CY 2027 PFS final rule, it would be added back into the applicable previously finalized specialty set(s) under Table Group B of this Appendix and the reason for its retention would be addressed under Table Group C of this Appendix.
Proposed for Removal from the Following Specialty Sets:	Family Medicine, Internal Medicine

Table Group D: Proposed Substantive Changes to Previously Finalized MIPS Quality Measures for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

The D Tables within this proposed rule provide the substantive changes proposed for the MIPS quality measures for CY 2027. Two measures have proposed substantive changes that would result in a new benchmark. All measures with substantive changes

are discussed in detail in the tables below. In addition, measures that are endorsed by a CBE are shown in Table D of this Appendix as follows: CBE # / eCQM CBE #.

We note that some MIPS quality measures available in traditional MIPS and MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP), specifically the inclusion of such measures in the APP measure set and/or APP Plus measure set, as finalized in the CY 2025 PFS final rule (89 FR 98363 through 98371). For such measures, the collection types solely applicable for purposes of the APP measure set and/or APP Plus measure set (Medicare Clinical Quality Measures for Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Medicare CQMs) collection type and newly proposed Medicare Electronic Clinical Quality Measures for ACOs Participating in the Medicare Shared Savings Program (Medicare eCQMs) collection type as described in section IV.A.4.d.(1)(c)(v) of this proposed rule) are also specified as a collection type available for such relevant measures described in Table Group D.

Changes made to denominator code sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2027 may not be identified within this proposed rule due to their later publication. Coding revisions to the denominator may be postponed until CY 2028, if measure steward review and their ability to implement the coding changes are impacted due to the timing of 2027 CPT and ICD-10 updates. The 2027 Quality Measure Release Notes provide a comprehensive, detailed reference of exact code changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types on the Quality Payment Program website at *https://qpp.cms.gov*.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but they are important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible population. Therefore, please refer to the current year measure specification and the 2027 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation. Language has been added to all quality measure specifications in the form of a revised 'Instructions Note' to clearly identify if telehealth encounters are allowed for denominator eligibility regardless of changes in coding or billing practices that may occur. Eligibility of telehealth encounters would be based on the intent of the measure and those settings that are appropriate for inclusion.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature; however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow for the most accurate implementation.

We request comments on these substantive changes.

D.1 Diabetes: Glycemic Status Assessment Greater Than 9%

Category	**Description**
CBE # / eCQM CBE #:	0059 / N/A
Quality#:	001
CMS eCQM ID:	CMS122v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients 18-75 years of age with diabetes who had a glycemic status assessment (hemoglobin A1c [HbA1c] or glucose management indicator [GMI]) > 9.0% during the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure, eCQM, Medicare CQM, MIPS CQM, Medicare eCQM collection types. **Updated logic: For the eCQM collection type: Revised:** to prioritize identifying numerical glycemic status results over null values.
Measure Steward:	National Committee for Quality Assurance
MIPS Core Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We are proposing to update the logic of the eCQM collection type to ensure clinically meaningful data is prioritized for inclusion in the measure, better aligning with the measure intent. We are also proposing to update the collection types available for this measure to include the Medicare eCQM collection type to allow choice in submission method for Medicare Shared Savings Program ACOs reporting the APP Plus measure set. See section IV.A.4.d.(1)(c)(v) of this proposed rule for further information on the Medicare eCQM collection type.

D.2 Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	102
CMS eCQM ID:	CMS129v16
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low (or very low) risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy who did not have a bone scan performed at any time since diagnosis of prostate cancer.
Substantive Change:	**Updated measure logic and logic definitions: For the eCQM collection type: Added:** Gleason Grade Group and anatomical site specificity for tumor staging. **Updated value set/coding: For the eCQM collection type: Added:** two direct reference codes representing Gleason Grade Group and value set 'Prostate Anatomical Site' (2.16.840.1.113762.1.4.1248.411). **Updated definition: For the MIPS CQM collection type**: **Added:** PET/CT, Ga-68 PSMA-11, F-18 flotufolastat PSMA PET/CT, PET/MRI (full body imaging) to 'Bone Scan'.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	For the eCQM collection type, we are proposing the addition of Gleason Grade Group and anatomical site specificity for tumor staging to facilitate the capture of low or very low risk of prostate cancer. With this addition to the eCQM, we also propose revising the measure logic to include coding that would capture Gleason Grade Group as an option for assessing prostate cancer risk, as well as the addition of value set 'Prostate Anatomical Site,' which would ensure anatomical site specificity for tumor staging. For the MIPS CQM collection type, we are proposing the addition of PET/CT, Ga-68 PSMA-11, F-18 flotufolastat PSMA PET/CT imaging, and PET/MRI (full body imaging). By incorporating PET/CT, Ga-68 PSMA-11, F-18 flotufolastat PSMA PET/CT imaging, and PET/MRI (full body imaging) into the measure, to align with guideline-directed avoidance of advanced imaging related to low or very low risk prostate cancer.

D.3 Documentation of Current Medications in the Medical Record

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	130
CMS eCQM ID:	CMS68v16
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of visits for which the eligible clinician attests to documenting a list of current medications using all immediate resources available on the date of the encounter.
Substantive Change:	**Updated value set/coding**: **For the eCQM collection type: Revised:** Direct Reference Code (DRC) "Acute health crisis (finding)" (SNOMEDCT Code (705016005)) to value set 'Acute Health Crisis' (OID: 2.16.840.1.113762.1.4.1248.429) to allow for additional conditions to qualify for the exception. **Updated value set/coding**: **For the eCQM collection type: Revised:** 'Encounter to Document Medications' (2.16.840.1.113883.3.600.1.1609) to remove CPT code 99211 and add CPT code 92622 as outlined in the previous EKI.[470]
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the coding for the eCQM collection type to ensure the measure includes additional coding for the denominator exception, aligning with measure intent and allowing for mapping to equivalent appropriate clinical circumstances. Additionally, the encounter coding has been revised to ensure the appropriate patient population is being captured in the denominator for assessment.

[470] See eCQM Known Issue (EKI) #39 at https://oncprojectracking.healthit.gov/support/browse/EKI-39.

D.4 Preventive Care and Screening: Screening for Depression and Follow-Up Plan

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	134
CMS eCQM ID:	CMS2v16
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of or up to two days after the date of the qualifying encounter.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure, eCQM, Medicare CQM, MIPS CQM, Medicare eCQM collection types. **The measure description is revised to read: For the eCQM collection type:** Percentage of patients aged 12 years and older screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented from the date of the screening to two days after the date of the qualifying encounter or an active depression medication or active depression management intervention was active or prescribed at any time on the date of qualifying encounter. **Updated definition: For the eCQM collection type: Added:** Active Depression Medication or Active Depression Management Intervention Documentation that patient is actively receiving interventions designed to treat depression such as behavioral health evaluation, psychotherapy, pharmacological interventions, or additional treatment options. **Updated guidance: For the eCQM collection type: Added:** clarifying language on screening tool to be used for screening a 17-year-old, and which screening should be used to satisfy the numerator. **The measure numerator is revised to read: For the eCQM collection type:** Patients screened for depression on the date of the encounter or up to 14 days prior to the date of the encounter using an age-appropriate standardized depression screening tool AND if positive, a follow-up plan is documented from the date of the screening to two days after the date of the qualifying encounter or an active depression medication or active depression management intervention was active or prescribed at any time during the qualifying encounter. **Updated numerator definition: For the MIPS CQM, Medicare CQM, and the Medicare Part B Claims Measure collection types: Added:** Prior screening within performance period: Patient previously screened by another clinician using an age-appropriate standardized depression screening tool with documented results within the performance period AND if positive, a follow-up plan is documented. **Updated denominator exception: For the MIPS CQM, Medicare CQM, and the Medicare Part B Claims Measure collection types: Added:** Screening for depression not completed, previous patient screening with results documented within performance period.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	For the eCQM collection type, we are proposing to expand the numerator so that an active depression medication or depression management intervention that is prescribed or in place at any time on the date of the qualifying encounter may meet the numerator quality action.[471] We propose to revise the language in the description, definitions, and numerator statement to reflect the proposed revision and align with measure logic. We are also proposing to clarify the screening tools that may be used to satisfy the measure for patients who are 17 years old at the start of the measurement period, as this age group may fall into a transitional category requiring unique considerations for tool selection. For the MIPS CQM, Medicare CQM, and Medicare Part B Claims Measure collection types, we are proposing to add a new denominator exception for patients with documentation of being previously screened, with a follow-up care plan documented if appropriate, in accordance with the measure requirements, by another clinician within the performance period to enhance team-based, coordinated, and patient-centered care processes between clinicians.[472]

[471] Zuckerbrot, R. A., Cheung, A., Jensen, P. S., Stein, R. E. K., Laraque, D., GLAD-PC Steering Group, Levitt, A., Birmaher, B., Campo, J., Clarke, G., Emslie, G., Kaufman, M., Kelleher, K. J., Kutcher, S., Malus, M., Sacks, D., Waslick, B., & Sarvet, B. (2018). Guidelines for Adolescent Depression in Primary Care (GLAD-PC): Part I. Practice Preparation, Identification, Assessment, and Initial Management. *Pediatrics*, *141*(3), e20174081. https://doi.org/10.1542/peds.2017-4081.

[472] Department of Veterans Affairs, & Department of Defense. (2022). VA/DoD Clinical Practice Guideline for the Management of Major Depressive Disorder (Version 4.0). https://www.healthquality.va.gov/guidelines/MH/mdd/VADODMDDCPGFinal508.pdf.

Category	Description
	We are also proposing to update the collection types available for this measure to include the Medicare eCQM collection type to allow choice in submission method for Medicare Shared Savings Program ACOs reporting the APP Plus measure set. See section IV.A.4.d.(1)(c)(v) of this proposed rule for further information on the Medicare eCQM collection type.

D.5 Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care

Category	Description
CBE # / eCQM CBE #:	0563 / N/A
Quality#:	141
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within the 12 month performance period.
Substantive Change:	**Measure description revised to read: For all collection types:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 20% from the pre-intervention level) OR if the most recent IOP was not reduced by at least 20% from the pre-intervention level, a plan of care was documented within 7 days after the patient encounter when IOP was assessed. **Updated denominator exclusions: For all collection types: Added:** 1. Eyes with absolute glaucoma blindness 2. Pre-existing visual acuity findings include: Count fingers (CF or FC), Hand motion (HM), Light perception (LP), No light perception (NLP) **Updated numerator: For all collection types: Added:** a plan of care was documented within 7 days after the patient encounter when IOP was assessed. **Updated numerator definition**: **For all collection types: Revised:** definition for Plan of Care to include: The plan of care must be documented within 7 days after the patient encounter when IOP was assessed. **Updated numerator options: For all collection types: Revised:** **Performance Met:** Glaucoma plan of care documented within 7 days after the patient encounter when IOP was assessed
Measure Steward:	American Academy of Ophthalmology
MIPS Core Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to update multiple components of the measure for all collection types to align with the added numerator definition that specifies the timing of when the plan of care must be documented in the patient's medical record after the IOP is assessed. This would ensure timely and optimal patient care across clinicians for measure performance, as well as reduce variability in how the measure is applied. We are proposing to add denominator exclusions for patients with absolute glaucoma blindness or specific visual acuity findings because they represent end-stage clinical conditions characterized by absolute blindness or profound vision loss, in which further IOP reduction is unlikely to provide meaningful benefit in preserving visual function or slowing glaucoma progression. The exclusions would align with the intent of the measure to assess IOP management in support of preserving remaining visual function and limiting disease progression, and would refine the denominator to reflect patients who may reasonably benefit from vision-preserving IOP management and related care planning.[473]

[473] Kastner, A., & King, A. J. (2020). Advanced Glaucoma at Diagnosis: Current Perspectives. *Eye (London, England)*, *34*(1), 116–128. https://doi.org/10.1038/s41433-019-0637-2.

D.6 Oncology: Medical and Radiation - Plan of Care for Pain

Category	Description
CBE # / eCQM CBE #:	0383 / N/A
Quality#:	144
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain.
Substantive Change:	**Updated denominator note: For Submission Criteria 2: Added:** definition for lookback period in the instance a code has a billing date different from the face-to-face encounter.
Measure Steward:	American Society of Clinical Oncology
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to add a defined look-back window to identify the encounter at which the plan of care to address pain should be documented for numerator assessment. This would clarify implementation of the numerator assessment, which would ensure reporting is appropriate and consistent across clinician submissions. Addressing treatment-induced pain improves patients' health, quality of life, and long-term survival,[474] and reduces interruption in radiation therapy due to pain, thereby ensuring treatment compliance.

[474] Konopka-Filippow, M., Polityńska, B., Wojtukiewicz, A. M., & Wojtukiewicz, M. Z. (2025). Cancer Pain: Radiotherapy as a Double-Edged Sword. *International Journal of Molecular Sciences*, *26*(11), 5223. https://doi.org/10.3390/ijms26115223.

D.7 Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure

Category	Description
CBE # / eCQM CBE #:	0114 / N/A
Quality#:	167
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older undergoing isolated coronary artery bypass graft (CABG) surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.
Substantive Change:	**Updated definitions: Added:** **Denominator:** **Baseline serum creatinine** – Most recent creatinine level obtained prior to the operating room entry **Numerator:** **Postoperative period** – Period begins upon operating room exit and continues to discharge from the hospital after cardiac surgery.
Measure Steward:	Society of Thoracic Surgeons
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We are proposing to add two definitions to clarify implementation of the denominator exclusion for documented history of baseline serum creatinine and the numerator assessment timeframe for patients who develop postoperative renal failure or require dialysis. The first definition (baseline serum creatinine) would ensure the denominator eligible patient population is appropriately identified, and the second definition (postoperative period) would clarify the numerator assessment timeframe. These additions would ensure appropriate and consistent implementation across clinician submissions.

D.8 Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration

Category	Description
CBE # / eCQM CBE #:	0115 / N/A
Quality#:	168
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older undergoing isolated coronary artery bypass graft (CABG) surgery who require a return to the operating room (OR) for mediastinal bleeding with or without tamponade, unplanned coronary artery intervention (native vessel, graft or both), valve dysfunction, aortic reintervention or other cardiac reason during the current hospitalization.
Substantive Change:	**Updated definition: Added:** **Postoperative period** – Period for surgical re-exploration begins upon OR exit and continues to discharge from the hospital after cardiac surgery.
Measure Steward:	Society of Thoracic Surgeons
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We are proposing to add a definition of postoperative period to clarify the numerator assessment timeframe, which would ensure appropriate and consistent implementation across clinician submissions.

D.9 Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	176
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	If a patient has been newly prescribed a biologic and/or immune response modifier that includes a warning for potential reactivation of a latent infection, then the medical record should indicate TB testing in the preceding 12-month period.
Substantive Change:	**The measure numerator is revised to read:** Patients for whom any record of TB testing is documented or performed (PPD, Tspot or QuantiFERON-TB Gold Plus) in the medical record in the 12 months preceding the biologic and/or immune response modifier prescription.
Measure Steward:	American College of Rheumatology
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing changes to the measure numerator to clarify the appropriate tests for TB screening to meet the numerator quality action. This revision would ensure the intent of the measure was met and numerator compliance is consistently assessed across all clinician submissions.

D.10 Rheumatoid Arthritis (RA): Functional Status Assessment

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	178
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 18 years and older with two or more diagnoses of rheumatoid arthritis (RA) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period.
Substantive Change:	**The measure title is revised from Rheumatoid Arthritis (RA): Functional Status Assessment to:** Rheumatic Disease: Functional Status Assessment. **The measure description is revised to read:** Percentage of patients aged 18 years and older with two or more encounters with a diagnosis of rheumatoid arthritis (RA), psoriatic arthritis (PsA), or systemic lupus erythematosus (SLE) at least 90 days apart for whom a functional status assessment was performed at least once during the performance period. **Updated intent and clinical applicability: Revised:** to include PsA and SLE. **The measure denominator is revised to read:** Patients aged 18 years and older with two or more RA, PsA, or SLE diagnoses documented at least 90 days apart with at least one encounter with an RA, PsA, or SLE diagnosis occurring during the performance period and an additional encounter with an RA, PsA or SLE diagnosis occurring in the performance period or prior performance period. **Updated denominator criteria: Revised:** to include diagnosis coding for PsA and SLE. Added PsA and SLE to the additional encounter criteria. **Updated denominator definition: Revised:** definition for additional encounter to include PsA and SLE. **Updated numerator definition: Revised:** definition for functional status assessment to include PsA and SLE.
Measure Steward:	American College of Rheumatology
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to revise multiple components of this measure by adding psoriatic arthritis (PsA) or systemic lupus erythematosus (SLE) to ensure that all patients diagnosed with rheumatic disease are included in the measure's denominator. The addition of PsA and SLE to the RA measure improves the comprehensiveness of the measure, aligns with shared disease characteristics and treatment approaches, and ensures appropriate care across rheumatic diseases. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for the creation of a performance period benchmark, a new benchmark would be used for scoring.

D.11 Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery

Category	Description
CBE # / eCQM CBE #:	0565 / 0565e
Quality#:	191
CMS eCQM ID:	CMS133v15
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of cataract surgeries for patients aged 18 years and older with a diagnosis of uncomplicated cataract and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved in the operative eye within 90 days following the cataract surgery.
Substantive Change:	**Updated value set/coding**: **For the eCQM collection type: Updated:** to a single value set for significant ocular conditions denominator exclusion.
Measure Steward:	American Academy of Ophthalmology
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We are proposing to replace the individual condition specific value sets for the ocular conditions denominator exclusion with a single value set of significant ocular conditions to streamline implementation.

D.12 Controlling High Blood Pressure

Category	Description
CBE # / eCQM CBE #:	NA / N/A
Quality#:	236
CMS eCQM ID:	CMS165v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients 18-85 years of age who had a diagnosis of essential hypertension starting before and continuing into, or starting during the first six months of the measurement period, and whose most recent blood pressure was adequately controlled (<140/90mmHg) during the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure, eCQM, Medicare CQM, MIPS CQM, Medicare eCQM collection types.
Measure Steward:	National Committee for Quality Assurance
MIPS Core Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We are proposing to update the collection types available for this measure to include the Medicare eCQM collection type to allow choice in submission method for Medicare Shared Savings Program ACOs reporting the APP Plus measure set. See section IV.A.4.d.(1)(c)(v) of this proposed rule for further information on the Medicare eCQM collection type.

D.13 Radical Prostatectomy Pathology Reporting

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	250
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.
Substantive Change:	**Updated denominator exclusion**: **For all collection types: Removed:** Specimen site other than anatomic location of prostate. **Updated denominator exception: For all collection types: Added:** Specimen site other than anatomic location of prostate.
Measure Steward:	College of American Pathologists
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to move the denominator exclusion for "Specimen site other than anatomic location of prostate" to the numerator options as a denominator exception. Moving this criteria from a denominator exclusion to a denominator exception would allow for more automated capture of the relevant cases for the measure with less manual intervention required for measure reporting.

D.14 Dementia: Education and Support of Caregivers for Patients with Dementia

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	288
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients with dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
Substantive Change:	**The measure description is revised to read:** Percentage of patients with dementia whose caregiver(s), who are not part of the licensed care team, were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months. **Updated intent and clinician applicability: Added:** whose caregiver(s), who are not part of the licensed care team, were provided with education on dementia disease. **The measure numerator is revised to read:** Patients with dementia whose caregiver(s), who are not part of the licensed care team, were provided with education on dementia disease management and health behavior changes AND were referred to additional resources for support in the last 12 months.
Measure Steward:	American Academy of Neurology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update multiple components of this measure to clarify that the education and support required as part of the numerator quality action is intended for caregivers who are not part of the licensed clinical care team. Consistent with the measure's intent, educating caregivers that are not part of the licensed care team recognizes their essential role in patient care, improves patient-centered care outcomes, enhances caregiver well-being, and strengthens the overall continuity of care across both formal and informal settings.

D.15 Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	291
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of all patients with a diagnosis of Parkinson's Disease (PD) who were assessed for cognitive impairment or dysfunction once during the measurement period.
Substantive Change:	**Updated denominator criteria: Added:** coding for physical therapy.
Measure Steward:	American Academy of Neurology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to add physical therapy coding as part of the denominator criteria for this measure as it is clinically appropriate for this clinician type to assess patients with a diagnosis of PD for cognitive impairment or dysfunction. Physical therapists play a critical role in identifying functional limitations linked to cognitive decline and tailoring interventions accordingly. These codes recognize that cognitive dysfunction significantly influences physical function and safety, and they integrate the expertise of physical therapists into the multidisciplinary care of PD.

D.16 Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	317
CMS eCQM ID:	CMS22v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / MIPS CQM
Current Measure Description:	Percentage of patient visits for patients aged 18 years and older seen during the measurement period who were screened for high blood pressure AND a recommended follow-up plan is documented, as indicated, if blood pressure is elevated or hypertensive.
Substantive Change:	**Updated denominator criteria: For all collection types: Added:** coding for physical and occupational therapy.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to update the denominator criteria to include coding for physical and occupational therapy (PT/OT) as it is clinically appropriate for these clinician types to assess for high blood pressure. By adding PT/OT professionals in this measure, healthcare organizations can help ensure a more inclusive, proactive, and effective approach to managing cardiovascular health in patients aged 18 and older, while also capitalizing on all patient touchpoints to achieve comprehensive wellness and improved health outcomes.

D.17 Maternity Care: Postpartum Follow-up and Care Coordination

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	336
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for postpartum care before or at 12 weeks of giving birth and received the following at a postpartum visit: breastfeeding evaluation and education, postpartum depression screening, intimate partner violence screening, postpartum glucose screening for gestational diabetes patients, family and contraceptive planning counseling, tobacco use screening and cessation education, healthy lifestyle behavioral advice, and an immunization review and update.
Substantive Change:	**The measure numerator is revised to read:** Patients receiving the following at a postpartum visit: • Evaluating the physical recovery from birth, including pain and incontinence • Evaluating and counseling for sleep hygiene and fatigue • Breastfeeding evaluation and education, including patient-reported breastfeeding • Postpartum depression and anxiety screening • Intimate partner violence screening • Postpartum glucose screening for gestational diabetes patients • Family and contraceptive planning counseling, including same-day placement of a long-acting reversible contraceptive (LARC) if desired • Tobacco use screening and cessation education • Substance use disorder /opioid use disorder screening • Physical activity and exercise counseling • Immunization review and update **Updated definitions: Added:** **Evaluating Physical Recovery From Birth –** Patients who were evaluated for physical recovery from birth, including pain and incontinence, with referral as indicated (e.g., to physical therapy, urogynecology). **Evaluating and Counseling for Sleep Hygiene and Fatigue –** Patients were evaluated for sleep hygiene and fatigue and clinicians discussed coping options for fatigue and sleep disruption. **Substance Use Disorder/Opioid Use Disorder Screening –** Patients were screened for substance use/opioid use and referred to postpartum psychosocial support services, including substance use disorder treatment and relapse prevention programs. **Revised:** **Physical Activity and Exercise Counseling –** Patients with uncomplicated pregnancies who were encouraged to undertake regular physical activity and/or to engage in aerobic and strength-conditioning exercises (of any intensity) after pregnancy, as part of efforts to recommend and reinforce a healthy lifestyle. **Postpartum Depression and Anxiety Screening –** added anxiety screening via a self-reported validated anxiety tool. **Updated Numerator Instructions: Revised:** to include evaluating for physical recovery from birth, including pain and incontinence; evaluating and counseling for sleep hygiene and fatigue; postpartum anxiety screening; same-day placement of a long-acting reversible contraceptive (LARC) if desired; substance use disorder /opioid use disorder screening; and physical activity and exercise counseling..
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise the measure numerator by adding evaluations for physical recovery from birth, including pain and incontinence; evaluations and counseling for sleep hygiene and fatigue; postpartum anxiety screening; same-day placement of a long-acting reversible contraceptive (LARC) if desired; substance use disorder /opioid use disorder screening; and physical activity and exercise counseling as recommended by The American College of Obstetricians and Gynecologists (ACOG).[475] The additional evaluations provide significant added value to postpartum care by addressing broader aspects of maternal health that may impact recovery, well-being, and long-term outcomes. Additionally, we are proposing to reflect this revision in the definitions and numerator instructions sections of the measure to ensure appropriate assessment of quality actions and consistent implementation across clinician submissions.

D.18 Closing the Referral Loop: Receipt of Specialist Report

Category	Description
CBE # / eCQM CBE #:	N/A / N/A

[475] American College of Obstetricians and Gynecologists. (2018). ACOG Committee Opinion No. 736: Optimizing Postpartum Care. *Obstetrics & Gynecology, 131*(5), e140–e150. https://doi.org/10.1097/AOG.0000000000002633.

Category	Description
Quality#:	374
CMS eCQM ID:	CMS50v15
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of patients with referrals, regardless of age, for which the referring clinician receives a report from the clinician to whom the patient was referred.
Substantive Change:	**Updated guidance: For the eCQM collection type: Added:** If two or more referrals have the same date/time stamp and are captured in the denominator as "first" referral, a consultant report for any of these "first" referrals will qualify the patient for the numerator. **Updated denominator criteria: For all collection types: Added:** coding for audiology visits. **Updated logic: For the eCQM collection type: Revised:** numerator logic to capture the 'first referral' when multiple instances of a "first referral" with the same date/time stamp are present.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the denominator criteria to include audiology visits as this measure is applicable to their scope of care. By including audiology visits in the measure, it would ensure that referrals made by audiologists are tracked, especially as specialization continues to increase in the provision of patient care, facilitating better coordination of care. Additionally, we are proposing to update the measure guidance and logic for the eCQM collection type to clarify implementation when multiple referrals are received and ensure the logic is aligned. This would ensure consistent reporting across clinician submitters.

D.19 Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Category	Description
CBE # / eCQM CBE #:	1879 / N/A
Quality#:	383
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of individuals at least 18 years of age as of the beginning of the performance period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the performance period.
Substantive Change:	**Updated denominator: Revised:** (Table 1) added oral antipsychotic medications: - pimavanserin - pimozide - olanzapine-fluoxetine - xanomeline-tropisum chloride
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We are proposing to update the list of medications used to identify denominator eligible patients by adding four oral antipsychotic medications to the existing list in the denominator. This expansion would provide an up-to-date list of appropriate oral antipsychotic medications that clinicians may have prescribed for their patients, thereby ensuring that as many of the appropriate patients are identified in the denominator of this measure as possible.

D.20 Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation

Category	Description
CBE # / eCQM CBE #:	2474 / N/A
Quality#:	392
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation. This measure is submitted as four rates stratified by age and sex. • Submission Age Criteria 1: Females 18-64 years of age • Submission Age Criteria 2: Males 18-64 years of age • Submission Age Criteria 3: Females 65 years of age and older • Submission Age Criteria 4: Males 65 years of age and older
Substantive Change:	**Updated reporting frequency and implementation considerations: Revised:** measure is to be submitted each time a denominator eligible procedure is performed.
Measure Steward:	American College of Cardiology Foundation
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We are proposing to update the measure submission frequency to each time a denominator eligible procedure is performed as cardiac tamponade is a life-threatening emergency.[476] Requiring this measure to be submitted for each procedure would ensure MIPS eligible clinicians are monitoring and assessing patients for all instances of cardiac tamponade and/or pericardiocentesis occurring within 30 days following atrial fibrillation ablation, as well as adhering to evidence-based practices, which will improve clinical outcomes for patients. This change reflects a transition towards higher standards of care, increased accountability, and greater alignment with the goals of modern healthcare delivery systems.

[476] Khan Z. (2023). Cardiac Tamponade During Catheter Atrial Fibrillation Ablation: A Life-Threatening Complication. *Cureus*, *15*(9), e44989. https://doi.org/10.7759/cureus.44989.

D.21 Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	393
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Infection rate following CIED device implantation, replacement, or revision.
Substantive Change:	**Updated reporting frequency and implementation considerations: Revised:** measure is to be submitted each time a denominator eligible procedure is performed. **The measure denominator is revised to read:** **For Submission Criteria 1:** All patients with a new CIED from January July 1, 2026, through June 30, 2027, of the performance period. **For Submission Criteria 2:** All patients with replacement or revision of a CIED from July 1, 2026, through June 30, 2027, of the performance period. **Updated denominator definition: Added:** Denominator Identification Period – The twelve month period in which eligible patients have a procedure. The "denominator identification period" includes dates of procedure 7/1/2026 to 6/30/2027.
Measure Steward:	American College of Cardiology Foundation
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We are proposing to update the measure submission frequency to each time a denominator eligible procedure is performed as infections resulting from implantable cardiac devices are associated with substantial morbidity. Requiring this measure to be submitted for each procedure would ensure MIPS eligible clinicians are monitoring and assessing patients for all instances of an infection requiring device removal or surgical revision within 180 days following CIED implantation, replacement, or revision, as well as adhering to evidence-based practices, which will improve clinical outcomes for patient. This change reflects a transition towards higher standards of care, increased accountability, and greater alignment with the goals of modern healthcare delivery systems.[477] We are also proposing to lengthen the denominator identification period from July of the previous year through June of the measurement period to allow for a full year of denominator eligibility, ensuring the denominator eligible patient population being assessed for the numerator action is complete.

[477] Lakkireddy, D. R., Rao, A., Theriot, P., Darden, D., Pothineni, N. V. K., Ram, R., Gao, Y. R., Cheung, J. W., & Birgersdotter-Green, U. (2023). Contemporary Management of Cardiac Implantable Electronic Device Infection: The American College of Cardiology COGNITO Survey. *JACC. Advances*, *3*(2), 100773. https://doi.org/10.1016/j.jacadv.2023.100773.

D.22 Lung Cancer Reporting (Biopsy/Cytology Specimens)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	395
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Pathology reports based on lung biopsy and/or cytology specimens with a diagnosis of primary non-small cell lung cancer classified into specific histologic type following the International Association for the Study of Lung Cancer (IASLC) guidance or classified as non-small cell lung cancer not otherwise specified (NSCLC-NOS) with an explanation included in the pathology report.
Substantive Change:	**Updated denominator exclusion: For all collection types: Removed:** Specimen site other than anatomic location of lung or is not classified as primary non-small cell lung cancer. **Updated denominator exception: For all collection types: Added:** Specimen site other than anatomic location of lung or is not classified as primary non-small cell lung cancer.
Measure Steward:	College of American Pathologists
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to move the denominator exclusion for "specimen site other than anatomic location of lung or is not classified as primary non-small cell lung cancer" to the numerator options as a denominator exception. Moving this criteria from a denominator exclusion to a denominator exception would allow for more automated capture of the relevant cases for the measure with less manual intervention required for measure reporting.

D.23 Lung Cancer Reporting (Resection Specimens)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	396
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Pathology reports based on lung resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer (NSCLC), histologic type.
Substantive Change:	**Updated denominator exclusion: For all collection types: Removed:** Specimen site other than anatomic location of lung OR classified as non-small cell lung cancer, not otherwise specified (NSCLC-NOS). **Updated denominator exception: For all collection types: Added:** Specimen site other than anatomic location of lung OR classified as NSCLC-NOS.
Measure Steward:	College of American Pathologists
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to move the denominator exclusion for "Specimen site other than anatomic location of lung OR classified as NSCLC-NOS" to the numerator options as a denominator exception. Moving this criteria from a denominator exclusion to a denominator exception would allow for more automated capture of the relevant cases for the measure with less manual intervention required for measure reporting.

D.24 Melanoma Reporting

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	397
CMS eCQM ID:	N/A
Current Collection Type:	Medicare Part B Claims Measure / MIPS CQM
Current Measure Description:	Pathology reports for primary malignant cutaneous melanoma that include the pT category, thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors.
Substantive Change:	**The measure description is revised to read**: **For all collection types:** Pathology reports for primary malignant cutaneous melanoma that include the thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors, and for excisions, pT category. **Updated intent and applicability: For all collection types: Revised:** to clarify pT category reporting is only required for excisions. **Updated denominator instructions: For the MIPS CQM collection type: Removed**: instructions moved to the numerator. **Updated denominator exclusion: For all collection types: Removed:** Specimen site other than anatomic cutaneous location. **The measure numerator is revised to read: For all collection types:** Pathology reports for primary malignant cutaneous melanoma that include the thickness, ulceration and mitotic rate, peripheral and deep margin status and presence or absence of microsatellitosis for invasive tumors, and in excisions, pT Category. **Updated numerator instructions: For all collection types: Revised:** to clarify pT category reporting is only required for excisions. **Updated numerator options: For all collection types: Revised:** to clarify pT category reporting is only required for excisions. **Updated denominator exception: For all collection types: Added:** Specimen site other than anatomic cutaneous location.
Measure Steward:	College of American Pathologists
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise multiple components of the measure to align with the College of American Pathologists 2025 Protocols[478] [479] and improve the quality of care for melanoma patients by mandating the inclusion of specific, evidence-based pathological parameters in all reports. We are specifically requiring pT category reporting for excisions only. By standardizing and ensuring completeness in pathology reporting, clinicians would significantly enhance diagnostic accuracy, treatment planning, and patient outcomes. Additionally, we are proposing to move the denominator exclusion for "Specimen site other than anatomic cutaneous location" to the numerator options as a denominator exception. Moving this criteria from a denominator exclusion to a denominator exception would allow for more automated capture of the relevant cases for the measure with less manual intervention required for measure reporting.

[478] College of American Pathologists. (2025). Protocol for the Examination of Excision Specimens from Patients with Invasive Melanoma of the Skin. https://documents.cap.org/documents/New-Cancer-Protocols-March-2025/Skin.Inv_Melanoma.Res_1.2.0.0.REL.CAPCP.pdf.

[479] College of American Pathologists. (2025). Protocol for the Examination of Biopsy Specimens from Patients with Invasive Melanoma of the Skin. https://documents.cap.org/documents/New-Cancer-Protocols-March-2025/Skin.Inv_Melanoma.Bx_1.1.0.0.REL.CAPCP.pdf.

D.25 Optimal Asthma Control

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	398
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Composite measure of the percentage of pediatric and adult patients whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools and not at risk for exacerbation.
Substantive Change:	**Updated numerator and component options: For Submission Criteria 1: Component 1: Removed:** Asthma control Questionnaire (ACQ) **Added:** Asthma Impairment and Risk Questionnaire (AIRQ) and Pediatric Asthma Impairment and Risk Questionnaire (Peds-AIRQ) **Updated numerator note: For Submission Criteria 1: Component 2: Revised:** to base exacerbation on one of two methods. **Added:** Method 2: Asthma Impairment and Risk Questionnaire (AIRQ) result of 0 or 1 – ages 12 and older Pediatric Asthma Impairment and Risk Questionnaire (Peds-AIRQ) result of 0 or 1 – ages 5 – 11 **Updated component options: For Submission Criteria 1: Component 2: Added:** **Performance Met:** Not at elevated risk of exacerbation based on AIRQ or Peds-AIRQ score and results documented **Performance Not Met:** At elevated risk of exacerbation based on AIRQ or Peds-AIRQ score and results documented OR specified asthma control tool not used, reason not given **Updated numerator and component options: For Submission Criteria 2: Component 1: Removed:** Asthma control Questionnaire (ACQ) **Added:** Asthma Impairment and Risk Questionnaire (AIRQ) **Updated numerator note: For Submission Criteria 2: Component 2: Revised:** to base exacerbation on one of two methods. **Added:** Method 2: Asthma Impairment and Risk Questionnaire (AIRQ) result of 0 or 1 – ages 12 and older **Updated component options: For Submission Criteria 2: Component 2: Added:** **Performance Met:** Not at elevated risk of exacerbation based on AIRQ score and results documented **Performance Not Met:** At elevated risk of exacerbation based on AIRQ score and results documented OR specified asthma control tool not used, reason not given
Measure Steward:	Minnesota Community Measurement
MIPS Core Measure:	Yes
Measure Type:	Outcome
Rationale:	We are proposing to remove ACQ tools from the list of acceptable patient-reported outcome tools for all submission criteria. We are proposing to add the AIRQ (both submission criteria) and Peds-AIRQ (Submission Criteria 1 only) tools for COMPONENT 1: Asthma well-controlled. Additionally, we are proposing to add the AIRQ (both submission criteria) and Peds-AIRQ (Submission Criteria 1 only) tools as a second method for determining exacerbation risk for COMPONENT 2: Patient not at elevated risk of exacerbation. These changes would ensure that the tools used are better suited to current evidence-based practices for asthma management.[480] The AIRQ and Peds-AIRQ tools support the shift toward standardization, accuracy, and relevance in clinical decision-making.[481]

[480] Murphy, K. R., Chipps, B., Lanz, M. J., Bacharier, L. B., Guilbert, T. W., George, M., Mohammad, A., Winders, T., LeNoir, M., Gilbert, I. A., Eudicone, J. M., Coyne, K. S., Harding, G., & Zeiger, R. S. (2025). Pediatric Asthma Impairment and Risk Questionnaire: A Control Assessment for Children Aged 5 to 11 years. *The Journal of Allergy and Clinical Immunology: In Practice, 13*(10), 2659–2671. https://doi.org/10.1016/j.jaip.2025.06.039.

[481] AstraZeneca. Pediatric Asthma Impairment and Risk Questionnaire. https://www.asthmaresourcecenter.com/home/peds_airq_studies.html.

D.26 Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	438
CMS eCQM ID:	CMS347v10
Current Collection Type:	eCQM / MIPS CQM
Current Measure Description:	Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • All patients who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent.
Substantive Change:	**The measure description is revised to read: For all collection types:** Percentage of the following patients - all considered at high risk of cardiovascular events - who were prescribed or were on statin therapy during the performance period: • Patients ≥18 years of age who were previously diagnosed with or currently have a diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD), including an ASCVD procedure; OR • Patients aged 20 to 75 years who have ever had a low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL or were previously diagnosed with or currently have an active diagnosis of familial hypercholesterolemia; OR • Patients aged 40 to 75 years with a diagnosis of diabetes; OR • Patients aged 40 to 75 with a 10-year ASCVD risk score of ≥ 20 percent. **Updated rate aggregation: For eCQM collection type: Revised: For Population 1:** Patients greater than or equal to 18 years of age at the beginning of the measurement period were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure before the end of the measurement period. **Updated measure strata and performance rates: For MIPS CQM collection type: Revised: For Submission Criteria 1**: Patients ≥ 18 years of age at the beginning of the performance period and reporting timeframe for diagnosis of clinical ASCVD, including ASCVD procedure. **Updated guidance: For the eCQM collection type: Revised:** age for initial patient population 1 to greater than or equal to 18 years. **Updated initial patient population: For the eCQM collection type: Revised: For population 1:** age greater than or equal to 18 years. **The measure denominator is revised to read: For the MIPS CQM collection type: For Submission Criteria 1:** Patients ≥18 years of age who were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure. **Updated denominator criteria: For the MIPS CQM collection type:** **Revised: For Submission Criteria 1:** age ≥ 18 years at the beginning of the performance period and reporting timeframe for diagnosis of clinical ASCVD, including ASCVD procedure. **Removed**: **For Submission Criteria 3:** presymptomatic diabetes codes. **Updated denominator exclusion: For all collection types: Added: For all Submission Criteria:** Patients who are pregnant at any time during the performance period.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise Patient Population 1 / Submission Criteria 1 for the eCQM and MIPS CQM collection types, to include patients 18 years of age and older who were previously diagnosed with or currently have a diagnosis of clinical ASCVD, including an ASCVD procedure before the end of the performance period to align with the intent of the measure and current guidelines for adults.[482] [483] In addition, we are proposing to

[482] de Ferranti, S. D., Steinberger, J., Ameduri, R., Baker, A., Gooding, H., Kelly, A. S., Mietus-Snyder, M., et al. (2019). Cardiovascular Risk Reduction in High-Risk Pediatric Patients: A Scientific Statement From the American Heart Association. *Circulation, 139*(13). https://doi.org/10.1161/CIR.0000000000000618.

[483] Blumenthal, R., Morris, P., Gaudino, M., et al. (2026). 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on

Category	Description
	update the rate aggregation and guidance for the eCQM collection type to align with the updated Patient Population 1. For the MIPS CQM collection type, we are updating the denominator criteria for Submission Criteria 1 with the updated age criteria. These updates aim to refine the population targeted by the measure and enhance alignment with clinical guidelines.[484] Additionally, we are proposing to remove patients with presymptomatic diabetes from the denominator of Patient Population 3 / Submission Criteria 3 to focus on patients with established clinical diagnoses rather than those at risk or presymptomatic. Evidence suggests that use of statins may increase the risk of progression of prediabetes to type 2 diabetes.[485] Excluding these patients from Submission Criteria 3 would allow clinicians to use their clinical judgement and appropriately prescribe statin therapy to those patients who would benefit most without affecting their performance on the measure. We are also proposing to add patients who are pregnant to the denominator exclusions, for all collection types, to align with current recommendations. It is recommended that patients stop statin therapy as soon as pregnancy is discovered.[486] Excluding pregnant patients would allow clinicians to align with evidence-based practices, ensuring safe and appropriate care for this patient population, without affecting their performance on the measure. We are proposing to revise the measure description for all collection types, to improve the clarity, clinical utility, and applicability of the measure by explicitly defining high-risk patient populations. These enhancements aim to ensure more accurate identification of eligible patients, assess appropriate use of statin therapy, and ultimately drive improvements in cardiovascular health outcomes.

Clinical Practice Guidelines. *Journal of the American College of Cardiology*, 0(0). https://doi.org/10.1016/j.jacc.2025.11.016.

[484] See footnote Blumenthal et al., 2026.

[485] See footnote Blumenthal et al., 2026.

[486] See footnote Blumenthal et al., 2026.

D.27 Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	440
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 7 days from the time when the tissue specimen was received by the pathologist.
Substantive Change:	**The measure description is revised to read:** Percentage of biopsies with a diagnosis of cutaneous basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), or melanoma (including in situ disease) in which the pathologist communicates results to the clinician within 5 business days from the time when the tissue specimen was received by the pathologist. **The measure numerator is revised to read:** Number of final pathology reports diagnosing cutaneous basal cell carcinoma or squamous cell carcinoma or melanoma (to include in situ disease) sent from the Pathologist/Dermatopathologist to the biopsying clinician for review within 5 business days from the time when the tissue specimen was received by the pathologist. **Updated the numerator option**: **Revised:** to within 5 business days.
Measure Steward:	American Academy of Dermatology
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to revise multiple components of this measure to clarify the timing of when a pathologist must communicate the results to the biopsying clinician. Reporting the results within 5 business days would enable clinicians to make timely decisions regarding patient management, scheduling surgeries or therapies, and planning follow-up consultations.

D.28 Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	441
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	The IVD All-or-None Measure is one outcome measure (optimal control). The measure contains four goals. All four goals within a measure must be reached in order to meet that measure. The numerator for the all-or-none measure should be collected from the organization's total IVD denominator. All-or-None Outcome Measure (Optimal Control) - Using the IVD denominator optimal results include: • Most recent blood pressure (BP) measurement is less than or equal to 130/80 mm Hg -- AND • Most recent tobacco status is Tobacco Free -- AND • Daily Aspirin or Other Antiplatelet Unless Contraindicated – AND • High Intensity Statin Use Unless Contraindicated
Substantive Change:	**Updated the measure strata and performance rates: Revised:** a patient will only be included in Submission Criteria 2 of the measure if they meet the denominator criteria for both Submission Criteria 1 and Submission Criteria 2.
Measure Steward:	Wisconsin Collaborative for Healthcare Quality
MIPS Core Measure:	Yes
Measure Type:	Intermediate Outcome
Rationale:	We are proposing to revise the measure strata and performance rates to clarify how to handle scenarios in which the patient meets denominator criteria for both Submission Criteria 1 and Submission Criteria 2. This change would ensure consistency in the abstraction of the measure's elements that support rigorous data for the calculation of MIPS performance rates.

D.29 Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)

Category	Description
CBE # / eCQM CBE #:	0210 / N/A
Quality#:	453
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who died from cancer receiving systemic cancer-directed therapy in the last 14 days of life.
Substantive Change:	**The measure title is revised from 'Percentage of Patients who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better)' to:** Percentage of Patients who Died with Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better) **The measure description is revised to read:** Percentage of patients, aged 18 years and older, who died with cancer receiving systemic cancer-directed therapy in the last 14 days of life. **Updated intent and clinician applicability: Revised:** patients aged 18 years and older. **Updated Implementation Considerations: Revised:** Measure type revised to Intermediate Outcome. **Updated denominator note: Revised:** The patient must have two encounters during the performance period and both eligible encounters must include a diagnosis of cancer. **The measure denominator is revised to read:** Patients, aged 18 years and older, who died with cancer. **Updated denominator criteria:** **Revised:** Patients aged ≥ 18 years and Diagnosis for cancer during the encounter. **Added:** Patients who died during performance period. **Removed:** Patients who died from cancer. **Updated denominator exclusion: Added:** Patients given hydroxyurea or bruton tyrosine kinase (BTK) inhibitors. **Updated numerator definition: Revised:** **Systemic Cancer-directed Therapy** – Includes: ▪ Cytotoxic chemotherapy ▪ Drugs and biologics which activate or inhibit the hallmarks of cancer (e.g., kinase inhibitors) ▪ Antineoplastic Agents • Alkylating agents (id: L01A) • Antimetabolites (id: L01B) • Cytotoxic antibiotics and related substances (id: L01D) • Monoclonal antibodies and antibody drug conjugates (id: L01F) • Other antineoplastic agents (id: L01X) • Plant alkaloids and other natural products (id: L01C) • Protein kinase inhibitors (id: L01E) o Exclude: Cyclin-dependent kinase (CDK) inhibitors (id: L01EF) ▪ Immunostimulants (Includes only those that apply to cancer) • Interferons (id: L03AB) o Include only: interferon alfa-2b, ropeginterferon alfa-2b, and ropeginterferon alfa-2b-njft • Interleukins (id: L03AC) o Include only: aldesleukin • Other immunostimulants (id: L03AX) o Include only: sipuleucel-T ▪ Immunosuppressants (Includes only those that apply to cancer) • Selective immunosuppressants (id: L04AA) o Include only: alemtuzumab, everolimus, and sirolimus • Other immunosuppressants (id: L04AX) o Include only: lenalidomide, pomalidomide, and thalidomide Excludes: • Hormones and hormone antagonists • Red Blood Cell (RBC) growth factors used to treat chemotherapy-induced anemia • White Blood Cell (WBC) growth factors used to treat chemotherapy-induced neutropenia • Bisphosphonates and biologics used to treat osteopenia or osteoporosis • Antiemetics and antinauseants • Pain medications Example: Drugs and biologics under the World Health Organization's (WHO) Anatomical Therapeutic Chemical (ATC) classification "Antineoplastic Agents" and select "Immunostimulants" and "Immunosuppressants".

Category	Description
	"Antineoplastic and Immunomodulating Agents" Drug Classes and Identifiers: Note: To find the drug members under each class, go to https://mor.nlm.nih.gov/RxClass/ and enter the class name or ID on the "Search" field of the RxClass browser. **Updated numerator instructions: Added:** • Receipt of systemic cancer-directed therapy in the last 14 days of life can be calculated as follows: • (Date of death minus Most Recent Systemic cancer-directed therapy Administration Date or Date Filled) < 14 days. **Updated numerator note: Added:** The measure includes intramuscular, intravenous, oral, and subcutaneous routes of administration of systemic cancer-directed therapy. Oral systemic cancer-directed therapy is oral prescription of extension of same oral drug or prescription of new oral drug. The measure is limited to medications approved by the United States Food and Drug Administration (FDA). Patients that are given bridging chemotherapy and other cancer-directed therapies while awaiting transplant or chimeric antigen receptor T-cell therapy (CAR T-cell therapy) should be reported as a denominator exception. For patients given Hydroxyurea and bruton tyrosine kinase (BTK) inhibitors, it may be inappropriate to withdraw at the end of life and/or are used for palliative purposes. For the purposes of reporting this inverse quality measure, this scenario is considered "performance not met" only in the absence of other systemic therapies. **Updated denominator exception: Added:** Patient received systemic cancer-directed therapy due to 1) receipt or in process of receipt of bone marrow or peripheral blood stem cell transplant (transplant status) in the last 60 days of life, or 2) receipt or in process of receipt of CAR T-cell therapy in the last 60 days of life. **Updated numerator options: Added:** **Performance Not Met:** Patients given hydroxyurea or BTK inhibitors.
Measure Steward:	American Society of Clinical Oncology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update multiple components of this measure to ensure the appropriate patient population is identified by including an age, defined encounter eligibility, and additional guidance for defining the eligible patient population. We are proposing to revise the measure type to intermediate outcome to be reflective of the quality action. Additionally, we propose to add a denominator exclusion for common drugs given for palliation or to prevent rapid disease acceleration at the end of life as recommended by ASCO's End of Life Technical Expert Panel as this conflicts with the measure's intent. We are proposing to add further clarification and granularity to the numerator definition of systemic cancer-directed therapy to ensure numerator assessment is consistent across clinician submissions. Additionally, we are proposing to add a denominator exception to remove patients receiving bone marrow or peripheral blood stem cell transplant, or CAR T-cell therapy as these patients are appropriately given bridging chemotherapy and other types of cancer-directed therapy beforehand. We are proposing these changes to better align with the intent of the measure and to ensure consistent implementation across submissions. In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for the creation of a performance period benchmark, a new benchmark would be used for scoring.

D.30 Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better)

Category	Description
CBE # / eCQM CBE #:	0216 / N/A
Quality#:	457
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who died from cancer, and admitted to hospice and spent less than 3 days there.
Substantive Change:	**The measure title is revised from Percentage of Patients who Died from Cancer Admitted to Hospice for Less than 3 Days (lower score – better) to:** Percentage of Patients who Died with Cancer Enrolled in Hospice for At Least 3 Days Immediately Before Death. **The measure description is revised to read:** Percentage of patients, aged 18 years and older, who died with cancer and were enrolled in hospice for at least 3 days immediately before and on date of death. **Updated Implementation Considerations: Revised:** Measure analytic to no longer be inverse and measure type to Intermediate Outcome. **The measure denominator is revised to read:** Patients, aged 18 years and older, who died with cancer. **Updated denominator note: Revised:** The patient must have two encounters during the performance period and both eligible encounters must include a diagnosis of cancer. **Updated denominator criteria:** **Revised:** Patients aged ≥ 18 years and Diagnosis for cancer during the encounter. **Removed:** Patients enrolled in hospice and Patients who died from cancer. **Added:** Patients who died during performance period. **The measure numerator is revised to read:** Patients enrolled in hospice for at least 3 days immediately before and on the date of death. **Updated numerator instructions: Removed:** Inverse measure analytic **Added:** • Patients should be currently enrolled in hospice on date of death to meet the numerator. • Enrolled in hospice for at least 3 days immediately before death can be calculated as follows: • (Date of death minus Most Recent Date of Hospice Admission) ≥ 3 days **Updated numerator note: Added:** • Receipt of or in the process of receipt of bone marrow transplant, peripheral blood stem cell transplant, or CAR T-cell therapy are typically not covered in hospice but may be appropriate for select patients at the end of life. In these scenarios, the denominator exception should be reported. • It may be inappropriate to withdraw Hydroxyurea and bruton tyrosine kinase (BTK) inhibitors at the end of life and/or are used for palliative purposes, however these treatments are not covered by hospice. In this situation, the denominator exception should be reported. **The measure numerator options are revised to read**: **Performance Met:** Patient enrolled in hospice for at least 3 days immediately before and on the date of death. **Denominator Exception:** Patient not enrolled in hospice due to 1) receipt or in process of receipt of bone marrow or peripheral blood stem cell transplant (transplant status) in the last 60 days of life, or 2) receipt or in process of receipt of CAR T-cell therapy in the last 60 days of life. **Denominator Exception:** Patients given hydroxyurea or BTK inhibitors. **Performance Not Met:** Patient enrolled in hospice less than 3 days immediately before death or on date of death.
Measure Steward:	American Society of Clinical Oncology
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to revise the measure type to intermediate outcome and to allow for a proportional non-inverse analytic for the purpose of determining measure performance. We are proposing these changes to better align with the intent of the measure and to provide a performance rate reflective of appropriate resource utilization. We are proposing to update multiple components of this measure to ensure the appropriate patient population is identified by including an age, defined encounter eligibility, and additional guidance for defining the eligible patient population. We are also proposing to update the numerator options to align with a proportional non-inverse measure analytic such that a higher score indicates better quality care; and add denominator exceptions to remove patients 1) receiving bone marrow or peripheral blood stem cell transplant, or CAR T-cell therapy or 2) receiving drugs for palliation or to prevent rapid disease acceleration at the end of life as recommended by ASCO's End Of Life Technical Expert Panel. We are proposing these changes to better align with the intent of the measure and to ensure consistent implementation across clinician submissions.

Category	Description
	In the event the proposed substantive change(s) are finalized, the substantive changes would not allow for a direct comparison of performance data from prior years to performance data submitted after the implementation of these substantive changes. As such, if the performance data submitted meets the criteria for the creation of a performance period benchmark, a new benchmark would be used for scoring.

D.31 Otitis Media with Effusion: Systemic Antimicrobials - Avoidance of Inappropriate Use

Category	Description
CBE # / eCQM CBE #:	0657 / N/A
Quality#:	464
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients aged 2 months through 12 years with a diagnosis of OME who were not prescribed systemic antimicrobials.
Substantive Change:	**The measure description is revised to read**: Percentage of patients aged 2 months through 12 years with a diagnosis of otitis media with effusion (OME) who were not prescribed systemic antimicrobials within 3 months of diagnosis. **Updated implementation and considerations: Revised:** 90 days to 3 months. **The measure numerator is revised to read:** Patients who were not prescribed systemic antimicrobials within 3 months of diagnosis. **Updated numerator options**: **Revised:** to include timeframe of within 3 months of diagnosis.
Measure Steward:	American Academy of Otolaryngology – Head and Neck Surgery Foundation
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update multiple components of the measure by adding "within 3 months of diagnosis" to clarify the timeframe during which systemic antimicrobials were not prescribed to patients. This clarification, based on AAO-HNS's Clinical Practice Guideline on Otitis Media with Effusion (Update),[487] would ensure the numerator quality action is appropriately and consistently assessed.

[487] Rosenfeld, R. M., Shin, J. J., Schwartz, S. R., Coggins, R., Gagnon, L., Hackell, J. M., Hoelting, D., Hunter, L. L., Kummer, A. W., Payne, S. C., Poe, D. S., Veling, M., Vila, P. M., Walsh, S. A., & Corrigan, M. D. (2016). Clinical Practice Guideline: Otitis Media with Effusion (Update). *Otolaryngology--Head and Neck Surgery: Official Journal of American Academy of Otolaryngology-Head and Neck Surgery*, *154*(1 Suppl), S1–S41. https://doi.org/10.1177/0194599815623467.

D.32 HIV Screening

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	475
CMS eCQM ID:	CMS349v9
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients aged 15-65 at the start of the measurement period who were between 15-65 years old when tested for Human immunodeficiency virus (HIV).
Substantive Change:	**Updated initial patient population: Removed:** without an HIV diagnosis prior to the start of the measurement period.
Measure Steward:	Centers for Disease Control and Prevention
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise the initial patient population language to better align with the logic of the measure as this patient population is removed by the denominator exclusion: Patients diagnosed with HIV prior to the day of the start of the measurement period.

D.33 Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	476
CMS eCQM ID:	CMS771v8
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients with an office visit within the measurement period and with a new diagnosis of clinically significant Benign Prostatic Hyperplasia who have International Prostate Symptoms Score (IPSS) or American Urological Association (AUA) Symptom Index (SI) documented at time of diagnosis and again 6-12 months later with an improvement of 3 points.
Substantive Change:	**The measure description is revised to read:** Percentage of patients with an office visit during the measurement period and a new diagnosis of clinically significant benign prostatic hyperplasia (BPH) who have International Prostate Symptom Score (IPSS) or American Urological Association Symptom Index (AUA-SI) documented within one month of diagnosis and again 6-12 months after diagnosis, with an improvement of at least 3 points. **The measure numerator is revised to read:** Patients with an improvement of at least 3 points in their IPSS or AUA-SI urinary symptom score from baseline to the 6-12 month follow-up assessment.
Measure Steward:	Large Urology Group Practice Association and Oregon Urology Institute
MIPS Core Measure:	No
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We are proposing to revise both the description of the measure and the numerator to include specific timeframes for completion of the assessments. By explicitly detailing timeframes (baseline within one month of diagnosis and follow-up assessment within 6–12 months) and the outcome metric (3-point improvement), the measure reduces ambiguity in performance measurement and ensures consistency in reporting.

D.34 Hospital-wide, 30-day, All-cause Unplanned Readmission (HWR) Rate for the Merit-based Incentive Payment System (MIPS) Groups

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	479
CMS eCQM ID:	N/A
Current Collection Type:	Administrative Claims
Current Measure Description:	This measure is a re-specified version of the measure, "Risk-adjusted readmission rate (RARR) of unplanned readmission within 30 days of hospital discharge for any condition" (NQF 1789), which was developed for patients 65 years and older using Medicare claims. This re-specified measure attributes outcomes to MIPS participating clinician groups and assesses each group's readmission rate. The measure comprises a single summary score, derived from the results of five models, one for each of the following specialty cohorts (groups of discharge condition categories or procedure categories): medicine, surgery/gynecology, cardio-respiratory, cardiovascular, and neurology.
Substantive Change:	**Updated denominator exclusion: Removed:** With a principal or a secondary diagnosis code of COVID-19 coded as present on admission (POA) on the index admission claim.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Outcome
Rationale:	We are proposing to remove the exclusion for admissions with either a principal or secondary diagnosis of COVID–19 present on admission from the measure denominator due to the end of the public health emergency. This proposed change would align this measure with language finalized under the Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization final rule (90 FR 36948 through 36950).

D.35 Intravesical Bacillus-Calmette-Guerin for Non-Muscle Invasive Bladder Cancer

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	481
CMS eCQM ID:	CMS646v7
Current Collection Type:	eCQM
Current Measure Description:	Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of bladder cancer staging.
Substantive Change:	**Measure description is revised to read:** Percentage of patients initially diagnosed with non-muscle invasive bladder cancer and who received intravesical Bacillus-Calmette-Guerin (BCG) within 6 months of initial diagnosis of bladder cancer. **Updated denominator exclusion: Revised:** timing is centered around diagnosis. **Updated numerator: Revised:** timing is centered around diagnosis. **Updated denominator exception: Revised:** timing is centered around diagnosis. **Updated logic and logic definitions: Revised:** timing is centered around diagnosis.
Measure Steward:	Oregon Urology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update multiple components of the measure to clarify that the timing for receipt of intravesical BCG is based on the initial diagnosis of bladder cancer and not staging. The revision to base the timing of intravesical BCG administration on the initial diagnosis of bladder cancer enhances clinical clarity, promotes consistency in care measurement and measure reporting, and encourages more timely treatment, all of which contributes to improved patient care.

D.36 Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status

Category	Description
CBE # / eCQM CBE #:	3661 / N/A
Quality#:	491
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of surgical pathology reports for primary colorectal, endometrial, gastroesophageal or small bowel carcinoma, biopsy or resection, that contain impression or conclusion of or recommendation for testing of mismatch repair (MMR) by immunohistochemistry (biomarkers MLH1, MSH2, MSH6, and PMS2), or microsatellite instability (MSI) by DNA-based testing status, or both.
Substantive Change:	**Updated denominator criteria: Added:** coding to diagnosis criteria for genetic susceptibility.
Measure Steward:	College of American Pathologists
MIPS Core Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to add additional codes to the denominator criteria for genetic susceptibility as it would ensure better targeting of high-risk populations, optimize resources, and contribute to improved patient outcomes and data reliability for cancer care.[488]

[488] Robson, M. E., Storm, C. D., Weitzel, J., Wollins, D. S., & Offit, K. (2015). American Society of Clinical Oncology Policy Statement Update: Genetic and Genomic Testing for Cancer Susceptibility. *Journal of Clinical Oncology, 33*, 3660–3667. https://doi.org/10.1200/JCO.2015.63.0996.

D.37 Preventive Care and Wellness (composite)

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	497
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who received age- and sex-appropriate preventive screenings and wellness services. This measure is a composite of seven component measures that are based on recommendations for preventive care by the U.S. Preventive Services Task Force (USPSTF), Advisory Committee on Immunization Practices (ACIP), American Association of Clinical Endocrinology (AACE), and American College of Endocrinology (ACE).
Substantive Change:	**Updated numerator definition: For Submission Criteria 3: Added: Reviewed –** to meet the quality action, there must be documentation in the medical record that the clinician reviewed the mammography report. The mammography report may also be provided by the patient for the clinician's review during the visit and should be documented in the medical record. **Updated numerator definition: For Submission Criteria 4: Added: Reviewed** – to meet the quality action, there must be documentation in the medical record that the clinician reviewed the colorectal screening report. The colorectal screening report may also be provided by the patient for the clinician's review during the visit and should be documented in the medical record. **Updated denominator criteria: For Submission Criteria 7: Added:** coding for physical and occupational therapy.
Measure Steward:	Centers for Medicare & Medicaid Services
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise the measure numerator definition for Submission Criteria 3 and 4, the medical record must document the clinician's review of the mammography or colorectal screening report, whether obtained directly or provided by the patient, during the visit. By specifying that the review should be documented in the medical record, the measure ensures clinicians are confirming review of mammography and colorectal screening results, not just receipt, and the measure encourages standardization in documentation practices across different clinical settings, which promotes care coordination and appropriate patient follow-up if needed. We are also proposing to update the denominator criteria for Submission Criteria 7 with physical and occupational therapy codes to align with the eCQM measure specifications. By adding PT/OT coding in this measure, healthcare organizations can help ensure a more inclusive, proactive, and effective approach to managing cardiovascular health, while also capitalizing on all patient touchpoints to achieve comprehensive wellness and improve health outcomes.

D.38 Reduction in Suicidal Ideation or Behavior Symptoms

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	505
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	The percentage of patients aged 18 and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale (C-SSRS) 'Screen Version' or 'Since Last Visit' within 120 days after an index assessment.
Substantive Change:	**The measure description is revised to read**: The percentage of patients aged 12 years and older with a mental and/or substance use disorder AND suicidal thoughts, behaviors or risk symptoms who demonstrated a reduction in suicidal ideation and/or behavior symptoms based on results from the Columbia-Suicide Severity Rating Scale 'Screen Version' or 'Since Last Visit' (C-SSRS), or other clinician rating tools such as the Clinician Rating of Potential Suicide Risk (CRPSR) or the Suicide Assessment Five-step Evaluation & Triage (SAFE-T) protocol with C-SSRS, within 120 days after an index assessment. **The measure denominator is revised to read**: Patients aged 12 and older with a mental and/or substance use disorder with an index assessment completed who were identified as having suicidal ideation and/or behavior symptoms as determined by a non-zero score on the patient-rated C-SSRS OR deemed a suicide risk based on their clinician's evaluation using a clinician rating tool such as the CRPSR or the SAFE-T protocol with C-SSRS during the denominator identification period. **Updated denominator definitions: Revised:** **Suicide risk based on clinician rating tool** – clarified suicide risk to be based on a clinician-rating tool, which may be C-SSRS or other. **Denominator Identification Period** and **Index Assessment** – updated to reflect use of other clinician-rating tools. **Updated the denominator criteria: Revised:** age to 12 **Removed:** 'Suicidal Ideation and/or Behavior Symptoms based on the C-SSRS' and 'Suicide risk based on their clinician's evaluation or a clinician-rated tool' **Revised:** index assessment criteria to reflect use of other clinician-rating tools. **The measure numerator is revised to read**: Patients who demonstrated a reduction in suicidal ideation and/or behavior symptoms as demonstrated by results of a follow-up assessment using the patient-rated C-SSRS OR reduction in suicide risk based on their clinician's evaluation using a clinician rating tool such as the CRPSR or the SAFE-T protocol with C-SSRS, within 120 days after the index assessment during the measurement period. **Updated numerator definitions: Revised:** **Reduction** – to account for use of other clinician-rating tools. **Follow-up Assessment** – to account for use of other clinician-rating tools and require consistency in index and follow-up assessment.
Measure Steward:	American Psychiatric Association
MIPS Core Measure:	No
Measure Type:	Patient-Reported Outcome-Based Performance Measure
Rationale:	We are proposing to update multiple components of the measure to lower the denominator eligible age to 12 years and older and expand the denominator requirements to allow use of other clinician-rating tools for the index assessment and follow-up, to ensure inclusion of a critical demographic group in suicide prevention and substance use disorder interventions. This measure enhances alignment with CMS' mental health priorities, leverages validated tools like the C-SSRS and promotes actionable insights into improved care outcomes for a vulnerable population. We are also proposing to update the numerator definition to clarify that the same patient-rated C-SSRS or clinician rating tool must be used at a follow-up encounter after the index assessment. This would ensure consistent implementation and ensure direct comparability of data between assessments.

D.39 Appropriate Germline Testing for Ovarian Cancer Patients

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	507
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients, aged 18 and older, diagnosed with epithelial ovarian, fallopian tube, or primary peritoneal cancer who undergo germline testing within 6 months of diagnosis.
Substantive Change:	**Updated denominator criteria**: **Removed:** Audio only Telehealth codes.
Measure Steward:	American Society of Clinical Oncology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to remove audio only visits from the denominator criteria because they lack the visual assessment necessary to confirm a patient's physical condition (e.g., performance status; physical signs of toxicity, pain, and distress) and the physical assessment required by the clinician providing the care and responsible for conducting germline testing.

D.40 Melanoma: Tracking and Evaluation of Recurrence

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	509
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients who had an excisional surgery for melanoma or melanoma in situ with initial American Joint Committee on Cancer (AJCC) staging of 0, I, or II, in the past 5 years in which the operating provider examines and/or diagnoses the patient for recurrence of melanoma.
Substantive Change:	**The measure description is revised to read**: Percentage of patients who had an excisional surgery for melanoma or melanoma in situ with initial American Joint Committee on Cancer (AJCC) staging of 0, I, or II, in the past 5 years for whom the clinician or practice responsible for longitudinal care documents examination and/or diagnosis for recurrence of melanoma during the performance period. **Updated intent and clinician applicability: Revised:** The examination for recurrence may be performed by any qualified clinician, provided that the clinician or practice reporting the measure documents that the examination occurred in the medical record. **Updated denominator note**: **Added**: The excisional surgery may have been performed by any clinician or practice, provided documentation of the qualifying procedure and staging is present in the medical record of the clinician or practice reporting the measure.
Measure Steward:	American Academy of Dermatology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise this measure to address instances where one clinician may perform the excision and another performs the subsequent skin examinations. This measure revision would ensure inclusiveness, continuity, and accuracy in reporting excisional surgery outcomes by allowing documentation from any qualified clinician or practice, as is common in clinical practice.

D.41 Patient Reported Falls and Plan of Care

Category	Description
CBE # / eCQM CBE #:	N/A / N/A
Quality#:	513
CMS eCQM ID:	N/A
Current Collection Type:	MIPS CQM
Current Measure Description:	Percentage of patients (or caregivers as appropriate) with an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke who reported a fall occurred and those that fell had a plan of care for falls documented at every visit.
Substantive Change:	**Updated denominator criteria: Removed: For all Submission Criteria:** diagnosis coding not specific to an active diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke. **Updated definitions: For all Submission Criteria: Added:** **Last Visit –** if the patient is established, this would be since the last visit with the same clinician/group. If the patient is new, it would be since the patient's last visit with any clinician. **Updated denominator**: **For Submission Criteria 2: Added**: Patient reported a fall since last visit OR Accidental Fall **Updated numerator note: For Submission Criteria 1: Added:** Denominator Exception medical reason(s) should be documented at the time of the denominator eligible encounter. **Updated numerator options: For Submission Criteria 2: Revised:** **Performance Met:** Patients that reported a fall occurred who had a plan of care for falls documented **Performance Not Met:** Patients that had a fall who did not have a plan of care for falls documented **Removed:** Denominator Exception
Measure Steward:	American Academy of Neurology
MIPS Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to revise multiple components of this measure to ensure alignment with intent and clinical workflow. We are proposing to remove coding that is broad in nature and not specific to the diagnosis of a movement disorder, multiple sclerosis, a neuromuscular disorder, dementia, or stroke. Removal will ensure the denominator does not include patients beyond those in neurology with symptomology who would not be appropriate for assessment of the quality action. While patient safety in context of falls is important in all patients, the quality action for this measure is specific for the patient population intended and may not be appropriate for any falls patient. For clarity we are proposing to add a definition for 'Last Visit' so that all clinicians reporting are following the same timeline, ensuring consistent implementation across clinician submissions. Additionally, we are proposing to add to the Submission Criteria 1 numerator note to clarify that the medical reason should be documented as active or present on the day of the denominator eligible encounter. This will ensure that regardless of condition, whether it be chronic or acute, active or historical, it will be attributable to that interaction. Finally, we are proposing to revise Submission Criteria 2 to focus on those patients who reported a fall since their last visit as this is the at-risk patient population requiring the quality action; plan of care for falls. This revision aligns with measure intent as well as the structure of other screening measures in MIPS for better consistency.

Table Group DD: Proposed Substantive Changes to Previously Finalized MIPS Quality Measures Available Only for Use in Relevant MVPs for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

As finalized for the CY 2024 performance period/2026 MIPS payment year and future years, the following three MIPS quality measures were retained for utilization in MVPs only while removed from traditional MIPS: Q112: Breast Cancer Screening, Q113: Colorectal Cancer Screening, and Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (88 FR 79897 through 79902). We note that measures Q112: Breast Cancer Screening and Q113: Colorectal Cancer Screening available only in MVPs are adopted by the Medicare Shared Savings Program for utilization in the Alternative Payment Model (APM) Performance Pathway (APP), specifically for inclusion in the APP Plus measure set, as finalized in the CY 2025 PFS final rule (89 FR 98363 through 98371). For such measures, the collection types solely applicable for purposes of the APP Plus measure set (Medicare Clinical Quality Measures for Accountable Care Organizations (ACOs) Participating in the Medicare Shared Savings Program (Medicare CQMs) collection type and newly proposed Medicare Electronic Clinical Quality Measures for ACOs Participating in the Medicare Shared Savings Program (Medicare eCQMs) collection type as described in section IV.A.4.d.(1)(c)(v) of this proposed rule) are also specified as a collection type available for such relevant measures described in Table Group DD of this Appendix.

Table Group DD within this proposed rule provides substantive changes proposed for the CY 2027 performance period/2029 MIPS payment year for MIPS quality measures available only in a relevant MVP. The changes that are made to the denominator codes sets are generalizations of the revisions communicated from the measure stewards to CMS. Additionally, International Classification of Diseases Tenth Edition (ICD-10) and Current Procedural Terminology (CPT) codes that are identified as invalid for CY 2025 may not be identified within this proposed rule due to the availability of these changes to the public. If coding revisions to the denominator are impacted due to the timing of 2027 CPT and ICD-10 updates and assessment of these codes' inclusion by the Measure Steward, these changes may be postponed until CY 2028. The 2026 Quality Measure Release Notes provide a comprehensive, detailed reference of exact codes changes to the denominators of the quality measures. The Quality Measure Release Notes are available for each of the collection types in the Quality Payment Program website at *https://qpp.cms.gov*.

Measures that are endorsed by a CBE are shown in Table DD of this Appendix as follows: CBE # / eCQM CBE #.

In addition to the proposed substantive changes, there may be changes to the coding utilized within the denominator that are not considered substantive in nature, but it is important to communicate to interested parties. These changes align with the scope of the current coding; however, though not substantive in nature, these changes would expand or contract the measure's current eligible patient population. Therefore, please refer to the current year measure specification and the 2027 Quality Measure Release Notes or the eCQM Technical Release Notes once posted to review all coding changes to ensure correct implementation.

The eCQM Technical Release Notes should also be carefully reviewed for revisions within the logic portion of the measure. In addition to the proposed substantive changes, there may be revisions within the logic that are not considered substantive in nature; however, it is important to review to ensure proper implementation of the measure. As not all systems and clinical workflows are the same, it is important to review these changes in the context of a specific system and/or clinical workflow.

There are no proposed substantive changes for measure Q128. We request comments on the substantive changes for the other measures outlined below.

DD.1 Breast Cancer Screening

Category	Description
CBE # / eCQM CBE #:	2372 / N/A
Quality#:	112
CMS eCQM ID:	CMS125v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of women 40-74 years of age who had a mammogram to screen for breast cancer in the 27 months prior to the end of the measurement period.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure, eCQM, Medicare CQM, MIPS CQM, Medicare eCQM collection types.
Measure Steward:	National Committee for Quality Assurance
Core Measure:	Yes
Measure Type:	Process
Rationale:	We are proposing to update the collection types available for this measure to include the Medicare eCQM collection type to allow choice in submission method for Medicare Shared Savings Program ACOs reporting the APP Plus measure set. See section IV.A.4.d.(1)(c)(v) of this proposed rule for further information on the Medicare eCQM collection type.

DD.2 Colorectal Cancer Screening

Category	Description
CBE # / eCQM CBE #:	0034 / N/A
Quality#:	113
CMS eCQM ID:	CMS130v15
Current Collection Type:	Medicare Part B Claims Measure / eCQM / Medicare CQM / MIPS CQM
Current Measure Description:	Percentage of patients 45-75 years of age who had appropriate screening for colorectal cancer.
Substantive Change:	**Modified collection type:** Medicare Part B Claims Measure, eCQM, Medicare CQM, MIPS CQM, Medicare eCQM collection types.
Measure Steward:	National Committee for Quality Assurance
Core Measure:	No
Measure Type:	Process
Rationale:	We are proposing to update the collection types available for this measure to include the Medicare eCQM collection type to allow choice in submission method for Medicare Shared Savings Program ACOs reporting the APP Plus measure set. See section IV.A.4.d.(1)(c)(v) of this proposed rule for further information on the Medicare eCQM collection type.

Appendix 2—Improvement Activities

In this proposed rule, for the CY 2027 performance period/2029 MIPS payment year and future years, we are proposing to add 6 new improvement activities, modify 5 previously finalized improvement activities, and remove 11 previously finalized improvement activities. These proposals are discussed in section IV.A.4.d.(3)(b) of this proposed rule and in more detail below. We request comment on our proposals.

TABLE F-B1: New Improvement Activities

New Improvement Activity	
Proposed Activity ID:	**IA_CC_XX**
Proposed Subcategory:	Care Coordination
Proposed Activity Title:	Use of Data to Improve Practice Workflows
Proposed Activity Description:	MIPS-eligible clinicians collaborate to design, implement, and continuously refine evidence based utilization pathways and clinical workflows that support the integration of current research and clinical guidelines into everyday practice. Eligible activities include the creation or maintenance of any algorithm, clinical pathway, process, or order set that is grounded in established clinical practice guidelines and/or peer reviewed literature. Actions that fulfill this activity may include: • Collecting and analyzing clinical data to identify the need for a new or revised pathway, order set, or process • Developing and deploying the updated pathway, order set, or process within clinical operations • Evaluating adoption, effectiveness, and clinical impact through ongoing monitoring and feedback. Additional qualifying activities may include, for example, conducting annual reviews of existing pathways or algorithms by a pathology group and/or in collaboration with ordering clinician, developing and disseminating educational materials, and identifying or engaging new stakeholders to support pathway improvement and implementation.
Rationale:	Promoting uptake of best clinical practices from guidelines and other resources is critical for improving quality of patient care. However, translating recommendation statements into action can be challenging for individual practices due to resource constraints. Clinical pathways and algorithms are effective ways to encourage implementation of guidelines.[489] Development of such pathways requires clinical expertise and time, although a 10-step process has been established by other organizations.[490] By including a multi-disciplinary team in pathway development, care coordination can be maximized and all stakeholders can ensure that the pathway is feasible to implement. Such guidance requires regular review as new clinical practice statements become available, especially if the pathway includes multiple specialties (e.g., oncology, radiology, pathology, pain management, etc.). Therefore, the effort involved in this activity is ongoing and requires input from many members of the care team.
New Improvement Activity	
Proposed Activity ID:	**IA_CC_XX**
Proposed Subcategory:	Care Coordination

[489] Fiordalisi, C., Borsky, A., Chang, S., & Guise, J.-M. (2019). AHRQ EPC Series on Improving Translation of Evidence into Practice for the Learning Health System: Introduction. Journal on Quality and Patient Safety, 45(8), 558-565. doi: 10.1016/j.jcjq.2019.05.006

[490] Flores, E. J., Jue, J. J., Giradi, G., Schoelles, K., Mull, N. K., & Umscheid, C. A. (2019). AHRQ EPC series on improving translation of evidence: use of a clinical pathway for C. Difficile treatment to facilitate the translation of research findings into practice. The Joint Commission Journal on Quality and Patient Safety, 45(12), 822-828. doi: 10.1016/j.jcjq.2019.10.002.

Proposed Activity Title:	Understand and Improve Diagnostic Performance
Proposed Activity Description:	This activity aims to improve patient safety by reducing diagnostic safety events, including delayed, inaccurate, or missed diagnoses, as well as failures to communicate correct diagnoses to patients and their families. This activity should support diagnostic transparency, build staff competency through training, and improve the completeness and accuracy of patient data. Understanding and improving diagnostic performance includes establishing a standardized process to monitor diagnostic discrepancies, diagnostic safety events, near misses, and miscommunications. Key components of this activity may include: • Identifying a metric to track (e.g., frozen section discrepancy rate) • Implementing a consistent tracking mechanism • Conducting ongoing monitoring • Initiating mitigation or education efforts when needed. Processes must incorporate both routine tracking and root cause analysis, followed by appropriate corrective actions such as workflow changes, education, and/or targeted training for individuals and/or groups.
Rationale:	Accurate and timely diagnosis is the cornerstone of effective patient care. Diagnostic performance directly influences treatment decisions, patient outcomes, and healthcare resource utilization. Recent studies have emphasized the importance of addressing diagnostic safety events in clinical settings.[491] A deeper understanding of diagnostic processes--including cognitive, systemic, and technological factors--enables healthcare providers to identify gaps, implement targeted interventions, and promote a culture of continuous learning and accountability. As healthcare becomes increasingly data-driven, integrating diagnostic improvement efforts with quality metrics, patient feedback, and interdisciplinary collaboration ensures that care is not only clinically sound but also patient-centered.
New Improvement Activity	
Proposed Activity ID:	**IA_AHW_XX**
Proposed Subcategory:	Advancing Health and Wellness
Proposed Activity Title:	Systematic Screening and Intervention for Nutrition and other Health-Impacting, Non-Clinical Issues
Proposed Activity Description:	This activity supports the implementation of standardized health-related, non-clinical issues screening tools and workflows to identify and address wellness-impacting factors such as poor nutrition, housing instability, transportation barriers, and financial strain. It may include: • Training staff on screening protocols • Embedding validated screening tools into the electronic health record (EHR) • Establishing referral pathways to community-based resources • Tracking follow-up and resolution of identified needs.
Rationale:	This activity addresses a gap for a nutrition-focused improvement activity. It aligns with CMS's focus on wellness and whole-person care, and supports Enhancing Oncology Model (EOM) and MVP efforts by integrating health-related, non-clinical issues into quality improvement strategies. This activity builds on existing patient navigation and care coordination activities but focuses specifically on upstream factors.
New Improvement Activity	
Proposed Activity ID:	**IA_AHW_XX**
Proposed Subcategory:	Advancing Health and Wellness
Proposed Activity Title:	Advance Care Planning Conversations to Support Patient Wellness and Care Preferences

[491] Auerbach, A. D., Lee, T. M., Hubbard, C. C., Ranji, S. R., Raffel, K., Valdes, G., ... & Schnipper, J. L. (2024). Diagnostic errors in hospitalized adults who died or were transferred to intensive care. JAMA Internal Medicine, 184(2), 164-173.

Proposed Activity Description:	MIPS-eligible clinicians engage patients and their caregivers in structured, proactive discussions about end-of-life preferences, advance care planning, and palliative care options as part of comprehensive wellness and care management. This activity integrates conversations about goals of care, symptom management, and quality of life into routine encounters with patients who have serious or life limiting illness.CMS reminds clinicians that they must not, under any circumstances, attempt to influence the ACP-related decisions of their patients. Participating clinicians must document: • Use of standardized communication tools or frameworks (e.g., Serious Illness Conversation Guide, Practitioner Orders for Life Sustaining Treatment (POLST)) to support consistent, high quality discussions; • Inclusion of wellness oriented topics, such as symptom relief, emotional wellbeing, social supports, and patient identified priorities; • Coordination and alignment of care plans across specialties, including primary care, palliative care, behavioral health, and other involved clinicians; and • Regular review and updates of advance directives or care preferences to ensure they remain accurate and reflective of the patient's evolving goals and clinical status.
Rationale:	End-of-life care planning discussions contribute to improved patient and caregiver well-being by reducing stress, enhancing understanding of care options, and ensuring treatment aligns with patient goals. Integrating these conversations into wellness and/or chronic care management visits supports a holistic approach to health, one that prioritizes quality of life, emotional and physical comfort, and patient autonomy. Evidence indicates that patients who engage in structured end-of-life care planning experience better symptom control, higher satisfaction, and reduced hospitalizations, aligning with MIPS goals of improved care coordination and patient-centered outcomes.
New Improvement Activity	
Proposed Activity ID:	**IA_AHW_XX**
Proposed Subcategory:	Advancing Health and Wellness
Proposed Activity Title:	Clinician Use of Artificial Intelligence (AI) to Improve Patient Care
Proposed Activity Description:	MIPS-eligible clinicians implement and participate in structured organizational initiatives that improve patient care through the responsible and transparent use of artificial intelligence (AI) in clinical and operational workflows. This activity supports the safe adoption of AI-enabled technologies while encouraging the development, evaluation, and refinement of AI resources designed to improve patient outcomes, care-team efficiency, and population health management. As part of this activity, participating clinicians and organizations must: • Establish and maintain organizational policies and procedures for AI use in healthcare settings that guide the evaluation, deployment, and monitoring of AI-enabled tools ○ These policies incorporate key AI model characteristics including fairness, appropriateness, validity, and effectiveness as foundational criteria for assessing model performance, identifying event patterns, and determining appropriate risk-mitigation and escalation actions and/or • Engage in or support innovative initiatives that encourage the creation, piloting, and/or enhancement of AI-enabled tools, workflows, and/or resources ○ Examples include developing risk-stratification models, AI-supported clinical decision support (CDS), predictive analytics for chronic-disease management, and/or tools that expand patient access, wellness interventions, and/or care-coordination capabilities. Additional examples include using AI tools to summarize medical literature for clinical decision making, support documentation (e.g., generate notes with AI for clinician review), and/or support population health management by identifying care gaps, determining patient eligibility for clinical trials, or generating draft responses to patient questions for clinician review.
Rationale:	The rapid expansion of artificial intelligence (AI) in healthcare presents significant opportunities to improve clinical outcomes, reduce clinician burden, and enhance population health management. However, realizing these benefits requires deliberate,

	responsible, and transparent implementation practices that ensure AI tools are safe, fair, reliable, and aligned with evidence-based care. This improvement activity encourages MIPS-eligible clinicians to adopt AI in a structured, governance-driven manner that promotes innovation while safeguarding patient well-being. Establishing organizational policies and procedures for AI use provides an essential foundation for ensuring that deployed tools are evaluated using key model characteristics (fairness, appropriateness, validity, and effectiveness). By incentivizing participation in innovation initiatives such as developing or piloting new AI-enabled tools and workflows, this activity further advances the field of applied clinical AI, encouraging clinicians and practices to collaborate in the creation and refinement of AI resources. This activity also aligns with the AI-related goals of the CMS ACCESS (Advancing Chronic Care with Effective, Scalable Solutions) Model, a 10-year voluntary Medicare program testing outcome-aligned payments to expand technology-supported chronic care for common conditions.[492]
New Improvement Activity	
Proposed Activity ID:	**IA_AHW_XX**
Proposed Subcategory:	Advancing Health and Wellness
Proposed Activity Title:	Lifestyle Approaches to Diabetes Remediation
Proposed Activity Description:	MIPS-eligible clinicians engage patients and their caregivers in structured, evidence-based lifestyle interventions to support the treatment and management of diabetes. Clinicians use the American College of Lifestyle Medicine's (ACLM) Lifestyle Empowerment Approach for Diabetes Remission (LEADR) or a similar diabetes-focused lifestyle program to help patients address modifiable behavioral factors and improve overall health status. These programs provide education, coaching, and support across key lifestyle domains such as nutrition, physical activity, sleep, stress management, and reducing harmful behaviors. Participating clinicians may use one or more of the following evidence-based programs and resources: • ACLM Lifestyle Empowerment Approach for Diabetes Remission (LEADR)[493] • CDC Diabetes Self-Management Education and Support (DSMES)[494] • American Diabetes Association Institute of Learning – Hands On Webinar: Diet, Lifestyle, Medicine, and Beyond—CardioKidneyMetabolic Strategies for Managing Obesity in People with Type 2 Diabetes[495]
Rationale:	This activity aligns with CMS's focus on wellness and whole-person care and supports MVP efforts by integrating health-related, non-clinical issues into quality improvement strategies.

In this proposed rule, we are proposing to modify **5** previously finalized improvement activities for the CY 2027 performance period/2029 MIPS payment year and future years. These proposed

[492] https://www.cms.gov/priorities/innovation/innovation-models/access.

[493] American College of Lifestyle Medicine. (n.d.). Research and innovation. https://lifestylemedicine.org/about-aclm/research-innovation/.

[494] Centers for Disease Control and Prevention. (n.d.). Diabetes self-management education and support. https://www.cdc.gov/diabetes/education-support-programs/index.html.

[495] American Diabetes Association. (n.d.). Hands On: Diet, Lifestyle, Medicine, and Beyond CardioKidneyMetabolic Strategies for Managing Obesity in People with Type 2 Diabetes https://professionaleducation.diabetes.org/ProductInfo/HandsOnFeb25OD.

changes are discussed in section IV.A.4.d.(3)(b)(IV) of this proposed rule and in more detail below.

TABLE F-B2: Modifications to Previously Finalized Improvement Activities

Current Improvement Activity	
Current Activity ID:	**IA_PSPA_16**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
Current Activity Description:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools—and standardized treatment protocols to manage workflow on the care team to meet patient needs. Clinicians should focus on utilizing open-source, freely available, interoperable CDS in completing the requirements of this activity.
Proposed Change and Rationale:	Stakeholder comments on the CY 2026 PFS NPRM supported stronger oversight of clinical AI, including monitoring, root cause analysis, and mitigation of AI-related diagnostic safety events and near-misses. This activity, IA_PSPA_16, already contains core patient safety elements, making it a strong candidate for modification to explicitly include AI-enabled decision support, aligned with the Office of the National Coordinator for Health Information Technology (ONC) definition of predictive decision-support interventions in 45 CFR 170.102 and stakeholder concerns about safety, liability, and governance.
Proposed Revised Activity Title:	Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools, including AI-enabled predictive decision-support interventions—and standardized treatment protocols to manage workflow on the care team to meet patient needs
Proposed Revised Activity Description:	MIPS-eligible clinicians use platform-agnostic, interoperable clinical decision support (CDS) tools—including artificial intelligence (AI)-enabled predictive decision-support interventions—to guide care-team workflow and support evidence-based, patient-centered decision-making. As part of this activity, clinicians prioritize open-source or freely available CDS tools where feasible and implement organizational policies to ensure the safe, appropriate, and effective use of these technologies. This activity may include: • Use of interoperable CDS tools, including AI-enabled technologies that meet the ONC definition of predictive decision-support interventions in 45 CFR 170.102: "technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis"[7] • Organizational policies for safe CDS and AI use, including processes to identify, review, and mitigate AI-related adverse events or near-misses, and to address clinician concerns about liability, model reliability, and appropriate use • Evaluation of AI-enabled CDS tools using the following quality principles: ○ Fairness: outputs free from bias or undue risk ○ Appropriateness: relevance to the clinical context ○ Validity: accurate and reliable predictions or recommendations ○ Effectiveness: demonstrated benefit in real-world use • Workflow integration practices showing that CDS recommendations—whether originally human-curated or AI-generated—are applied consistently in treatment planning, patient counseling, and follow-up • Periodic review and updating of CDS tools and related protocols to maintain alignment with best practices, organizational policies, and patient-safety standards.
Current Improvement Activity	
Current Activity ID:	**IA_BMH_4**
Current Subcategory:	Behavioral And Mental Health
Current Activity Title:	Depression screening
Current Activity	Depression screening and follow-up plan: Regular engagement of MIPS eligible

Description:	clinicians or groups in integrated prevention and treatment interventions, including depression screening and follow-up plan (refer to NQF #0418) for patients with co-occurring conditions of behavioral or mental health conditions
Proposed Change and Rationale:	IA_BMH_4 and IA_BMH_5 contain similar elements that could be combined into one, more robust activity.
Proposed Revised Activity Title:	Depression Screening, Treatment, and Prevention
Proposed Revised Activity Description:	MIPS-eligible clinicians or groups regularly engage in integrated screening, treatment, and/or prevention interventions for patients with behavioral or mental health conditions, with a focus on early identification and coordinated management of major depressive disorder and associated risks. This activity includes systematic depression screening and follow-up planning, along with suicide risk assessment for individuals at elevated risk. Clinicians participating in this activity should implement and document: • Use of validated depression screening tools administered at appropriate intervals for patients • Completion of suicide risk assessments when clinically indicated, using standardized tools for patients who screen positive for depression or exhibit mental-illness warning signs • Development and execution of evidence-based follow-up plans, including safety planning, symptom management, referral to behavioral health specialists, and monitoring of treatment response • Integrated, team-based coordination of care between primary care, behavioral health, psychiatry, and other relevant specialties to support continuity, patient safety, and positive patient outcomes • Routine monitoring and reassessment, including documentation of treatment adjustments, patient (and/or family/caregiver) engagement, and adherence to follow-up intervals consistent with clinical guidelines.
Current Improvement Activity	
Current Activity ID:	**IA_CC_8**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of documentation improvements for practice/process improvements
Current Activity Description:	Implementation of practices/processes that document care coordination activities (e.g., a documented care coordination encounter that tracks all clinical staff involved and communications from date patient is scheduled for outpatient procedure through day of procedure).
Proposed Change and Rationale:	IA_CC_8, IA_CC_10, IA_CC_11, and IA_CC_12 all contain similar elements that could be combined into one, more robust activity.
Proposed Revised Activity Title:	Implementation of Documentation and/or Operational Improvements for Practice/Process Improvements
Proposed Revised Activity Description:	This activity aims to strengthen communication, transparency, and patient-centered care across all transitions—outpatient, inpatient, specialty, and community settings. It seeks to promote clinicians' proactively coordinating care, tracking patient progress, documenting actions taken, and maintaining clear, structured processes that reduce fragmentation and improve clinical outcomes. This activity may include: • Documentation of care coordination encounters that track all clinical staff involved, communication steps, and handoffs from the time a patient is scheduled for an outpatient procedure or referral through completion of the episode of care • Systematic tracking of patients referred to consultants or specialists, including confirmation that the referral was received, appointments were completed, and recommendations were integrated into the plan of care • Documentation of care transition practices reflecting a patient-centered action plan aligned with the patient's values, preferences, and social context • Implementation of care coordination agreements with frequently used consultants or facilities that set expectations for timely, bidirectional information sharing and clearly define responsibilities across settings.
Current Improvement Activity	
Current Activity ID:	**IA_CC_9**
Current Subcategory:	Care Coordination
Current Activity Title:	Implementation of practices/processes for developing regular individual care plans

Current Activity Description:	Implementation of practices/processes, including a discussion on care, to develop regularly updated individual care plans for at-risk patients that are shared with the beneficiary or caregiver(s). Individual care plans should include consideration of a patient's goals and priorities, as well as desired outcomes of care.
Proposed Change and Rationale:	IA_CC_9 and IA_BE_15 contain similar elements that could be combined into one, more robust activity.
Proposed Activity Title:	Implementation of Practices/Processes for Developing Regular Individual Care Plans
Proposed Revised Activity Description:	Implementation of practices/processes, including a discussion about care goals and preferences, to develop regularly updated individual care plans for at-risk patients that are developed and shared with the beneficiary and family and/or caregiver(s). Individual care plans should include consideration of a patient's (and family/caregiver's, as appropriate) goals and priorities, as well as desired outcomes of care.
Current Improvement Activity	
Current Activity ID:	**IA_PM_4**
Current Subcategory:	Population Management
Current Activity Title:	Glycemic management services
Current Activity Description:	For outpatient Medicare beneficiaries with diabetes and who are prescribed antidiabetic agents (e.g., insulin, sulfonylureas), MIPS eligible clinicians and groups must attest to having: For the first performance year, at least 60 percent of medical records with documentation of an individualized glycemic treatment goal that: a) Considers patient-specific factors, including, at least 1) age, 2) comorbidities, and 3) risk for hypoglycemia, and b) Is reassessed at least annually. The performance threshold will increase to 75 percent for the second performance year and onward. Clinician would attest that, 60 percent for first year, or 75 percent for the second year, of their medical records that document individualized glycemic treatment represent patients who are being treated for at least 90 days during the performance period.
Proposed Change and Rationale:	IA_PM_4, IA_PM_19, and IA_PM_20 all contain similar elements that could be combined into one, more robust activity.
Proposed Revised Activity Title:	Glycemic Screening, Referral, and Management
Proposed Revised Activity Description:	For outpatient Medicare beneficiaries, MIPS-eligible clinicians and groups must attest to having: For the first performance year, at least 60 percent of medical records with documentation of screening patients for abnormal blood glucose, referring eligible patients with prediabetes to a CDC-recognized diabetes prevention program, and developing individualized glycemic treatment plans that: a) Consider patient-specific factors, including, at least 1) age, 2) comorbidities, and 3) risk for hypoglycemia, and b) Are reassessed at least annually. The performance threshold will increase to 75 percent for the second performance year and onward. Clinicians must attest that 60 percent (for the first year) and 75 percent (for the second year and beyond) of their medical records include documentation of screening patients for abnormal blood glucose according to current US Preventive Services Task Force (USPSTF) and/or American Diabetes Association (ADA) guidelines. Clinicians must attest that 60 percent (for the first year) and 75 percent (for the second year and beyond) of their medical records include documentation of referring eligible

	patients with prediabetes to a CDC-recognized diabetes prevention program operating under the framework of the National Diabetes Prevention Program. Clinicians must attest that 60 percent (for the first year) and 75 percent (for the second year and beyond) of their medical records document individualized glycemic treatment plans representing patients who are being seen for at least 90 days during the performance period.

In this proposed rule, we are proposing to remove **11** previously finalized improvement activities beginning with the CY 2027 performance period/2029 MIPS payment year. These changes are discussed in section IV.A.4.d.(3)(b)(V) of this proposed rule and in more detail below; activity removal factors are discussed in the CY 2020 PFS final rule (84 FR 62568 through 63563).

TABLE F-B3: Improvement Activities Being Removed

Current Improvement Activity	
Current Activity ID:	**IA_BMH_5**
Current Subcategory:	Behavioral And Mental Health
Current Activity Title:	MDD prevention and treatment interventions
Current Activity Description:	Major depressive disorder: Regular engagement of MIPS eligible clinicians or groups in integrated prevention and treatment interventions, including suicide risk assessment (refer to NQF #0104) for mental health patients with co-occurring conditions of behavioral or mental health conditions.
Removal Rationale:	Proposed removal to combine with IA_BMH_4; Factor 1, activity is duplicative
Current Improvement Activity	
Current Activity ID:	**IA_CC_10**
Current Subcategory:	Care Coordination
Current Activity Title:	Care transition documentation practice improvements
Current Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must document practices/processes for care transition with documentation of how a MIPS eligible clinician or group carried out an action plan for the patient with the patient's preferences in mind (that is, a "patient-centered" plan) during the first 30 days following a discharge. Examples of these practices/processes for care transition include: staff involved in the care transition; phone calls conducted in support of transition; accompaniments of patients to appointments or other navigation actions; home visits; patient information access to their medical records; real time communication between PCP and consulting clinicians; PCP included on specialist follow-up or transition communications.
Removal Rationale:	Proposed removal to combine with IA_CC_8; Factor 1, activity is duplicative
Current Improvement Activity	
Current Activity ID:	**IA_CC_11**
Current Subcategory:	Care Coordination
Current Activity Title:	Care transition standard operational improvements
Current Activity Description:	Establish standard operations to manage transitions of care that could include one or more of the following: • Establish formalized lines of communication with local settings in which empaneled patients receive care to ensure documented flow of information and seamless transitions in care; and/or • Partner with community or hospital-based transitional care services.
Removal Rationale:	Proposed removal to combine with IA_CC_8; Factor 1, activity is duplicative
Current Improvement Activity	

Current Activity ID:	**IA_CC_12**
Current Subcategory:	Care Coordination
Current Activity Title:	Care coordination agreements that promote improvements in patient tracking across settings
Current Activity Description:	Establish effective care coordination and active referral management that could include one or more of the following: • Establish care coordination agreements with frequently used consultants that set expectations for documented flow of information and MIPS eligible clinician or MIPS eligible clinician group expectations between settings. Provide patients with information that sets their expectations consistently with the care coordination agreements; • Track patients referred to specialist through the entire process; and/or • Systematically integrate information from referrals into the plan of care.
Removal Rationale:	Proposed removal to combine with IA_CC_8; Factor 1, activity is duplicative
Current Improvement Activity	
Current Activity ID:	**IA_PSPA_2**
Current Subcategory:	Patient Safety and Practice Assessment
Current Activity Title:	Participation in MOC Part IV
Current Activity Description:	In order to receive credit for this activity, a MIPS eligible clinician must participate in Maintenance of Certification (MOC) Part IV. Maintenance of Certification (MOC) Part IV requires clinicians to perform monthly activities across practice to regularly assess performance by reviewing outcomes addressing identified areas for improvement and evaluating the results. Some examples of activities that can be completed to receive MOC Part IV credit are: the American Board of Internal Medicine (ABIM) Approved Quality Improvement (AQI) Program, National Cardiovascular Data Registry (NCDR) Clinical Quality Coach, Quality Practice Initiative Certification Program, American Board of Medical Specialties Practice Performance Improvement Module or American Society of Anesthesiologists (ASA) Simulation Education Network, for improving professional practice including participation in a local, regional or national outcomes registry or quality assessment program; specialty- specific activities including Safety Certification in Outpatient Practice Excellence (SCOPE); American Psychiatric Association (APA) Performance in Practice modules.
Removal Rationale:	Many physicians are already required (e.g., by states) to participate in MOC; therefore, this activity is not likely to be driving additional meaningful clinical care improvement; Factors 1 & 7, activity is duplicative and/or obsolete
Current Improvement Activity	
Current Activity ID:	**IA_CC_16**
Current Subcategory:	Care Coordination
Current Activity Title:	Primary Care Physician and Behavioral Health Bilateral Electronic Exchange of Information for Shared Patients
Current Activity Description:	The primary care and behavioral health practices use the same electronic health record system for shared patients or have an established bidirectional flow of primary care and behavioral health records.
Removal Rationale:	Given advancements in EHR adoption and data-sharing practices, this activity is no longer likely driving additional meaningful clinical care improvement; Factor 7, activity is obsolete.
Current Improvement Activity	
Current Activity ID:	**IA_BE_15**

Current Subcategory:	Beneficiary Engagement
Current Activity Title:	Engagement of Patients, Family, and Caregivers in Developing a Plan of Care
Current Activity Description:	Engage patients, family, and caregivers in developing a plan of care and prioritizing their goals for action, documented in the electronic health record (EHR) technology.
Removal Rationale:	Proposed removal to combine with IA_CC_9; Factor 1, activity is duplicative
Current Improvement Activity	
Current Activity ID:	**IA_PM_19**
Current Subcategory:	Population Management
Current Activity Title:	Glycemic Screening Services
Current Activity Description:	For at-risk outpatient Medicare beneficiaries, individual MIPS eligible clinicians and groups must attest to implementation of systematic preventive approaches in clinical practice for at least 60 percent for the 2018 performance period and 75 percent in future years, of electronic medical records with documentation of screening patients for abnormal blood glucose according to current US Preventive Services Task Force (USPSTF) and/or American Diabetes Association (ADA) guidelines.
Removal Rationale:	Proposed removal to be combined with IA_PM_4; Factor 1, activity is duplicative
Current Improvement Activity	
Current Activity ID:	**IA_PM_20**
Current Subcategory:	Population Management
Current Activity Title:	Glycemic Referring Services
Current Activity Description:	For at-risk outpatient Medicare beneficiaries, individual MIPS eligible clinicians and groups must attest to implementation of systematic preventive approaches in clinical practice for at least 60 percent for the CY 2018 performance period and 75 percent in future years, of medical records with documentation of referring eligible patients with prediabetes to a CDC-recognized diabetes prevention program operating under the framework of the National Diabetes Prevention Program.
Removal Rationale:	Proposed removal to be combined with IA_PM_4; Factor 1, activity is duplicative
Current Improvement Activity	
Current Activity ID:	**IA_EPA_4**
Current Subcategory:	Expanded Practice Access
Current Activity Title:	Additional improvements in access as a result of QIN/QIO TA
Current Activity Description:	As a result of Quality Innovation Network(QIN)-Quality Improvement Organization (QIO) technical assistance, performance of additional activities that improve access to services or improve care coordination (for example, investment of on-site diabetes educator).
Removal Rationale:	This activity is one of several focused on improvements that can be supported and/or driven by QIN/QIOs. This particular activity could be attested to with relatively low levels of effort and without a need to measure specific outcomes. If this concept is important to eligible clinicians, they can attest to IA_PSPA_19. Other QIN/QIO-relevant activities will remain in the Inventory. Factor 2; There is an alternative activity with a stronger relationship to quality care or improvements in clinical practice.

Current Improvement Activity	
Current Activity ID:	**IA_PM_2**
Current Subcategory:	Population Management
Current Activity Title:	Anticoagulant management improvements
Current Activity Description:	Individual MIPS eligible clinicians and groups who prescribe anti-coagulation medications (including, but not limited to oral Vitamin K antagonist therapy, including warfarin or other coagulation cascade inhibitors) must attest that for 75 percent of their ambulatory care patients receiving these medications are being managed with support from one or more of the following improvement activities: • Participation in a systematic anticoagulation program (coagulation clinic, patient self-reporting program, or patient self-management program); • Patients are being managed by an anticoagulant management service, that involves systematic and coordinated care, incorporating comprehensive patient education, systematic prothrombin time (PT-INR) testing, tracking, follow-up, and patient communication of results and dosing decisions; • Patients are being managed according to validated electronic decision support and clinical management tools that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; • For rural or remote patients, patients are managed using remote monitoring or telehealth options that involve systematic and coordinated care, incorporating comprehensive patient education, systematic PT-INR testing, tracking, follow-up, and patient communication of results and dosing decisions; or • For patients who demonstrate motivation, competency, and adherence, patients are managed using either a patient self-testing (PST) or patient-self-management (PSM) program.
Removal Rationale:	Direct oral anticoagulant medications (DOACs) have dramatically changed clinical practice, with significantly decreased use of warfarin over the last decade. Despite these changes, there are still specific circumstances that require use of warfarin, including the presence of prosthetic valves, antiphospholipid syndrome, and a high risk of bleeding complications, particularly gastrointestinal bleeding. This activity drives 'classic' quality actions related to the use of warfarin. Given the transition away from warfarin's common use, removing this activity is likely appropriate. We acknowledge the ongoing importance of medication management and will work to ensure that, going forward, improvement activities that support continued enhancement and maintenance of anticoagulation medication management are reflected in MIPS. Factor 7; activity is obsolete.

</EXTRACT><HD1>APPENDIX 3: MVP INVENTORY<EXTRACT>

MVP Development: Background

In the CY 2021 PFS final rule (85 FR 84849 through 84854), the CY 2022 PFS final rule (86 FR 65998 through 66031), and the CY 2023 PFS final rule (87 FR 70210 through 70211) we finalized a set of criteria to use in the development of MVPs. These criteria include MVP reporting requirements, MVP maintenance, and the selection of measures and activities within an MVP.

This appendix includes three groups of proposed MVP tables: Table 1 covers the MVP Foundational Layer, Group A presents 3 proposed new MVPs, and Group B outlines proposed modifications to 27 previously finalized MVPs.

Each MVP is composed of measures and activities from the quality, improvement activities, and cost performance categories relevant to the clinical specialty of the MVP. Additionally, every MVP includes a foundational layer which consists of population health measures and Promoting Interoperability performance category objectives and measures. The foundational layer is consistent across all MVPs and is detailed in Table 1: MVP Foundational Layer.

When applicable and substantive, we include a brief overview of the planned modifications to QCDR measures within relevant MVPs. Although QCDR measures are exempt from public notice and comment, providing this overview ensures transparency and offers interested parties an opportunity to provide comment on all aspects of each MVP prior to finalization. Final decisions regarding modifications to QCDR measure specifications are made by QCDR measure stewards independently of the rulemaking process, though these modifications may influence the finalized decisions in the final rule.

IA_PCMH: Electronic submission of Patient Centered Medical Home Accreditation is not listed in the newly proposed or previously finalized MVP tables. In accordance with § 414.1380(b)(3)(ii), MIPS eligible clinicians in practices certified or recognized as a patient-centered medical home or comparable specialty practice, as determined by the Secretary, may attest to this activity and receive an improvement activities performance category score of 100 percent (81 FR 77179 through 77180).

MVP Development: Performance Category Sources

Table 1, Group A, and Group B MVP tables include foundational measures and sets of MIPS quality measures, QCDR measures (as applicable), improvement activities, and cost measures organized around clinical topics. For further reference, the sources for the measures and activities included in the MVP tables can be found on the Quality Payment Program website, as detailed below:

- Existing MIPS quality measures are included in the 2026 MIPS Quality Measures List.[496] For details on proposed changes, refer to Appendix 1: MIPS Quality Measures in this proposed rule, which outlines the following: proposed additions (Table Group A), proposed removals (Table Group C), and proposed modifications to existing quality measures (Table Groups D and DD).

[496] See the 2026 MIPS Quality Measures List: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3570/2026-MIPS-Quality-Measures-List.xlsx.*

- Existing QCDR measures are derived from the latest publication of the 2026 QCDR Measure Specification file.[497] We anticipate updating the list of 2027 QCDR measures in December 2026.
- Existing improvement activities are included in the 2026 Improvement Activities Inventory and the 2026 MIPS Data Validation Criteria.[498] For details on proposed changes, refer to proposed changes Appendix 2: Improvement Activities in this proposed rule, which outlines the following: proposed additions (Table Group A), proposed modifications to existing improvement activities (Table Group B), and proposed removals (Table Group C).
- Existing cost measures are included in the 2026 Cost Measures Inventory.[499] There are no proposed changes to cost measures included in the proposed CY 2027 MVPs.
- Existing Promoting Interoperability measures and attestations, adopted in prior rulemaking and included in the foundational layer, can be found on the Quality Payment Program website.[500] For details on Promoting Interoperability performance category proposals, we refer readers to section IV.A.4.d.(4) of this proposed rule. Proposals include a modification to the definition of CEHRT, a reduction in requirements, and the following: A modification to the PI_HIE_7: Electronic Prior Authorization measure, which would change the measure from being a required measure to an optional measure for the CY 2027 performance period/2029 MIPS payment year (measure was previously finalized as a required measure in the CMS Interoperability and Prior Authorization final rule (89 FR 8915 through 8927); and the addition of a new measure, Electronic Prior Authorization for Prescription Drugs (PI_HIE_8), which would be a required measure starting with the CY 2028 performance period/2030 MIPS payment year.
- For more information on the population health measures, attributed to the quality performance category and included in the foundational layer, refer to the CY 2022 PFS final rule (86 FR 65408 through 65409).

MVP Development: Measure and Improvement Activity Updates

- Group A and Group B MVPs include an additional table to identify the proposed MIPS core measures within each MVP. For details on the MIPS core measure proposal and selection criteria for MVPs refer to section IV.A.4.d.(1)(c) of this proposed rule.
- Refer to Appendix 1: MIPS Quality Measures (Table Group C) in this proposed rule for details on the proposed removal of MIPS quality measures.
- Refer to Appendix 2: Improvement Activities (Table Group C) in this proposed rule for details on the proposed removal of improvement activities.
- Refer to section IV.A.4.d.(4) Promoting Interoperability Performance Category measures in this proposed rule for details on the proposed removal of Promoting Interoperability Performance Category measures. The following Promoting Interoperability measures, previously included in the foundational layer of MVPs, are now proposed for removal from MIPS: **PI_PPHI_1:** Security Risk Analysis, **PI_ONCDIR_1:** ONC Direct Review Attestation, and **PI_ONCACB_1:** ONC-ACB Surveillance Attestation (Optional).

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[497] See the 2026 QCDR Measure Specification file: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3573/2026_QCDR_Measure_Specifications.xlsx* for QCDR measures.

[498] See the 2026 Improvement Activities Inventory: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3567/2026-Improvement-Activities-Inventory.zip* and 2026 MIPS Data Validation Criteria: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3574/2026-MIPS-Data-Validation-Criteria.zip.* for improvement activity details.

[499] See the 2026 Cost Measures Inventory: *https://qpp.cms.gov/reporting-requirements/measures-activities/explore?tab=costMeasures&py=2026.*

[500] See the 2026 Promoting Interoperability Measure Specifications: *https://qpp-cm-prod-content.s3.amazonaws.com/uploads/3566/2026-MIPS-Promoting-Interoperability-Measure-Specifications.zip* for Promoting Interoperability measure details.

MVP Symbol Information and Definitions

Please note the following symbols and definitions used within the MVP tables in this appendix:

- Quality measures proposed as MIPS core measures in an MVP are identified with a single exclamation point (!).
- Quality measures, improvement activities, cost measures, and Promoting Interoperability measures proposed for addition to a previously finalized MVP are identified with a plus sign (+).
- Proposed new MIPS quality measures, improvement activities, and Promoting Interoperability measures proposed for inclusion in an MVP beginning with the CY 2027 performance period/2029 MIPS payment year and future years are identified with a caret symbol (^). See Appendix 1: MIPS Quality Measures: Table Group A, Appendix 2: Improvement Activities: Table Group A, and section IV.A.4.d.(4) of this proposed rule for further information regarding new MIPS quality measures, improvement activities and Promoting Interoperability measures.
- Existing measures and improvement activities with proposed revisions are identified with a single asterisk (*). For further information regarding proposed revisions see Appendix 1: MIPS Quality Measures: Tables Group D and DD for revisions to MIPS quality measures, Appendix 2: Improvement Activities: Table Group B for revisions to improvement activities, and section IV.A.4.d.(4) for revisions to Promoting Interoperability measures. Unless changes were required to continue to meet programmatic standards for inclusion, we intend to include existing measures or activities with proposed revisions in MVPs (as applicable) regardless of whether the proposed revisions are finalized beginning with the CY 2027 performance period/2029 MIPS payment year.
- QCDR measures undergoing modifications planned by the QCDR measure stewards are identified in this appendix with a single asterisk (*). When applicable and substantive in nature, we provide a brief overview of the planned modifications within applicable MVPs. Since QCDR measures are exempt from public notice and comment, this overview allows for transparency with interested parties and an opportunity to comment on all aspects of each MVP prior to finalization. Final decisions to modify QCDR measure specifications are determined by QCDR measure stewards, separate from rulemaking, but may impact decisions as finalized in the final rule.
- Quality measures and improvement activities identified with a double asterisk (**) can only be submitted when included in an MVP.
- Improvement activities that include an advancing health and wellness component are identified with a double exclamation point (!!).
- Quality measure collection types are identified in parentheses after each quality measure title.

Foundational Layer

Each MVP contains a foundational layer, which includes the entire set of Promoting Interoperability performance category measures and two population health measures. The foundational layer is the same for all MVPs, as listed in Table 1.

Symbol Key:

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.

TABLE 1: MVP Foundational Layer

Population Health Measures	Promoting Interoperability Measures
(*) Q479: Hospital-wide, 30-Day, All-cause Unplanned Readmission (HWR) Rate for the Merit-based Incentive Payment System (MIPS) Groups (Collection Type: Administrative Claims) **Q484:** Clinician and Clinician Group Risk-Standardized Hospital Admission Rates for Patients with Multiple Chronic Conditions (MCC) (Collection Type: Administrative Claims)	**PI_PPHI_2:** High Priority Practices Safety Assurance Factors for EHR Resilience (SAFER) Guide **PI_EP_1:** e-Prescribing **PI_EP_2:** Query of Prescription Drug Monitoring Program (PDMP) **PI_PEA_1:** Provide Patients Electronic Access to Their Health Information **PI_HIE_1:** Support Electronic Referral Loops By Sending Health Information AND **PI_HIE_4:** Support Electronic Referral Loops By Receiving and Reconciling Health Information OR **PI_HIE_5:** Health Information Exchange (HIE) Bi-Directional Exchange OR **PI_HIE_6:** Enabling Exchange Using the Trusted Exchange Framework and Common Agreement (TEFCA) **(+)(*) PI_HIE_7:** Electronic Prior Authorization (Optional) **PI_PHCDRR_1:** Immunization Registry Reporting **PI_PHCDRR_2:** Syndromic Surveillance Reporting (Optional) **PI_PHCDRR_3:** Electronic Case Reporting **PI_PHCDRR_4:** Public Health Registry Reporting (Optional) **PI_PHCDRR_5:** Clinical Data Registry Reporting (Optional) **PI_PHCDRR_6:** Public Health Reporting Using TEFCA (Optional) **PI_INFBLO_1:** Actions to Limit or Restrict Compatibility or Interoperability of CEHRT Attestation

Group A: New MVPs Proposed for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

A.1 Diabetic Disease MVP

The proposed Diabetic Disease MVP assesses meaningful outcomes in diabetic disease care. This MVP would be most applicable to clinicians who provide diabetic disease patient care, including primary care, endocrinology, ophthalmology, podiatry, and nonphysician practitioners (NPPs) such as nurse practitioners, clinical nurse specialists, and physician assistants. We request public comment on this proposal.

Quality Measures

We are proposing to include 11 MIPS quality measures and 2 QCDR measures within the quality performance category of this MVP, which are relevant to the clinical topic of diabetic disease care. We reviewed the MIPS quality measure inventory and considered feedback received during the 2026 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

For the reasons stated in the introduction of this appendix[501], we are proposing the following measures as MIPS core measures for the Diabetic Disease MVP:

- **Q001**: Diabetes: Glycemic Status Assessment Greater Than 9%
- **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
- **Q317**: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented
- **Q488**: Kidney Health Evaluation

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in diabetic disease care:

- **Q001**: Diabetes: Glycemic Status Assessment Greater Than 9%: This inverse outcome MIPS quality measure assesses patients diagnosed with diabetes mellitus for poor control of their HbA1c.
- **Q019**: Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care: This MIPS quality measure focuses on the communication between the primary physician managing ongoing care and the physician performing the dilated macular or fundus exam on patients with diabetic retinopathy.
- **Q117**: Diabetes: Eye Exam: This MIPS quality measure supports eye screening for diabetic retinal disease.
- **Q126**: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation: This MIPS quality measure ensures patients diagnosed with diabetes mellitus have a lower extremity neurological exam performed at least once every 12 months.
- **Q127**: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear: Outcome Survey: This MIPS quality measure ensures patients diagnosed with diabetes mellitus are evaluated for proper footwear and sizing at least once every 12 months.
- **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients for a documented BMI with a follow-up plan documented if their most recent documented BMI was outside of normal parameters

[501] See MVP Development: Quality Measure and Improvement Activity Updates

- **Q317**: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: This MIPS quality measure ensures all adult patients are screened for high blood pressure at each visit and have a recommended follow-up plan if blood pressure is elevated or hypertensive.
- **Q438**: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: This MIPS quality measure identifies patients at high risk of cardiovascular events and ensures they are prescribed or currently on a statin therapy.
- **Q488**: Kidney Health Evaluation: This MIPS quality measure ensures patients with diabetes receive a kidney health evaluation including both an estimated glomerular filtration rate (eGFR) and a urine albumin-creatinine ratio (uACR).
- **IRIS58**: Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days: This QCDR measure assesses success of vitrectomy procedures in patients with diabetic retinopathy by reviewing patients for complications within 120 days of the procedure.
- **USWR35**: Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer: This QCDR measure assesses for adequate off-loading for diabetic foot ulcers during patient visits, which supports positive outcomes of Diabetic Foot Ulcer (DFU) healing.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in diabetic disease care. The quality measures below assess for screenings and follow-up actions for select measures:

- **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan: This MIPS quality measure ensures all patients are screened for depression with a follow-up plan documented for those patients who screen positive.
- **Q226**: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 13 improvement activities that reflect actions and processes undertaken by clinicians who specialize in diabetic disease care, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision-making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- **IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_AHW_X:** Lifestyle Approaches to Diabetes Remediation
- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_3:** Engagement with QIN-QIO to implement self-management training programs
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_19:** Use group visits for common chronic conditions (e.g., diabetes)
- **IA_BE_23:** Integration of patient coaching practices between visits
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_4:** Glycemic management services

- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

Cost Measures

We are proposing to include two MIPS cost measures within the cost performance category of this MVP, which apply to the clinical topic of diabetes. We reviewed the MIPS cost measure inventory and considered feedback received during the 2026 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measures provide a meaningful assessment of the clinical care for clinicians who specialize in interventional radiology and aligns with other measures and activities within this MVP:

- **COST_D_1**: Diabetes: This MIPS cost measure applies to clinicians providing diabetic care.
- **TPCC_1:** Total Per Capita Cost (TPCC): This MIPS cost measure assesses the overall cost of care delivered to a Medicare patient with a focus on the primary care the patient receives from their providers.

Symbol Key:

Single exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): proposed new measure or improvement activity.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE A.1a: Diabetic Disease MVP MIPS Core Measures

Diabetic Disease MVP MIPS Core Measures
Q001: Diabetes: Glycemic Status Assessment Greater Than 9%
Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented
Q488: Kidney Health Evaluation

TABLE A.1b: Diabetic Disease MVP Clinical Groupings

Diabetic Disease MVP		
Clinical Grouping	**Quality**	**Cost**
Ophthalmology	**Q019:** Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (Collection Type: eCQM)	**N/A**
	Q117: Diabetes: Eye Exam (Collection Type: eCQM, MIPS CQM)	
	IRIS58: Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days (Collection Type: QCDR)	
Podiatry	**Q126:** Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (Collection Type: MIPS CQM)	**N/A**

Diabetic Disease MVP		
Clinical Grouping	**Quality**	**Cost**
	Q127: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear (Collection Type: MIPS CQM)	
	USWR35: Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer (Collection Type: QCDR)	
Multispecialty	**(!)(*) Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: eCQM, MIPS CQM, Medicare Part B Claims)	**COST_D_1:** Diabetes **TPCC_1:** Total Per Capita Cost
	(*) Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	
	(!) Q488: Kidney Health Evaluation (Collection Type: eCQM, MIPS CQM)	
Advancing Health and Wellness	**(!)(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: eCQM, MIPS CQM, Medicare Part B Claims)	**COST_D_1:** Diabetes **TPCC_1:** Total Per Capita Cost
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: eCQM, MIPS CQM, Medicare Part B Claims)	
	(!)(*) Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented (Collection Type: eCQM, MIPS CQM, Medicare Part B Claims)	

Diabetic Disease Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **(^)(!!) IA_AHW_X:** Lifestyle Approaches to Diabetes Remediation
- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_3:** Engagement with QIN-QIO to implement self-management training programs
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_19:** Use group visits for common chronic conditions (e.g., diabetes)
- **(!!) IA_BE_23:** Integration of patient coaching practices between visits
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(*)(!!) IA_PM_4:** Glycemic management services
- **IA_PM_16:** Implementation of medication management practice improvements
- **(!!) IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

A.2 Hospitalist MVP

The proposed Hospitalist MVP assesses meaningful outcomes for patients receiving care provided by hospitalists. This MVP would be most applicable to hospitalists, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We request public comment on this proposal.

Quality Measures

We are proposing to include four MIPS quality measures and five QCDR measures within the quality performance category of this MVP, which are relevant to care provided by hospitalists. We reviewed the MIPS quality measure inventory and considered feedback received during the 2026 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

For the reasons stated in the introduction of this appendix[502], we are proposing the following measures as MIPS core measures for the Hospitalist MVP:

- **Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- **Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- **Q047:** Advance Care Plan

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for hospitalists:

- **Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD): This MIPS quality measure ensures patients diagnosed with heart failure and a left ventricular ejection fraction of less than or equal to 40% are prescribed an ACE inhibitor, ARB or ARNI therapy.
- **Q008:** Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD): This MIPS quality measure ensures patients diagnosed with heart failure and a left ventricular ejection fraction of less than or equal to 40% are prescribed beta-blocker therapy.
- **Q238:** Use of High-Risk Medications in Older Adults: This inverse MIPS quality measure supports patient safety by assessing high-risk medication utilization in the older adult population.
- **ECPR51:** Discharge Prescription of Naloxone after Opioid Poisoning or Overdose: This QCDR measure ensures patients treated for opioid poisoning in the acute care setting are prescribed naloxone and receive education on its proper use before discharge.
- **HCPR24:** Appropriate Utilization of Vancomycin for Cellulitis: This QCDR measure ensures the appropriate use of vancomycin for patients diagnosed with cellulitis in the hospital setting, whether admitted or under observation.
- **HCPR25:** Physician's Orders for Life-Sustaining Treatment (POLST) Form: This QCDR measure ensures patients with advanced illness have a completed POLST form during their hospitalization.
- **HCPR27:** Point-of-Care Ultrasound: Evaluation for Pneumothorax after Central Venous Catheter (CVC) Placement: This QCDR measure ensures patients undergoing CVC placement receive appropriate pneumothorax evaluation using point-of-care ultrasound.
- **HCPR30**: Avoidance of Sliding-Scale Insulin Monotherapy for Admitted Diabetic Patients: This QCDR measure ensures patients admitted to the hospital with a diagnosis of diabetes mellitus receive an order for basal insulin therapy.

The following broadly applicable MIPS quality measure is relevant to clinicians who specialize in hospitalist care.

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[502] See MVP Development: Quality Measure and Improvement Activity Updates

- **Q047:** Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decisions maker.

Modifications are being considered for the following QCDR measure:

- **ECPR51:** Discharge Prescription of Naloxone after Opioid Poisoning or Overdose: This QCDR measure is undergoing modifications to expand the measure to include the treatment for opioid withdrawal in additional care settings.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 12 improvement activities that reflect actions and processes undertaken by hospitalists, as well as activities that promote advancing health and wellness, patient engagement and patient-centeredness, shared decision-making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities are proposed for inclusion in this MVP:

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BMH_12:** Promoting Clinician Well-Being
- **IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults
- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_8:** Use of patient safety tools
- **IA_PSPA_15:** Implementation of an ASP
- **IA_PSPA_21:** Implementation of fall screening and assessment programs

Cost Measures

We are proposing to include one MIPS cost measure within the cost performance category of this MVP, which applies to hospitalists. We reviewed the MIPS cost measure inventory and considered feedback received during the 2026 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides a meaningful assessment of the clinical care for hospitalists and aligns with other measures and activities within this MVP:

- **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician: This MIPS cost measure applies to hospitalists.

Symbol Key:

Single exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE A.2a: Hospitalist MVP MIPS Core Measures

Hospitalist MVP MIPS Core Measures
Q005: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
Q047: Advance Care Plan

TABLE A.2b: Hospitalist MVP Clinical Groupings

Hospitalist MVP		
Clinical Grouping	**Quality**	**Cost**
Medication	**(!) Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM^^, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM^^, MIPS CQM)	
	(*) ECPR51: Discharge Prescription of Naloxone after Opioid Poisoning or Overdose (Collection Type: QCDR)	
	HCPR24: Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	
General Clinical Care	**HCPR27:** Point-of-Care Ultrasound: Evaluation for Pneumothorax after Central Venous Catheter (CVC) Placement (Collection Type: QCDR)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	HCPR30: Avoidance of Sliding-Scale Insulin Monotherapy for Admitted Diabetic Patients (Collection Type: QCDR)	
Advancing Health and Wellness	**Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	HCPR25: Physician's Orders for Life-Sustaining Treatment (POLST) Form (Collection Type: QCDR)	

^^Please note this collection type does not include inpatient coding and may not be applicable.

Hospitalist Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BMH_12:** Promoting Clinician Well-Being
- **(!!) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening & Referral for Older Adults
- **(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_8:** Use of patient safety tools
- **(!!) IA_PSPA_15:** Implementation of an ASP
- **(!!) IA_PSPA_21:** Implementation of fall screening and assessment programs

A.3 Hypertension MVP

The proposed Hypertension MVP assesses meaningful outcomes for patients receiving care for hypertension and appropriate preventive interventions for those considered high-risk. This MVP would be most applicable to clinicians who treat patients at risk for hypertension and with a hypertension diagnosis, including cardiology, family medicine, geriatrics, internal medicine,

nutrition and dietician, preventive medicine, and NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We request public comment on this proposal.

Quality Measures

We are proposing to include 13 MIPS quality measures within the quality performance category of this MVP, which are specific to the clinical topic of hypertension. We reviewed the MIPS quality measure inventory and considered feedback received during the 2026 MVP candidate feedback period to determine which quality measures best represent the clinical topic of this MVP.

For the reasons stated in the introduction of this appendix[503], we are proposing the following measures as MIPS core measures for the Hypertension MVP:

- **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
- **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
- **Q236:** Controlling High Blood Pressure

The following quality measures provide a meaningful and comprehensive assessment of the clinical care for clinicians who specialize in the treatment of hypertension:

- **Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan: This MIPS quality measure assesses patients for a documented BMI with a follow-up plan documented if their most recent documented BMI was outside of normal parameters.
- **Q236:** Controlling High Blood Pressure: This intermediate outcome MIPS quality measure assesses patients diagnosed with hypertension for adequately controlled blood pressure.
- **Q239:** Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents: This MIPS quality measure ensures that patients aged 3-17 years have a BMI recorded with appropriate nutrition and physical activity counseling.
- **Q317:** Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented: This MIPS quality measure ensures all adult patients are screened for high blood pressure at each visit and have a recommended follow-up plan if blood pressure is elevated or hypertensive.
- **Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control): This intermediate outcome MIPS quality measure ensures optimal control of patients with IVD by assessing goals for blood pressure management, smoking cessation, antiplatelet use, and high intensity statin use.
- **Q489:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy: This MIPS quality measure ensures patients diagnosed with chronic kidney disease and proteinuria are prescribed and ACE inhibitor or ARB therapy.
- **TBD:** Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management: This proposed intermediate outcome MIPS quality measure ensures lipid monitoring in patients with atherosclerotic cardiovascular disease (ASCVD) and achieving the target goal of an LDL-C less than 70mg/dL.

The following broadly applicable MIPS quality measures are relevant to clinicians who specialize in the treatment of hypertension. The quality measures below assess for age-specific screenings and follow-up actions for select measures:

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[503] See MVP Development: Quality Measure and Improvement Activity Updates

- **Q047:** Advance Care Plan: This MIPS quality measure assesses for medical record documentation of an advance care plan or surrogate decision maker.
- **Q130:** Documentation of Current Medications in the Medical Record: This MIPS quality measure assesses for review and documentation of all current medications at each visit.
- **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: This MIPS quality measure screens patients for tobacco use. Any patients that are found to be tobacco users should receive tobacco cessation intervention.
- **Q374:** Closing the Referral Loop: Receipt of Specialist Report: This MIPS quality measure is attributable to the clinician referring the patient and ensures that the referring clinician receives a report from the clinician to whom the patient was referred, therefore closing the communication loop.
- **Q431:** Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: This MIPS quality measure screens patients for unhealthy alcohol use. Any patients that screen positive for unhealthy alcohol use should receive brief counseling.
- **Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months: This MIPS quality measure ensures capture of the patient voice and experience of care related to the patient's understanding and confidence in the clinician's ability to manage their health and be an active partner in the health care journey.

Improvement Activities

We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP candidate feedback period to determine the set of improvement activities to include in this MVP. We are proposing to include 11 improvement activities that reflect actions and processes undertaken by clinicians who specialize in the treatment of hypertension, as well as activities that promote advancing health and wellness, engagement and patient-centeredness, shared decision-making, and care coordination. These improvement activities provide opportunities for clinicians, in collaboration with patients, to drive outcomes and improve quality of care. The following improvement activities were proposed for inclusion in this MVP:

- **IA_AHW_1:** Chronic care and preventative care management for empaneled patients
- **IA_AHW_X:** Lifestyle Approaches to Diabetes Remediation
- **IA_BE_16:** Promote Self-management in Usual Care
- **IA_BMH_2:** Tobacco use
- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PM_4:** Glycemic management services
- **IA_PM_5:** Engagement of community for health status improvement
- **IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk
- **IA_PSPA_16:** Use of decision support —ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

Cost Measures

We are proposing to include one MIPS cost measure within the cost performance category of this MVP, which applies to the clinical topic of hypertension. We reviewed the MIPS cost measure inventory and considered feedback received during the 2025 MVP candidate feedback period to determine the set of cost measures to include in this MVP. The following cost measure provides

a meaningful assessment of the clinical care for clinicians who care for patients with hypertension:

- **TPCC_1:** Total Per Capita Cost (TPCC): This MIPS cost measure assesses the overall cost of care delivered to a Medicare patient with a focus on the primary care the patient receives from their providers.

Symbol Key:
Single exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): proposed new measure or improvement activity.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE A.3a: Hypertension MVP MIPS Core Measures

Hypertension MVP MIPS Core Measures
Q128: Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan
Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
Q236: Controlling High Blood Pressure

TABLE A.3b: Hypertension MVP Clinical Groupings

Hypertension MVP		
Clinical Grouping	**Quality**	**Cost**
Prevention	**(!)(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	Q239: Weight Assessment and Counseling for Nutrition and Physical Activity for Children/Adolescents (Collection Type: eCQM)	
	(*) Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q489: Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQM)	
Treatment and Control	**(!)(*) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(*) Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM)	
	(^) TBD: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(!) Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Hypertension Improvement Activities

- **(!!) IA_AHW_1:** Chronic care and preventative care management for empaneled patients
- **(^)(!!) IA_AHW_X:** Lifestyle Approaches to Diabetes Remediation
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **(!!) IA_BMH_2:** Tobacco use
- **(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **(*)(!!) IA_PM_4:** Glycemic management services
- **(!!) IA_PM_5:** Engagement of community for health status improvement
- **(!!) IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

- **(*) IA_PSPA_16:** Use of decision support —ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

Group B: Modifications to Previously Finalized MVPs for the CY 2027 Performance Period/2029 MIPS Payment Year and Future Years

B.1: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP

Table B.1a represents the proposed MIPS core measures for the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP. The B.1b table, followed by a list of improvement activities, represents the measures and activities finalized within the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP (90 FR 50406 through 50408) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP focuses on important assessors of the care emergency clinicians provide to patients. By focusing on these specific measures and activities, emergency clinicians can reduce clinical variability, improve the quality of emergency care and potentially lower costs. This MVP would be most applicable to clinicians who treat patients within the practice of emergency medicine, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[504], we are proposing the following measures as MIPS core measures for the Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP:

- **Q116:** Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis
- **Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)
- **Q416:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years

We are proposing to add one MIPS quality measure:

- **Q066:** Appropriate Testing for Pharyngitis: This appropriate use MIPS quality measure assesses for completion of a group A streptococcus test for patients diagnosed with pharyngitis or tonsilitis who were prescribed an antibiotic.

For the reasons stated in the introduction of this appendix[505], we are proposing to remove **Q415:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older. We are proposing to remove one QCDR measure due to low adoption, no benchmark after 2 consecutive years in MIPS and one high performing QCDR measure:

- **ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Acute Atraumatic Low Back Pain (low adoption, no benchmark after 2 consecutive years in MIPS)
- **ECPR46:** Avoidance of Opiates for Low Back Pain or Migraines (high performing)

[504] See MVP Development: Quality Measure and Improvement Activity Updates
[505] Ibid.

Modifications are being considered for the following QCDR measure:

- **ACEP52:** Appropriate Emergency Department Utilization of Lumbar Spine Imaging for Acute Atraumatic Low Back Pain: If the measure is not finalized for removal in the CY 2027 PFS final rule, this QCDR measure would undergo modifications to the denominator to exclude patients aged 65 and older, as they experience higher rates of osteoporosis-related vertebral fractures during routine activities and have higher rates of malignancies with spinal metastases compared to patients under 65 years old.

Symbol Key:
Single exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.1a: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP MIPS Core Measures

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP MIPS Core Measures
Q116: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis
Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)
Q416: Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years

TABLE B.1b: Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP Clinical Groupings

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine MVP		
Clinical Grouping	**Quality**	**Cost**
Infectious Disease/ Antibiotic Stewardship	**Q065:** Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM, MIPS CQM)	**COST_EDV_1:** Emergency Medicine
	(+) Q066: Appropriate Testing for Pharyngitis (Collection Type: eCQM, MIPS CQM)	
	(!) Q116: Avoidance of Antibiotic Treatment for Acute Bronchitis/Bronchiolitis (Collection Type: MIPS CQM)	
	(!) Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQM)	
	HCPR24: Appropriate Utilization of Vancomycin for Cellulitis (Collection Type: QCDR)	
Trauma	**(!) Q416:** Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 Through 17 Years (Collection Type: MIPS CQM)	**COST_EDV_1:** Emergency Medicine
Experience of Care	**Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CMS-approved Survey Vendor)	**COST_EDV_1:** Emergency Medicine
	ACEP50: ED Median Time from ED arrival to ED departure for all Adult Patients (Collection Type: QCDR)	

Adopting Best Practices and Promoting Patient Safety within Emergency Medicine Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BMH_12:** Promoting Clinician Wellbeing
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **(!!) IA_PSPA_15:** Implementation of an ASP

B.2: Advancing Cancer Care MVP

Table B.2a represents the proposed MIPS core measures for the Advancing Cancer Care MVP. The B.2b table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Cancer Care MVP (90 FR 50408 through 50411) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Advancing Cancer Care MVP focuses on the clinical specialty of providing fundamental treatment and management of cancer care. This MVP would be most applicable to clinicians who treat patients within the practices of oncology and hematology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[506], we are proposing the following measures as MIPS core measures for the Advancing Cancer Care MVP:

- **Q102:** Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients
- **Q144:** Oncology: Medical and Radiation - Plan of Care for Pain
- **Q451:** RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy
- **Q457:** Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better)
- **Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood
- **Q506:** Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy

We are proposing to add two QCDR measures:

- **PIMSH19:** Antiemetic Therapy for Low- and Minimal-Emetic-Risk Antineoplastic Agents - Avoidance of Overuse (Lower Score - Better): This QCDR measure is an inverse measure (lower score is better) that ensures clinicians follow clinical guidelines for patients treated with low- or minimal-emetic-risk antineoplastic agents by assessing for inappropriate pre-treatment antiemetic therapy.
- **PIMSH20:** Appropriate Antiemetic Therapy for High- and Moderate-Emetic-Risk Antineoplastic Agents: This QCDR measure ensures clinicians follow clinical guidelines for patients treated with high- or moderate-emetic-risk antineoplastic agents by ensuring they receive the appropriate pre-treatment antiemetic therapy, which could result in improved control of nausea and vomiting in patients.

For the reasons stated in the introduction of this appendix[507], we are proposing to remove **Q143:** Oncology: Medical and Radiation – Pain Intensity Quantified.

Modifications are being considered for the following QCDR measure:

- **PIMSH13:** Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy: This QCDR measure is undergoing modifications to provide additional clarification and to emphasize its focus on first-line treatment. Updates are being made to the description, denominator, denominator exclusions, and numerator, along with the addition of a numerator note.

Improvement Activities

We are proposing to add one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix[508], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Single exclamation point (!): MIPS core measure within an MVP.

Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.

Single asterisk (*): existing measures and improvement activities with proposed revisions.

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[506] See MVP Development: Quality Measure and Improvement Activity Updates

[507] Ibid.

[508] Ibid.

Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.2a: Advancing Cancer Care MVP MIPS Core Measures

Advancing Cancer Care MVP MIPS Core Measures
Q102: Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients
Q144: Oncology: Medical and Radiation - Plan of Care for Pain
Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy
Q457: Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better)
Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood
Q506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy

TABLE B.2b: Advancing Cancer Care MVP Clinical Groupings

Advancing Cancer Care MVP		
Clinical Grouping	**Quality**	**Cost**
Medical Oncology	**Q450:** Appropriate Treatment for Patients with Stage I (T1c) – III HER2 Positive Breast Cancer (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(!) Q451: RAS (KRAS and NRAS) Gene Mutation Testing Performed for Patients with Metastatic Colorectal Cancer who receive Anti-epidermal Growth Factor Receptor (EGFR) Monoclonal Antibody Therapy (Collection Type: MIPS CQM)	
	Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM)	**COST_PC_1:** Prostate Cancer **TPCC_1:** Total Per Capita Cost
	Q490: Appropriate Intervention of Immune-related Diarrhea and/or Colitis in Patients Treated with Immune Checkpoint Inhibitors (Collection Type: MIPS CQM)	
	(!) Q506: Positive PD-L1 Biomarker Expression Test Result Prior to First-Line Immune Checkpoint Inhibitor Therapy (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(*) Q507: Appropriate Germline Testing for Ovarian Cancer Patients (Collection Type: MIPS CQM)	
	(*) PIMSH13: Oncology: Mutation Testing for Stage IV Lung Cancer Completed Prior to the Start of Targeted Therapy (Collection Type: QCDR)	
	PIMSH17: Oncology: Utilization of Prophylactic GCSF for Cancer Patients Receiving Low-Risk Chemotherapy (inverse measure) (Collection Type: QCDR)	**TPCC_1:** Total Per Capita Cost

Advancing Cancer Care MVP		
Clinical Grouping	**Quality**	**Cost**
	(+) PIMSH19: Antiemetic Therapy for Low- and Minimal-Emetic-Risk Antineoplastic Agents - Avoidance of Overuse (Lower Score - Better) (Collection Type: QCDR)	**COST_PC_1:** Prostate Cancer **TPCC_1:** Total Per Capita Cost
	(+) PIMSH20: Appropriate Antiemetic Therapy for High- and Moderate-Emetic-Risk Antineoplastic Agents (Collection Type: QCDR)	
Radiation Oncology	**(!)(*) Q102:** Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients (Collection Type: eCQM, MIPS CQM)	**COST_PC_1:** Prostate Cancer **TPCC_1:** Total Per Capita Cost
	(!)(*) Q144: Oncology: Medical and Radiation - Plan of Care for Pain (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_PC_1:** Prostate Cancer **TPCC_1:** Total Per Capita Cost
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_PC_1:** Prostate Cancer **TPCC_1:** Total Per Capita Cost
	Q321: CAHPS for MIPS Clinician/Group Survey (Collection Type: CMS-approved Survey Vendor)	
	(*) Q453: Percentage of Patients Who Died from Cancer Receiving Systemic Cancer-Directed Therapy in the Last 14 Days of Life (lower score – better) (Collection Type: MIPS CQM)	
	(!)(*) Q457: Percentage of Patients Who Died from Cancer Admitted to Hospice for Less than 3 days (lower score – better) (Collection Type: MIPS CQM)	
	(!) Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Advancing Cancer Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_24:** Financial Navigation Program
- **(!) IA_BMH_12:** Promoting Clinician Well-Being
- **(+)(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles
- **IA_CC_17:** Patient Navigator Program
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high-risk patients
- **IA_PM_15:** Implementation of episodic care management practice improvements
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative
- **(*) IA_PSPA_16:** Use of decision support —ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs

- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

B.3: Advancing Care for Heart Disease MVP

Table B.3a represents the proposed MIPS core measures for the Advancing Care for Heart Disease MVP. The B.3b table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Care for Heart Disease MVP (90 FR 50411 through 50415) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Advancing Care for Heart Disease MVP focuses on the clinical theme of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, heart disease. This MVP would be most applicable to clinicians who treat patients within the practices of cardiology, internal medicine and family medicine, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[509], we are proposing the following measures as MIPS core measures for the Advancing Care for Heart Disease MVP:

- **Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)
- **Q492:** Risk-standardized Acute Cardiovascular-related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System
- **TBD:** Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management

We are proposing to add one MIPS quality measure:

- **TBD:** Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management: This proposed intermediate outcome MIPS quality measure ensures lipid monitoring in patients with atherosclerotic cardiovascular disease (ASCVD) and achieving the target goal of an LDL-C less than 70mg/dL.

For the reasons stated in the introduction of this appendix[510], we are proposing to remove **Q006:** Coronary Artery Disease (CAD): Antiplatelet Therapy, **Q007:** Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%), and **Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy.

Improvement Activities

For the reasons stated in the introduction of this appendix[511], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): proposed new measure or improvement activity.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.

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[509] See MVP Development: Quality Measure and Improvement Activity Updates
[510] See MVP Development: Quality Measure and Improvement Activity Updates
[511] Ibid.

Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.3a: Advancing Care for Heart Disease MVP MIPS Core Measures

Advancing Care for Heart Disease MVP MIPS Core Measures
Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)
Q492: Risk-standardized Acute Cardiovascular-related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System
TBD: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management

TABLE B.3b: Advancing Care for Heart Disease MVP Clinical Groupings

Advancing Care for Heart Disease MVP		
Clinical Grouping	**Quality**	**Cost**
Congestive Heart Failure	**Q005:** Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) or Angiotensin Receptor-Neprilysin Inhibitor (ARNI) Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM, MIPS CQM)	**COST_HF_1:** Heart Failure **TPCC_1:** Total Per Capita Cost
	Q008: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD) (Collection Type: eCQM, MIPS CQM)	
	Q377: Functional Status Assessments for Heart Failure (Collection Type: eCQM)	
	(!) Q492: Risk-standardized Acute Cardiovascular-related Hospital Admission Rates for Patients with Heart Failure under the Merit-based Incentive Payment System (Collection Type: Administrative Claims)	
General Cardiology	**Q118:** Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF $\leq$ 40%) (Collection Type: MIPS CQM)	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **TPCC_1:** Total Per Capita Cost
	Q243: Cardiac Rehabilitation Patient Referral from an Outpatient Setting (Collection Type: MIPS CQM)	
	(!)(*) Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(!)(^)(+) TBD: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management	

Advancing Care for Heart Disease MVP		
Clinical Grouping	**Quality**	**Cost**
Electrophysiology	**(*) Q392:** Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q393: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision (Collection Type: MIPS CQM)	**COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **TPCC_1:** Total Per Capita Cost **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q238: Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_HF_1:** Heart Failure **COST_EOPCI_1:** Elective Outpatient Percutaneous Coronary Intervention (PCI) **COST_STEMI_1:** Inpatient (IP) Percutaneous Coronary Intervention (PCI) **TPCC_1:** Total Per Capita Cost **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Advancing Care for Heart Disease Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **IA_BE_24:** Financial Navigation Program
- **IA_BE_25:** Drug Cost Transparency
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program

- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PSPA_4:** Administration of the AHRQ Survey of Patient Safety Culture
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements

B.4: Advancing Rheumatology Patient Care MVP

Table B.4a represents the proposed MIPS core measures for the Advancing Rheumatology Patient Care MVP. The B.4b table, followed by a list of improvement activities, represents the measures and activities finalized within the Advancing Rheumatology Patient Care MVP (90 FR 50415 through 50418) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Advancing Rheumatology Patient Care MVP focuses on the clinical theme of providing fundamental treatment and management of rheumatological conditions. This MVP would be most applicable to clinicians who treat patients within the practice of rheumatology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[512], we are proposing the following measures as MIPS core measures for the Advancing Rheumatology Patient Care MVP:

- **Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age
- **Q178:** Rheumatoid Arthritis (RA): Functional Status Assessment
- **Q180:** Rheumatoid Arthritis (RA): Glucocorticoid Management

We are proposing to add one QCDR measure:

- **UREQA8:** Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved: This QCDR measure ensures that patients diagnosed with osteopenia or osteoporosis maintain a hydroxy-vitamin D level at or above the targeted threshold.

We are proposing to remove one process QCDR measure that does not include a quality action:

- **ACR12:** Disease Activity Measurement for Patients with PsA

Modifications are being considered for the following QCDR measures:

- **ACR10:** Hepatitis B Safety Screening: This QCDR measure is undergoing modifications to add denominator instructions that provide clearer guidance on what qualifies as a 'newly initiated' biologic.
- **ACR12:** Disease Activity Measurement for Patients with PsA: If the measure is not finalized for removal in the CY 2027 PFS final rule, this QCDR measure would undergo modifications to the denominator to add a specific age-related timeframe and clarify the required timeframe for the additional face-to-face encounter.
- **ACR14:** Gout: Serum Urate Target: This QCDR measure is undergoing modifications to the denominator to include a specific age-related timeframe. There would also be updates to the denominator exceptions to align with the American College of Rheumatology (ACR) clinical guidelines.
- **ACR15:** Safe Hydroxychloroquine Dosing: This QCDR measure is undergoing modifications to the description and numerator to add a second option for meeting numerator compliance. An alternative criterion, allowing completion and documentation

[512] See MVP Development: Quality Measure and Improvement Activity Updates

of an Hydroxychloroquine (HCQ) whole blood level measurement would satisfy numerator requirements.

Improvement Activities

We are proposing to add one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix[513], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.4a: Advancing Rheumatology Patient Care MVP MIPS Core Measures

Advancing Rheumatology Patient Care MVP MIPS Core Measures
Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age
Q178: Rheumatoid Arthritis (RA): Functional Status Assessment
Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management

[513] Ibid.

TABLE B.4b: Advancing Rheumatology Patient Care MVP Clinical Groupings

Advancing Rheumatology Patient Care MVP		
Clinical Grouping	**Quality**	**Cost**
Rheumatoid Arthritis	**Q177:** Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity (Collection Type: MIPS CQM)	**COST_RA_1:** Rheumatoid Arthritis **TPCC_1:** Total Per Capita Cost
	(!)(*) Q178: Rheumatoid Arthritis (RA): Functional Status Assessment (Collection Type: MIPS CQM)	
	(!) Q180: Rheumatoid Arthritis (RA): Glucocorticoid Management (Collection Type: MIPS CQM)	
Autoimmune/ Inflammatory Diseases	**(*) ACR14:** Gout: Serum Urate Target (Collection Type: QCDR)	**TPCC_1:** Total Per Capita Cost
	(*) ACR15: Safe Hydroxychloroquine Dosing (Collection Type: QCDR)	**COST_RA_1:** Rheumatoid Arthritis **TPCC_1:** Total Per Capita Cost
	UREQA10: Ankylosing Spondylitis: Controlled Disease Or Improved Disease Function (Collection Type: QCDR)	**TPCC_1:** Total Per Capita Cost
Advancing Health and Wellness	**(!) Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_RA_1:** Rheumatoid Arthritis **TPCC_1:** Total Per Capita Cost
	(*) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(*) Q176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQM)	
	(*) ACR10: Hepatitis B Safety Screening (Collection Type: QCDR)	
	(+) UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved (Collection Type: QCDR)	
	UREQA9: Screening for Osteoporosis for Men Aged 70 Years and Older (Collection Type: QCDR)	
	Q493: Adult Immunization Status (Collection Type: MIPS CQM)	
Experience of Care	**Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	**COST_RA_1:** Rheumatoid Arthritis **TPCC_1:** Total Per Capita Cost

Advancing Rheumatology Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_24:** Financial Navigation Program
- **IA_BE_25:** Drug Cost Transparency
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools

- **(!!) IA_BMH_2:** Tobacco use
- **(+)(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_28:** Completion of an Accredited Safety or Quality Improvement Program

B.5 Complete Ophthalmologic Care MVP

Table B.5a represents the proposed MIPS core measures for the Complete Ophthalmologic Care MVP. The B.5b table, followed by a list of improvement activities, represents the measures and activities finalized within the Complete Ophthalmologic Care MVP (90 FR 50418 through 50421) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. This MVP would be most applicable to clinicians who treat patients within the practices of ophthalmology and optometry, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[514], we are proposing the following measures as MIPS core measures for the Complete Ophthalmologic Care MVP:

- **Q012:** Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation
- **Q141:** Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care
- **Q304:** Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery
- **Q385:** Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery
- **Q501:** Acute posterior vitreous detachment and acute vitreous hemorrhage appropriate examination and follow-up

Modifications are being considered for the following QCDR measure:

- **IRIS2:** Glaucoma – Intraocular Pressure Reduction: This QCDR measure is undergoing modifications to ensure compliance is based upon assessment of intraocular pressure for each eye effected.

For the reasons stated in the introduction of this appendix[515], we are proposing to remove **Q384:** Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery. We are proposing to remove two high performing QCDR measures:

- **IRIS13:** Diabetic Macular Edema - Loss of Visual Acuity
- **IRIS54:** Complications After Cataract Surgery

Improvement Activities

We are proposing to add one improvement activity relevant to this MVP, which includes elements of an activity that is proposed for removal from MIPS:

- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements.

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[514] See MVP Development: Quality Measure and Improvement Activity Updates

[515] Ibid.

For the reasons stated in the introduction of this appendix[516], we are proposing to remove **IA_CC_10:** Care transition documentation practice improvements.

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.5a: Complete Ophthalmologic Care MVP MIPS Core Measures

Complete Ophthalmologic Care MVP MIPS Core Measures
Q012: Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation
Q141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care
Q304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery
Q385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery
Q501: Acute posterior vitreous detachment and acute vitreous hemorrhage appropriate examination and follow-up

TABLE B.5b: Complete Ophthalmologic Care MVP Clinical Groupings

Complete Ophthalmologic Care MVP		
Clinical Grouping	**Quality**	**Cost**
Cataract	**(*) Q191:** Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery (Collection Type: eCQM, MIPS CQM)	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	Q303: Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (Collection Type: MIPS CQM)	
	(!) Q304: Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery (Collection Type: MIPS CQM)	
	Q389: Cataract Surgery: Difference Between Planned and Final Refraction (Collection Type: MIPS CQM)	
	IRIS61: Visual Acuity Improvement Following Cataract Surgery and Minimally Invasive Glaucoma Surgery (Collection Type: QCDR)	
General Ophthalmology	**Q117:** Diabetes: Eye Exam (Collection Type: eCQM, MIPS CQM)	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	

[516] See MVP Development: Quality Measure and Improvement Activity Updates

Complete Ophthalmologic Care MVP		
Clinical Grouping	**Quality**	**Cost**
Retinal Disease	**Q019:** Diabetic Retinopathy: Communication with the Physician Managing Ongoing Diabetes Care (Collection Type: eCQM)	**N/A**
	(!) Q385: Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery (Collection Type: MIPS CQM)	
	Q499: Appropriate Screening and Plan of Care for Elevated Intraocular Pressure Following Intravitreal or Periocular Steroid Therapy (Collection Type: MIPS CQM)	
	Q500: Acute Posterior Vitreous Detachment Appropriate Examination and Follow-up (Collection Type: MIPS CQM)	
	(!) Q501: Acute Posterior Vitreous Detachment and Acute Vitreous Hemorrhage Appropriate Examination and Follow-up (Collection Type: MIPS CQM)	
	IRIS58: Improved Visual Acuity after Vitrectomy for Complications of Diabetic Retinopathy within 120 Days (Collection Type: QCDR)	
Glaucoma	**(!) Q012:** Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation (Collection Type: eCQM)	**N/A**
	(!)(*) Q141: Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 20% OR Documentation of a Plan of Care (Collection Type: Medicare Part B Claims, MIPS CQM)	
	(*) IRIS2: Glaucoma – Intraocular Pressure Reduction (Collection Type: QCDR)	
	IRIS39: Intraocular Pressure Reduction Following Trabeculectomy or an Aqueous Shunt Procedure (Collection Type: QCDR)	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
Experience of Care	**Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	**COST_IOL_1** Cataract Removal with Intraocular Lens (IOL) Implantation

Complete Ophthalmologic Care Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_25:** Drug Cost Transparency
- **(+)(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations

- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements

B.6: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP

Table B.6a represents the proposed MIPS core measures for the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP. The B.6b table, followed by a list of improvement activities, represents the measures and activities finalized within the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP (90 FR 50422 through 50424) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP focuses on the clinical theme of providing fundamental prevention and treatment of those patients at risk for or have had a stroke. This MVP would be most applicable to clinicians who treat patients within the practices of neurology, neurosurgical, and vascular surgery, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[517], we are proposing the following measures as MIPS core measures for the Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP:

- **Q047:** Advance Care Plan
- **Q236:** Controlling High Blood Pressure
- **Q441:** Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control).

For the reasons stated in the introduction of this appendix[518], we are proposing to remove **Q326:** Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy.

Symbol Key:

Exclamation point (!): MIPS core measures within MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.6a: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP MIPS Core Measures

[517] See MVP Development: Quality Measure and Improvement Activity Updates
[518] See MVP Development: Quality Measure and Improvement Activity Updates

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP MIPS Core Measures
Q047: Advance Care Plan
Q236: Controlling High Blood Pressure
Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control)

TABLE B.6b: Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP Clinical Groupings

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes MVP		
Clinical Grouping	**Quality**	**Cost**
Stroke Prevention	**(!)(*) Q236:** Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q344: Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQM)	
	(*) Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	
	(!)(*) Q441: Ischemic Vascular Disease (IVD) All or None Outcome Measure (Optimal Control) (Collection Type: MIPS CQM)	
Stroke Care	**Q187:** Stroke and Stroke Rehabilitation: Thrombolytic Therapy (Collection Type: MIPS CQM)	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q413: Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQM)	
Experience of Care	**(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	

Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_24:** Financial Navigation Program
- **IA_BMH_l5:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_CC_17:** Patient Navigator Program
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_l5:** Implementation of episodic care management practice improvements

B.7: Dermatological Care MVP

Table B.7a represents the proposed MIPS core measures for the Dermatological MVP. The B.7b table, followed by a list of improvement activities, represents the measures and activities finalized within the Dermatological MVP (90 FR 50424 through 50428) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Dermatological Care MVP focuses on the clinical theme of providing treatment and management of dermatologic care. This MVP would be most applicable to clinicians who treat patients within the practice of dermatology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP

maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[519], we are proposing the following measures as MIPS core measures for the Dermatological Care MVP:

- **Q176:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy
- **Q410:** Psoriasis: Clinical Response to Systemic Medications
- **Q486:** Dermatitis – Improvement in Patient-Reported Itch Severity

We are proposing to remove one high performing QCDR measure:

- **AAD16:** Avoidance of Post-operative Systemic Antibiotics for Office-based Closures and Reconstruction After Skin Cancer Procedures

Modifications are being considered for the following QCDR measures:

- **AAD6:** Skin Cancer: Biopsy Reporting Time - Clinician to Patient: This QCDR measure is undergoing modifications to update the description and numerator to reflect a shortened timeframe for clinician notification of final pathology findings, reducing the requirement from 8 days to 7 days.
- **AAD12:** Melanoma: - Appropriate Surgical Margins: This QCDR measure is undergoing modifications to update the title, description, denominator, and numerator to reflect a broader measure that would include additional skin cancers, specifically squamous cell carcinoma and basal cell carcinoma.

Improvement Activities

We are proposing to add one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix[520], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.7a: Dermatological Care MVP MIPS Core Measures

[519] See MVP Development: Quality Measure and Improvement Activity Updates
[520] Ibid.

Dermatological Care MVP MIPS Core Measures
Q176: Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy
Q410: Psoriasis: Clinical Response to Systemic Medications
Q486: Dermatitis – Improvement in Patient-Reported Itch Severity

TABLE B.7b: Dermatological Care MVP Clinical Groupings

Dermatological Care MVP		
Clinical Grouping	**Quality**	**Cost**
Skin Cancer	**(*) Q397:** Melanoma Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_MR_1:** Melanoma Resection
	(*) Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician (Collection Type: MIPS CQM)	
	(*) Q509: Melanoma: Tracking and Evaluation of Recurrence (Collection Type: MIPS CQM)	
	(*) **AAD12:** Melanoma: - Appropriate Surgical Margins (Collection Type: QCDR)	
	(*) AAD6: Skin Cancer: Biopsy Reporting Time – Clinician to Patient (Collection Type: QCDR)	
Inflammatory Conditions	**(!)(*) Q176:** Tuberculosis Screening Prior to First Course of Biologic and/or Immune Response Modifier Therapy (Collection Type: MIPS CQM)	**N/A**
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_MR_1:** Melanoma Resection
	(!) Q410: Psoriasis: Clinical Response to Systemic Medications (Collection Type: MIPS CQM)	**N/A**
	Q485: Psoriasis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQM)	
	(!) Q486: Dermatitis – Improvement in Patient-Reported Itch Severity (Collection Type: MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_MR_1:** Melanoma Resection
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	
	AAD8: Chronic Skin Conditions: Patient Reported Quality-of-Life (Collection Type: QCDR)	
Advancing Health and Wellness	**Q238:** Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	**COST_MR_1:** Melanoma Resection

Dermatological Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(+)(*)(!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(!!) IA_EPA_8:** Provide Education Opportunities for New Clinicians

- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PSPA_8:** Use of Patient Safety Tools

B.8 Diagnostic Radiology MVP

Table B.8a represents the proposed MIPS core measures for the Diagnostic Radiology MVP. The B.8b table, followed by a list of improvement activities, represents the measures and activities finalized within the Diagnostic Radiology MVP (90 FR 50376 through 50381) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Diagnostic Radiology MVP assesses meaningful outcomes in diagnostic radiology. This MVP would be most applicable to clinicians who treat patients within the practices of diagnostic radiology and nuclear medicine. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[521], we are proposing the following measures as MIPS core measures for the Diagnostic Radiology MVP:

- **Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy
- **Q360:** Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies
- **Q405:** Appropriate Follow-up Imaging for Incidental Abdominal Lesions

We are proposing to add four MIPS quality measures to the new Nuclear Medicine clinical grouping:

- **Q282:** Dementia: Functional Status Assessment: This MIPS quality measure focuses on the importance of ensuring that patients diagnosed with dementia receive a comprehensive functional assessment annually.
- **Q286:** Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia: This MIPS quality measure aims to address safety concerns in patients diagnosed with dementia by ensuring that appropriate screening and follow-up actions are conducted.
- **Q288:** Dementia: Education and Support of Caregivers for Patients with Dementia: This MIPS quality measure focuses on the importance of providing education and support to caregivers of patients with Dementia.
- **Q386:** Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences: This MIPS quality measure focuses on the importance of addressing end-of-life care preferences for patients diagnosed with ALS.

We are proposing to add one QCDR measure:

- **ACRAD34:** Multi-strata weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT abdomen-pelvis with contrast/single-phase scan, CT chest without contrast/single-phase scan, and CT head/brain without contrast/single-phase scan): This QCDR measure ensures that all CT scans—abdomen-pelvis with contrast, chest without contrast, and head/brain single-phase—maintain a Dose Length Product at or below the established threshold to help manage patient radiation exposure.

[521] See MVP Development: Quality Measure and Improvement Activity Updates

Improvement Activities

For the reasons stated in the introduction of this appendix[522], we are proposing to remove **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings and **IA_PSPA_2:** Participation in MOC Part IV.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.8a: Diagnostic Radiology MVP MIPS Core Measures

Diagnostic Radiology MVP MIPS Core Measures
Q145: Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy
Q360: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies
Q405: Appropriate Follow-up Imaging for Incidental Abdominal Lesions

TABLE B.8b: Diagnostic Radiology MVP Clinical Groupings

Diagnostic Radiology MVP		
Clinical Grouping	**Quality**	**Cost**
General Diagnostic Radiology	**(!) Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy (Collection Type: MIPS CQM, Medicare Part B Claims)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q360: Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies (Collection Type: MIPS CQM)	
	Q494: Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Clinician Level) (Collection Type: eCQM)	
	(+) ACRAD34: Multi-strata weighted average for 3 CT Exam Types: Overall Percent of CT exams for which Dose Length Product is at or below the size-specific diagnostic reference level (for CT abdomen-pelvis with contrast/single-phase scan, CT chest without contrast/single-phase scan, and CT head/brain without contrast/single-phase scan) (Collection Type: QCDR)	
Body Imaging (Thoracic/Abdominal)	**Q364:** Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines (Collection Type: MIPS CQM)	**N/A**

[522] See MVP Development: Quality Measure and Improvement Activity Updates

Diagnostic Radiology MVP		
Clinical Grouping	**Quality**	**Cost**
	(!) Q405: Appropriate Follow-up Imaging for Incidental Abdominal Lesions (Collection Type: Medicare Part B Claims, MIPS CQM)	
	Q406: Appropriate Follow-up Imaging for Incidental Thyroid Nodules (Collection Type: Medicare Part B Claims, MIPS CQM)	
	QMM17: Appropriate Follow-up Recommendations for Ovarian-Adnexal Lesions using the Ovarian-Adnexal Reporting and Data System (O-RADS) (Collection Type: QCDR)	
Nuclear Medicine	**(+) Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQM)	**N/A**
	(+) Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM)	
	(+)(*) Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM)	
	(+) Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**QMM18:** Use of Breast Cancer Risk Score on Mammography (Collection Type: QCDR)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	QMM26: Screening Abdominal Aortic Aneurysm Reporting with Recommendations (Collection Type: QCDR)	

Diagnostic Radiology Improvement Activities

- **IA_BE_6**: Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BMH_12**: Promoting Clinician Well-Being
- **IA_CC_7**: Regular training in care coordination
- **(*) IA_CC_8**: Implementation of documentation improvements for practice/process improvements
- **IA_CC_19**: Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(**) IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1**: Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_7**: Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_12**: Participation in private payer CPIA

B.9: Focusing on Women's Health MVP

Table B.9a represents the proposed MIPS core measures for the Focusing on Women's Health MVP. The B.9b table, followed by a list of improvement activities, represents the measures and activities finalized within the Women's Health MVP (90 FR 50428 through 50430) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Focusing on Women's Health MVP focuses on the clinical specialty of providing treatment and management of women's health. This MVP would be most applicable to clinicians who treat patients within the practices of gynecology, obstetrics, and urogynecology, including NPPs such as certified nurse-midwives, nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which

measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[523], we are proposing the following measures as MIPS core measures for the Focusing on Women's Health MVP:

- **Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age
- **Q112:** Breast Cancer Screening
- **Q432:** Proportion of Patients Sustaining a Bladder or Bowel Injury at the Time of any Pelvic Organ Prolapse Repair

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.9a: Focusing on Women's Health MVP MIPS Core Measures

Focusing on Women's Health MVP MIPS Core Measures
Q039: Screening for Osteoporosis for Women Aged 65-85 Years of Age
Q112: Breast Cancer Screening
Q432: Proportion of Patients Sustaining a Bladder or Bowel Injury at the Time of any Pelvic Organ Prolapse Repair

TABLE B.9b: Focusing on Women's Health MVP Clinical Groupings

Focusing on Women's Health MVP		
Clinical Grouping	**Quality**	**Cost**
Obstetrics	**Q335:** Maternity Care: Elective Delivery (Without Medical Indication) at < 39 Weeks (Overuse) (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q336: Maternity Care: Postpartum Follow-up and Care Coordination (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **TPCC_1:** Total Per Capita Cost
	Q496: Cardiovascular Disease (CVD) Risk Assessment Measure - Proportion of Pregnant/Postpartum Patients that Receive CVD Risk Assessment with a Standardized Instrument (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
Gynecology	**Q422:** Performing Cystoscopy at the Time of Hysterectomy for Pelvic Organ Prolapse to Detect Lower Urinary Tract Injury (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

[523] See MVP Development: Quality Measure and Improvement Activity Updates

Focusing on Women's Health MVP		
Clinical Grouping	**Quality**	**Cost**
	(!) Q432: Proportion of Patients Sustaining a Bladder or Bowel Injury at the Time of any Pelvic Organ Prolapse Repair (Collection Type: MIPS CQM)	
	Q448: Appropriate Workup Prior to Endometrial Ablation (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(!) Q039:** Screening for Osteoporosis for Women Aged 65-85 Years of Age (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **TPCC_1:** Total Per Capita Cost
	Q048: Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	
	(!)(**) Q112: Breast Cancer Screening (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q309: Cervical Cancer Screening (Collection Type: eCQM)	
	Q310: Chlamydia Screening in Women (Collection Type: eCQM)	
	Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	
	Q431: Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (Collection Type: MIPS CQM)	
	(*) Q475: HIV Screening (Collection Type: eCQM)	
	Q493: Adult Immunization Status (Collection Type: MIPS CQM)	
	UREQA8: Vitamin D level: Effective Control of Low Bone Mass/Osteopenia and Osteoporosis: Therapeutic Level Of 25 OH Vitamin D Level Achieved (Collection Type: QCDR)	

Focusing on Women's Health Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_BMH_11:** Implementation of a Trauma-Informed Care (TIC) Approach to Clinical Practice
- **(!!) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations

- **(**) IA_MVP:** Practice-Wide Quality Improvement in the MIPS Value Pathways Program
- **(!!) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines

B.10: Gastroenterology Care MVP

Table B.10a represents the proposed MIPS core measures for the Gastroenterology Care MVP. The B.10b table, followed by a list of improvement activities, represents the measures and activities finalized within the Gastroenterology Care MVP (90 FR 50430 through 50434) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Gastroenterology Care MVP focuses on the clinical theme of providing treatment and management of the digestive system and the liver. This MVP would be most applicable to clinicians who treat patients within the practice of gastroenterology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality and cost measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[524], we are proposing the following measures as MIPS core measures for the Gastroenterology Care MVP:

- **Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
- **Q275:** Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy
- **Q516:** Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

For the reasons stated in the introduction of this appendix[525], we are proposing to remove **Q320:** Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients. We are proposing to remove one high performing QCDR measure:

- **NHCR4:** Repeat screening or surveillance colonoscopy recommended within one year due to inadequate bowel preparation.

Modifications are being considered for the following QCDR measures:

- **GIQIC23:** Appropriate follow-up interval based on pathology findings in screening colonoscopy: This QCDR measure is undergoing modifications to ensure patients are receiving appropriate follow up within the recommended timeframe.

Improvement Activities

We are proposing to add one improvement activity relevant to this MVP:

- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements.

For the reasons stated in the introduction of this appendix[526], we are proposing to remove **IA_CC_10:** Care transition documentation practice improvements.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.

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[524] See MVP Development: Quality Measure and Improvement Activity Updates

[525] Ibid.

[526] Ibid.

Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.10a: Gastroenterology Care MVP MIPS Core Measures

Gastroenterology Care MVP MIPS Core Measures
Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention
Q275: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy
Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

TABLE B.10b: Gastroenterology Care MVP Clinical Groupings

Gastroenterology Care MVP		
Clinical Grouping	**Quality**	**Cost**
Interventional/ Endoscopy	**GIQIC26:** Screening Colonoscopy Adenoma Detection Rate (Collection Type: QCDR)	**COST_SSC_1:** Screening/Surveillance Colonoscopy
	N/A	**COST_LGH_1:** Lower Gastrointestinal Hemorrhage
Hepatobiliary	**Q400:** One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQM)	
	(!) Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR) (Collection Type: MIPS CQM)	
Inflammatory	**(!) Q275**: Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
General Gastroenterology	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	**COST_SSC_1:** Screening/Surveillance Colonoscopy **TPCC_1:** Total Per Capita Cost **COST_LGH_1:** Lower Gastrointestinal Hemorrhage
Advancing Health and Wellness	**(**) Q113:** Colorectal Cancer Screening (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_SSC_1:** Screening/Surveillance Colonoscopy **TPCC_1:** Total Per Capita Cost
	(*) Q130: Documentation of Current Medications in the Medical Record	

Gastroenterology Care MVP		
Clinical Grouping	**Quality**	**Cost**
	(Collection Type: eCQM, MIPS CQM)	**COST_LGH_1:** Lower Gastrointestinal Hemorrhage
	(!) Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(*) GIQIC23: Appropriate follow-up interval based on pathology findings in screening colonoscopy (Collection Type: QCDR)	
Experience of Care	**Q503:** Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	**COST_SSC_1:** Screening/Surveillance Colonoscopy **TPCC_1:** Total Per Capita Cost **COST_LGH_1:** Lower Gastrointestinal Hemorrhage

Gastroenterology Care Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7:** Regular training in care coordination
- **(+)(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(!!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways

B.11: Improving Care for Lower Extremity Joint Repair MVP

Table B.11a represents the proposed MIPS core measures for the Improving Care for Lower Extremity Joint Repair MVP. The B.11b table, followed by a list of improvement activities, represents the measures and activities finalized within the Improving Care for Lower Extremity Joint Repair MVP (90 FR 50434 through 50435) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Improving Care for Lower Extremity Joint Repair MVP focuses on the clinical theme of providing fundamental treatment and management of patients with osteoarthritis and lower extremity surgical repair, such as fracture and total joint replacement, to ensure appropriate care and reduce costs. This MVP would be most applicable to clinicians who treat patients within the practice of orthopedic surgery, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[527], we are proposing the following measures as MIPS core measures for the Improving Care for Lower Extremity Joint Repair

[527] See MVP Development: Quality Measure and Improvement Activity Updates

MVP:

- **Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation
- **Q470:** Functional Status After Primary Total Knee Replacement
- **Q480:** Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

For the reasons stated in the introduction of this appendix[528], we are proposing to remove **Q350:** Total Knee or Hip Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy.

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.11a: Improving Care for Lower Extremity Joint Repair MVP MIPS Core Measures

Improving Care for Lower Extremity Joint Repair MVP MIPS Core Measures
Q351: Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation
Q470: Functional Status After Primary Total Knee Replacement
Q480: Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS)

[528] See MVP Development: Quality Measure and Improvement Activity Updates

TABLE B.11b: Improving Care for Lower Extremity Joint Repair MVP Clinical Groupings

Improving Care for Lower Extremity Joint Repair MVP		
Clinical Grouping	**Quality**	**Cost**
Non-Surgical	**Q024:** Communication with the Physician or Other Clinician Managing On-Going Care Post-Fracture for Men and Women Aged 50 Years and Older (Collection Type: Medicare Part B Claims, MIPS CQM)	**N/A**
Surgical	**(!) Q351:** Total Knee or Hip Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation (Collection Type: MIPS CQM)	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty
	Q376: Functional Status Assessments for Total Hip Replacement (Collection Type: eCQM)	**COST_PHA_1:** Elective Primary Hip Arthroplasty
	(!) Q470: Functional Status After Primary Total Knee Replacement (Collection Type: MIPS CQM)	**COST_KA_1:** Knee Arthroplasty
	(!) Q480: Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) for Merit-based Incentive Payment System (MIPS) (Collection Type: Administrative Claims)	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_PHA_1:** Elective Primary Hip Arthroplasty **COST_KA_1:** Knee Arthroplasty

Improving Care for Lower Extremity Joint Repair Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7:** Regular training in care coordination
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice Improvements to Align with OpenNotes Principles
- **IA_CC_15:** PSH Care Coordination
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level

B.12 Interventional Radiology MVP

Table B.12a represents the proposed MIPS core measures for the Interventional Radiology MVP. The B.12b table, followed by a list of improvement activities, represents the measures and activities finalized within the Interventional Radiology MVP (90 FR 50381 through 50386) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Interventional Radiology MVP assesses meaningful outcomes in interventional radiology. This MVP would be most applicable to clinicians who treat patients within the practice of interventional radiology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance

period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[529], we are proposing the following measures as MIPS core measures for the Interventional Radiology MVP:

- **Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy
- **Q413:** Door to Puncture Time for Endovascular Stroke Treatment
- **Q420:** Varicose Vein Treatment with Saphenous Ablation: Outcome Survey

Improvement Activities

We are proposing to remove one improvement activity as the activity is more relevant to general surgery and surgical subspecialties:

- **IA_CC_15:** PSH Care Coordination

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.12a: Interventional Radiology MVP MIPS Core Measures

Interventional Radiology MVP MIPS Core Measures
Q145: Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy
Q413: Door to Puncture Time for Endovascular Stroke Treatment
Q420: Varicose Vein Treatment with Saphenous Ablation: Outcome Survey

[529] See MVP Development: Quality Measure and Improvement Activity Updates

TABLE B.12b: Interventional Radiology MVP Clinical Groupings

Interventional Radiology MVP		
Clinical Grouping	**Quality**	**Cost**
Vascular	**(!) Q420:** Varicose Vein Treatment with Saphenous Ablation: Outcome Survey (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q421: Appropriate Assessment of Retrievable Inferior Vena Cava (IVC) Filters for Removal (Collection Type: MIPS CQM)	
	Q465: Uterine Artery Embolization Technique: Documentation of Angiographic Endpoints and Interrogation of Ovarian Arteries (Collection Type: MIPS CQM)	
Dialysis-Related	**RCOIR12:** Tunneled Hemodialysis Catheter Clinical Success Rate (Collection Type: QCDR)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	RCOIR13: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate (Collection Type: QCDR)	
	RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate (Collection Type: QCDR)	
	RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate (Collection Type: QCDR)	
Neurological Intervention	**(!) Q413:** Door to Puncture Time for Endovascular Stroke Treatment (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_IHCI_1:** Intracranial Hemorrhage or Cerebral Infarction
General Interventional Radiology	**(!) Q145:** Radiology: Exposure Dose Indices Reported for Procedures Using Fluoroscopy (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	(*) Q374: Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	

Interventional Radiology Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!!) IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_7:** Regular training in care coordination
- **(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_17:** Patient Navigator Program
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **(!!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP**: Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_17:** Participation in Population Health Research
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization.

- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_25:** Cost Display for Laboratory and Radiographic Orders

B.13 Neuropsychology MVP

Table B.13a represents the proposed MIPS core measures for the Neuropsychology MVP. The B.13b table, followed by a list of improvement activities, represents the measures and activities finalized within the Neuropsychology MVP (90 FR 50386 through 50390) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Neuropsychology MVP focuses on the clinical specialty of providing treatment and management of neuropsychological care. This MVP would be most applicable to clinicians who treat patients within the practice of neuropsychology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[530], we are proposing the following measures as MIPS core measures for the Neuropsychology MVP:

- **Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan
- **Q181:** Elder Maltreatment Screen and Follow-up Plan
- **Q282:** Dementia: Functional Status Assessment

Improvement Activities

For the reasons stated in the introduction of this appendix[531], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.13a: Neuropsychology MVP MIPS Core Measures

Neuropsychology MVP MIPS Core Measures
Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan
Q181: Elder Maltreatment Screen and Follow-up Plan
Q282: Dementia: Functional Status Assessment

[530] See MVP Development: Quality Measure and Improvement Activity Updates
[531] Ibid.

TABLE B.13b: Neuropsychology MVP Clinical Groupings

Neuropsychology MVP		
Clinical Grouping	**Quality**	**Cost**
Neurodegenerative Disorders	**(!) Q282:** Dementia: Functional Status Assessment (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **TPCC_1:** Total Per Capita Cost
	Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM)	
	(*) Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **TPCC_1:** Total Per Capita Cost
	(!)(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(!) Q181: Elder Maltreatment Screen and Follow-up Plan (Collection Type: Medicare Part B Claims, MIPS CQM	

Neuropsychology Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(!!) IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_22:** Improved Practices that Engage Patients Pre-Visit
- **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **(*) IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_21:** Advance Care Planning

B.14: Optimal Care for Kidney Health MVP

Table B.14a represents the proposed MIPS core measures for the Optimal Care for Kidney Health MVP. The B.14b table, followed by a list of improvement activities, represents the measures and activities finalized within the Optimal Care for Kidney Health MVP (90 FR 50435 through 50438) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Optimal Care for Kidney Health MVP focuses on the clinical specialty of providing fundamental treatment and management of costly clinical conditions that contribute to, or may result from, kidney disease. This MVP would be most applicable to clinicians who treat patients within the practice of nephrology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[532], we are proposing the following measures as MIPS core measures for the Optimal Care for Kidney Health MVP:

- **Q236:** Controlling High Blood Pressure

[532] See MVP Development: Quality Measure and Improvement Activity Updates

- **Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate
- **Q489:** Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Improvement Activities

We are proposing to add one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix[533], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.14a: Optimal Care for Kidney Health MVP MIPS Core Measures

Optimal Care for Kidney Health MVP MIPS Core Measures
Q236: Controlling High Blood Pressure
Q482: Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate
Q489: Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

TABLE B.14b: Optimal Care for Kidney Health MVP Clinical Groupings

Optimal Care for Kidney Health MVP		
Clinical Grouping	**Quality**	**Cost**
General Nephrology	**(*) Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management
	(!)(*) Q236: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	

[533] Ibid.

Optimal Care for Kidney Health MVP		
Clinical Grouping	**Quality**	**Cost**
		TPCC_1: Total Per Capita Cost
	Q488: Kidney Health Evaluation (Collection Type: eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(!) Q489: Adult Kidney Disease: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (Collection Type: MIPS CQM)	**COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **TPCC_1:** Total Per Capita Cost
Dialysis/Transplant	**(!) Q482:** Hemodialysis Vascular Access: Practitioner Level Long-term Catheter Rate (Collection Type: MIPS CQM)	**COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **TPCC_1:** Total Per Capita Cost
	Q510: First Year Standardized Waitlist Ratio (FYSWR) (Collection Type: MIPS CQM)	**COST_ESRD_1:** End-Stage Renal Disease **TPCC_1:** Total Per Capita Cost
	Q511: Percentage of Prevalent Patients Waitlisted for Kidney Transplant (PPPW) and Percentage of Prevalent Patients Waitlisted for Kidney Transplant in Active Status (aPPPW) (Collection Type: MIPS CQM)	
	Q512: Prevalent Standardized Kidney Transplant Waitlist Ratio (PSWR) (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management **TPCC_1:** Total Per Capita Cost
	Q493: Adult Immunization Status (Collection Type: MIPS CQM)	

Optimal Care for Kidney Health MVP		
Clinical Grouping	**Quality**	**Cost**
Experience of care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_AKID_1:** Acute Kidney Injury Requiring New Inpatient Dialysis **COST_CKD_1:** Chronic Kidney Disease (CKD) **COST_ESRD_1:** End-Stage Renal Disease **COST_KTM_1:** Kidney Transplant Management **TPCC_1:** Total Per Capita Cost
	Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Optimal Care for Kidney Health Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_14:** Engage Patients and Families to Guide Improvement in the System of Care
- **(!!) IA_BE_16**: Promote Self-management in Usual Care
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(+)(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13**: Practice Improvements to Align with OpenNotes Principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular Review Practices in Place on Targeted Patient Population Needs
- **IA_PM_16:** Implementation of medication management practice improvements
- **(*) IA_PSPA_16:** Use of decision support —ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs

B.15: Optimal Care for Patients with Urologic Conditions MVP

Table B.15a represents the proposed MIPS core measures for the Optimal Care for Patients with Urologic Conditions MVP. The B.15b table, followed by a list of improvement activities, represents the measures and activities finalized within the Optimal Care for Patients with Urologic Conditions MVP (90 FR 50438 through 50441) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Optimal Care for Patients with Urologic Conditions MVP focuses on assessing optimal care for patients treated for a broad range of urologic conditions, including kidney stones, urinary incontinence, bladder cancer, and prostate cancer. This MVP would be most applicable to clinicians who treat patients within the practices of urology, general urologists, urology oncologists, and urogynecology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[534], we are proposing the following measures as MIPS core measures for the Optimal Care for Patients with Urologic Conditions MVP:

- **Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older
- **Q358:** Patient-Centered Surgical Risk Assessment and Communication
- **Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

We are proposing to remove two high performance QCDR measures, one process QCDR measure, and one QCDR measure due to low adoption, no benchmark after 2 consecutive years in MIPS:

- **AQUA8:** Hospital Admissions or Infectious Complications Within 30 days of Prostate Biopsy (high performing)
- **AQUA14:** Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment (high performing)
- **AQUA15:** Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures (process measure)
- **AQUA16:** Non-Muscle Invasive Bladder Cancer: Repeat Transurethral Resection of Bladder Tumor (TURBT) for T1 Disease (low adoption, no benchmark after 2 consecutive years in MIPS)

Modifications are being considered for the following QCDR measures:

- **AQUA14:** Stones: Repeat Shock Wave Lithotripsy (SWL) Within 6 Months of Initial Treatment: If the measure is not finalized for removal in the CY 2027 PFS final rule, this QCDR measure would undergo modifications to the title, description, and numerator to align with the American Urological Association (AUA) updated clinical guidelines, which recommend a second SWL or ureteroscopy (URS) when the initial SWL does not achieve complete clearance.
- **AQUA15:** Stones: Urinalysis or Urine Culture Performed Before Surgical Stone Procedures: If the measure is not finalized for removal in the CY 2027 PFS final rule, this QCDR measure would undergo modifications to add a quality action to the numerator to ensure abnormal results are appropriately addressed.
- **MUSIC4:** Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low Risk Prostate Cancer Patients: This QCDR measure is undergoing modifications to ensure patients newly diagnosed with low-risk prostate cancer on active surveillance undergo a confirmation biopsy within 24 months of their diagnosis.

Improvement Activities

We are proposing to add two improvement activities relevant to this MVP, both of which include an advancing health and wellness component:

- **IA_BE_16:** Promote Self-management in Usual Care
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix[535], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

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[534] See MVP Development: Quality Measure and Improvement Activity Updates

[535] See MVP Development: Quality Measure and Improvement Activity Updates

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.15a: Optimal Care for Patients with Urologic Conditions MVP MIPS Core Measures

Optimal Care for Patients with Urologic Conditions MVP MIPS Core Measures
Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older
Q358: Patient-Centered Surgical Risk Assessment and Communication
Q462: Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy

TABLE B.15b: Optimal Care for Patients with Urologic Conditions MVP Clinical Groupings

Optimal Care for Patients with Urologic Conditions MVP		
Clinical Grouping	**Quality**	**Cost**
Urological Cancer	**(!) Q462:** Bone Density Evaluation for Patients with Prostate Cancer and Receiving Androgen Deprivation Therapy (Collection Type: eCQM)	**COST_PC_1:** Prostate Cancer **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q476: Urinary Symptom Score Change 6-12 Months After Diagnosis of Benign Prostatic Hyperplasia (Collection Type: eCQM)	
	(*) Q481: Intravesical Bacillus-Calmette Guerin for Non-muscle Invasive Bladder Cancer (Collection Type: eCQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) MUSIC4: Prostate Cancer: Active Surveillance/Watchful Waiting for Newly Diagnosed Low Risk Prostate Cancer Patients (Collection Type: QCDR)	**COST_PC_1:** Prostate Cancer **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
General Urology	**(!) Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	**COST_RUSST_1:** Renal or Ureteral Stone Surgical Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**Q318:** Falls: Screening for Future Fall Risk (Collection Type: eCQM)	**COST_PC_1:** Prostate Cancer **COST_RUSST_1:** Renal or Ureteral Stone Surgical Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**Q321:** CAHPS for MIPS Clinician/Group Survey (Collection Type: CMS-approved Survey Vendor)	**COST_PC_1:** Prostate Cancer **COST_RUSST_1:** Renal or Ureteral Stone Surgical Treatment **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Optimal Care for Patients with Urologic Conditions Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(+)(!!) IA_BE_16:** Promote Self-management in Usual Care
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_7**: Regular training in care coordination
- **(+)(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **IA_CC_17:** Patient Navigator Program
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_17:** Participation in Population Health Research
- **IA_PM_21:** Advance Care Planning

- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_12:** Participation in private payer CPIA
- **IA_PSPA_21:** Implementation of fall screening and assessment programs

B.16 Pathology MVP

Table B.16a represents the proposed MIPS core measures for the Pathology MVP. The B.16b table, followed by a list of improvement activities, represents the measures and activities finalized within the Pathology MVP (90 FR 50390 through 50395) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Pathology MVP focuses on assessing meaningful outcomes in pathology. This MVP would be most applicable to pathology clinicians. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[536], we are proposing the following measures as MIPS core measures for the Pathology MVP:

- **Q396:** Lung Cancer Reporting (Resection Specimens)
- **Q440:** Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician
- **Q491:** Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status

We are proposing to add one QCDR measure that is relevant to this MVP:

- **QMM33:** Immunohistochemistry (IHC) and/or Molecular BRAF Testing Status in Metastatic Melanoma: This QCDR measure ensures that pathologists include a recommendation for BRAF testing, documentation of current or prior BRAF test results, or confirmation that BRAF testing is pending in all final immunohistochemical staining reports for patients with an initial diagnosis of metastatic melanoma.

We are proposing to remove one QCDR measure due to low adoption, no benchmark after 2 consecutive years in MIPS:

- **QMM25:** Use of Structured Reporting for Urine Cytology Specimens

Modifications are being considered for the following QCDR measures:

- **CAP30:** Urinary Bladder Cancer: Complete Analysis and Timely Reporting: This QCDR measure is undergoing modifications to the title and description to clarify the quality action in relation to patient outcomes and the overarching goal of supporting informed treatment decisions.

Improvement Activities

We are proposing to add four additional improvement activities relevant to this MVP, all of which include an advancing health and wellness component:

- **IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **IA_CC_XX:** Use of Data to Improve Practice Workflows
- **IA_CC_XX:** Understand and Improve Diagnostic Performance
- **IA_ EPA_8:** Provide Education Opportunities for New Clinicians

[536] See MVP Development: Quality Measure and Improvement Activity Updates

For the reasons stated in the introduction of this appendix[537], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care, **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings and **IA_PSPA_2:** Participation in MOC Part IV.

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): proposed new measure or improvement activity.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.16a: Pathology MVP MIPS Core Measures

Pathology MVP MIPS Core Measures
Q396: Lung Cancer Reporting (Resection Specimens)
Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician
Q491: Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status

[537] See MVP Development: Quality Measure and Improvement Activity Updates

TABLE B.16b: Pathology MVP Clinical Groupings

Pathology MVP		
Clinical Grouping	**Quality**	**Cost**
Pathology	**Q249:** Barrett's Esophagus (Collection Type: Medicare Part B Claims, MIPS CQM)	**N/A**
	(*) Q250: Radical Prostatectomy Pathology Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q395: Lung Cancer Reporting (Biopsy/Cytology Specimens) (Collection Type: Medicare Part B Claims, MIPS CQM)	**N/A**
	(!)(*) Q396: Lung Cancer Reporting (Resection Specimens) (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q397: Melanoma Reporting (Collection Type: Medicare Part B Claims, MIPS CQM)	**N/A**
	(!)(*) Q440: Skin Cancer: Biopsy Reporting Time – Pathologist to Clinician (Collection Type: MIPS CQM)	
	(!)(*) Q491: Mismatch Repair (MMR) or Microsatellite Instability (MSI) Biomarker Testing Status (Collection Type: MIPS CQM)	
	(*) CAP30: Urinary Bladder Cancer: Complete Analysis and Timely Reporting (Collection Type: QCDR)	
	CAP34: Molecular Assessment: Biomarkers in Non-Small Cell Lung Cancer (Collection Type: QCDR)	
	CAP40: Squamous Cell Skin Cancer: Complete Reporting (Collection Type: QCDR)	
	QMM21: Incorporating results of concurrent studies into Final Reports for Bone Marrow Aspirate of patients with Leukemia, Myelodysplastic syndrome, or Chronic Anemia (Collection Type: QCDR)	
	QMM29: Use of Appropriate Classification System for Lymphoma Specimen (Collection Type: QCDR)	
	QMM30: Appropriate Use of Bethesda System for Reporting Thyroid Cytopathology on Fine Needle Aspirations (FNA) of Thyroid Nodule(s) (Collection Type: QCDR)	
	(+) QMM33: Immunohistochemistry (IHC) and/or Molecular BRAF Testing Status in Metastatic Melanoma (Collection Type: QCDR)	

Pathology Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!!) IA_BMH_12:** Promoting Clinician Well-Being
- **(+)(*)(!!) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(^)(+) IA_CC_XX:** Use of Data to Improve Practice Workflows

- **(^)(+) IA_CC_XX:** Understand and Improve Diagnostic Performance
- **(+) IA_ EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_12:** Participation in private payer CPIA
- **IA_PSPA_13:** Participation in Joint Commission Evaluation Initiative
- **IA_PSPA_35:** Adopt Certified Health Information Technology for Security Tags for Electronic Health Record Data

B.17: Patient Safety and Support of Positive Experiences with Anesthesia MVP

Table B.17a represents the proposed MIPS core measures for the Patient Safety and Support of Positive Experiences with Anesthesia MVP. The B.17b table, followed by a list of improvement activities, represents the measures and activities finalized within the Patient Safety and Support of Positive Experiences with Anesthesia MVP (90 FR 50441 through 50444) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Patient Safety and Support of Positive Experiences with Anesthesia MVP focuses on increasing the quality of anesthesia care, improving postoperative outcomes, promoting patient safety, and enhancing satisfaction for patients receiving anesthesia. The measures are used for a variety of surgical procedures that anesthesiologists deliver care for, and are broadly applicable to anesthesiologists practicing within ambulatory, outpatient, and inpatient hospital settings, including NPPs such as certified registered nurse anesthetists (CRNAs), nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[538], we are proposing the following measures as MIPS core measures for the Patient Safety and Support of Positive Experiences with Anesthesia MVP:

- **Q404:** Anesthesiology Smoking Abstinence
- **Q477:** Multimodal Pain Management
- **TBD:** Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases

We are proposing to add two new MIPS quality measures and two QCDR measures:

- **TBD:** Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases: This proposed MIPS quality measure assesses the mean arterial pressure (MAP) of patients undergoing noncardiac, non-emergency surgery that requires general anesthesia or monitored anesthesia.
- **TBD:** Patient-Reported Experience with Anesthesia: This proposed MIPS quality measure assesses patient experience and satisfaction with anesthesia care.
- **AQI65:** Avoidance of Cerebral Hyperthermia for Procedures Involving Cardiopulmonary Bypass: This QCDR measure ensures patients receive appropriate intraoperative temperature monitoring during cardiopulmonary bypass, with documentation that pulmonary artery, oropharyngeal, or nasopharyngeal temperatures are maintained at or above 37.0 degrees Celsius.

[538] See MVP Development: Quality Measure and Improvement Activity Updates

- **AQI71:** Ambulatory Glucose Management: This QCDR measure ensures patients with diabetes undergoing office-based or ambulatory surgery receive appropriate blood glucose monitoring and intervention throughout the entire anesthesia care episode.

For the reasons stated in the introduction of this appendix[539], we are proposing to remove **Q430:** Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy and **Q463:** Prevention of Post-Operative Vomiting (POV) – Combination Therapy (Pediatrics). We are proposing to remove one high performing QCDR measure and two QCDR measures proposed to transition to MIPS measures:

- **ABG44:** Low Flow Inhalational General Anesthesia (high performing)
- **AQI48:** Patient-Reported Experience with Anesthesia (proposed as a MIPS measure)
- **EPREOP31:** Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases (proposed as a MIPS measure)

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.17a: Patient Safety and Support of Positive Experiences with Anesthesia MVP MIPS Core Measures

Patient Safety and Support of Positive Experiences with Anesthesia MVP MIPS Core Measures
Q404: Anesthesiology Smoking Abstinence
Q477: Multimodal Pain Management
TBD: Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases

[539] See MVP Development: Quality Measure and Improvement Activity Updates

TABLE B.17b: Patient Safety and Support of Positive Experiences with Anesthesia MVP Clinical Groupings

Patient Safety and Support of Positive Experiences with Anesthesia MVP		
Clinical Grouping	**Quality**	**Cost**
Sedation/General Anesthesia	**(!) Q404:** Anesthesiology Smoking Abstinence (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!)(^)(+) TBD: Intraoperative Hypotension (IOH) among Non-Emergent Noncardiac Surgical Cases (Collection Type: MIPS CQM)	
	(+) AQI65: Avoidance of Cerebral Hyperthermia for Procedures Involving Cardiopulmonary Bypass (Collection Type: QCDR)	
	(+) AQI71: Ambulatory Glucose Management (Collection Type: QCDR)	
Pain Management	**(!) Q477**: Multimodal Pain Management (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**(^)(+) TBD:** Patient-Reported Experience with Anesthesia (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Patient Safety and Support of Positive Experiences with Anesthesia Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_22:** Improved practices that engage patients pre-visit
- **(!!) IA_BMH_2:** Tobacco use
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **(*) IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs

B.18 Podiatry MVP

Table B.18a represents the proposed MIPS core measures for the Podiatry MVP. The B.18b table, followed by a list of improvement activities, represents the measures and activities finalized within the Podiatry MVP (90 FR 50395 through 50400) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Podiatry MVP focuses on assessing meaningful outcomes in foot and ankle care for patients with chronic conditions, wound/ulcers, and general care for the podiatry patient. This MVP would be most applicable to podiatry clinicians, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[540], we are proposing the following measures as MIPS core measures for the Podiatry MVP:

[540] See MVP Development: Quality Measure and Improvement Activity Updates

- **Q126:** Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation
- **Q155:** Falls: Plan of Care
- **Q358:** Patient-Centered Surgical Risk Assessment and Communication

We are proposing to remove two QCDR measures due to low adoption, no benchmark after 2 consecutive years in MIPS:

- **REGCLR5:** Offloading with Remote Monitoring
- **REGCLR8:** Monitor and Improve Treatment Outcomes in Chronic Wound Healing

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.18a: Podiatry MVP MIPS Core Measures

Podiatry MVP MIPS Core Measures
Q126: Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation
Q155: Falls: Plan of Care
Q358: Patient-Centered Surgical Risk Assessment and Communication

TABLE B.18b: Podiatry MVP Clinical Groupings

Podiatry MVP		
Clinical Grouping	**Quality**	**Cost**
Chronic Conditions	**(!) Q126:** Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q127: Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear (Collection Type: MIPS CQM)	
Wound/Ulcer	**USWR32:** Adequate Compression at each visit for Patients with Venous Leg Ulcers (VLUs) appropriate to arterial supply (Collection Type: QCDR)	**N/A**
	USWR33: Diabetic Foot Ulcer (DFU) Healing or Closure (Collection Type: QCDR)	
	USWR34: Venous Leg Ulcer (VLU) Healing or Closure (Collection Type: QCDR)	
	USWR35: Adequate Off-loading of Diabetic Foot Ulcers performed at each visit, appropriate to location of ulcer (Collection Type: QCDR)	
General Podiatry	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM,)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(!) Q155:** Falls: Plan of Care (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(*) Q317: Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(!) Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	
	MEX5: Hammer Toe Outcome (Collection Type: QCDR)	**N/A**
	REGCLR1: Heel Pain Treatment Outcomes for Adults (Collection Type: QCDR)	
	REGCLR3: Bunion Outcome - Adult and Adolescent (Collection Type: QCDR)	

Podiatry Improvement Activities

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BMH_12:** Promoting Clinician Well-Being
- **IA_CC_19:** Tracking of clinician's relationship to and responsibility for a patient by reporting MACRA patient relationship codes
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_18:** Measurement and improvement at the practice and panel level
- **IA_PSPA_22:** CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain
- **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship

B.19: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP

Table B.18a represents the proposed MIPS core measures for the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP. The B.18b table, followed by a list of improvement activities, represents the measures and activities finalized within the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP (90 FR 50444 through 50447) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP focuses on promoting quality care for patients suffering from infectious disorders. This MVP would be most applicable to clinicians who treat patients within the practices of infectious disease and immunology, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality and cost measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[541], we are proposing the following measures as MIPS core measures for the Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP:

- **Q205:** Sexually Transmitted Infection (STI) Testing for People with HIV
- **Q338:** HIV Viral Suppression
- **Q516:** Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

Improvement Activities

We are proposing to add one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix[542], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.19a: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP MIPS Core Measures

[541] See MVP Development: Quality Measure and Improvement Activity Updates
[542] Ibid.

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP MIPS Core Measures
Q205: Sexually Transmitted Infection (STI) Testing for People with HIV
Q338: HIV Viral Suppression
Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR)

TABLE B.19b: Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP Clinical Groupings

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV MVP		
Clinical Grouping	**Quality**	**Cost**
Chronic: Hep C, HIV/AIDS	**(!) Q205:** Sexually Transmitted Infection (STI) Testing for People with HIV (Collection Type: eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	(!) Q338: HIV Viral Suppression (Collection Type: eCQM, MIPS CQM)	
	Q340: HIV Annual Retention in Care (Collection Type: eCQM, MIPS CQM)	
	Q387: Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users (Collection Type: MIPS CQM)	
	Q401: Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis (Collection Type: MIPS CQM)	
	(!) Q516: Hepatitis C Virus (HCV): Sustained Virological Response (SVR) (Collection Type: MIPS CQM)	
Acute Infection	**Q065:** Appropriate Treatment for Upper Respiratory Infection (URI) (Collection Type: eCQM, MIPS CQM)	**N/A**
	N/A	**COST_RIH_1:** Respiratory Infection Hospitalization **COST_S_1:** Sepsis **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**COST_RIH_1:** Respiratory Infection Hospitalization **COST_S_1:** Sepsis **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **TPCC_1:** Total Per Capita Cost
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	Q240: Childhood Immunization Status (Collection Type: eCQM)	
	Q310: Chlamydia Screening in Women (Collection Type: eCQM)	
	Q400: One-Time Screening for Hepatitis C Virus (HCV) and Treatment Initiation (Collection Type: MIPS CQM)	
	(*) Q475: HIV Screening (Collection Type: eCQM)	
	Q493: Adult Immunization Status (Collection Type: MIPS CQM)	

Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(+)(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways

- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **(!!) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- **IA_PSPA_23:** Completion of CDC Training on Antibiotic Stewardship
- **(!!) IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

B.20: Pulmonology Care MVP

Table B.20a represents the proposed MIPS core measures for the Pulmonology Care MVP. The B.20b table, followed by a list of improvement activities, represents the measures and activities finalized within the Pulmonology Care MVP (90 FR 50447 through 50449) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Pulmonology Care MVP focuses on assessing optimal care for patients treated for a broad range of pulmonology conditions including COPD, asthma, sleep apnea, and general pulmonology. This MVP would be most applicable to clinicians who specialize in pulmonology and sleep medicine, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[543], we are proposing the following measures as MIPS core measures for the Pulmonology Care MVP:

- **Q052:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy
- **Q279:** Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy
- **Q398:** Optimal Asthma Control

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.20a: Pulmonology Care MVP MIPS Core Measures

Pulmonology Care MVP MIPS Core Measures
Q052: Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy
Q279: Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy
Q398: Optimal Asthma Control

TABLE B.20b: Pulmonology Care MVP Clinical Groupings

[543] See MVP Development: Quality Measure and Improvement Activity Updates

Pulmonology Care MVP		
Clinical Grouping	**Quality**	**Cost**
Asthma	**(!)(*) Q398:** Optimal Asthma Control (Collection Type: MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD)
COPD	**(!) Q052:** Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation and Long-Acting Inhaled Bronchodilator Therapy (Collection Type: MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	ACEP25: Tobacco Use: Screening and Cessation Intervention for Patients with Asthma and COPD (Collection Type: QCDR)	
Sleep Medicine	**Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQM)	**N/A**
	(!) Q279: Sleep Apnea: Assessment of Adherence to Obstructive Sleep Apnea (OSA) Therapy (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_COPDE_1:** Inpatient Chronic Obstructive Pulmonary Disease (COPD) Exacerbation
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Pulmonology Care Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **(!!) IA_BE_23:** Integration of patient coaching practices between visits
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_16:** Implementation of medication management practice improvements

B.21: Quality Care for Patients with Neurological Conditions MVP

Table B.21a represents the proposed MIPS core measures for the Quality Care for Patients with Neurological Conditions MVP. The B.21b table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care for Patients with Neurological Conditions MVP (90 FR 50449 through 50451) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Quality Care for Patients with Neurological Conditions MVP focuses on the clinical theme of promoting quality care for patients suffering from neurological conditions. This MVP would be most applicable to clinicians who specialize in neurology care, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which

measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[544], we are proposing the following measures as MIPS core measures for the Quality Care for Patients with Neurological Conditions MVP:

- **Q238:** Use of High-Risk Medications in Older Adults
- **Q282:** Dementia: Functional Status Assessment
- **Q495:** Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.21a: Quality Care for Patients with Neurological Conditions MVP MIPS Core Measures

Quality Care for Patients with Neurological Conditions MVP MIPS Core Measures
Q238: Use of High-Risk Medications in Older Adults
Q282: Dementia: Functional Status Assessment
Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood

TABLE B.21b: Quality Care for Patients with Neurological Conditions MVP Clinical Groupings

Quality Care for Patients with Neurological Conditions MVP		
Clinical Grouping	**Quality**	**Cost**
Brain Conditions	**Q268:** Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Dementia	**Q281:** Dementia: Cognitive Assessment (Collection Type: eCQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q282: Dementia: Functional Status Assessment (Collection Type: MIPS CQM)	
	Q286: Dementia: Safety Concern Screening and Follow-Up for Patients with Dementia (Collection Type: MIPS CQM)	
	(*) Q288: Dementia: Education and Support of Caregivers for Patients with Dementia (Collection Type: MIPS CQM)	
Neurodegenerative Disorders	**(*) Q291:** Assessment of Cognitive Impairment or Dysfunction for Patients with Parkinson's Disease (Collection Type: MIPS CQM)	**MSPB_1**: Medicare Spending Per Beneficiary (MSPB) Clinician

[544] See MVP Development: Quality Measure and Improvement Activity Updates

Quality Care for Patients with Neurological Conditions MVP		
Clinical Grouping	**Quality**	**Cost**
	Q293: Rehabilitative Therapy Referral for Patients with Parkinson's Disease (Collection Type: MIPS CQM)	
	Q386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(*) Q130:** Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q238: Use of High-Risk Medications in Older Adults (Collection Type: eCQM, MIPS CQM)	
	(*) Q513: Patient reported falls and plan of care (Collection Type: MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q495: Ambulatory Palliative Care Patients' Experience of Feeling Heard and Understood (Collection Type: MIPS CQM)	
	Q503: Gains in Patient Activation Measure (PAM®) Scores at 12 Months (Collection Type: MIPS CQM)	

Quality Care for Patients with Neurological Conditions Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **IA_BE_24:** Financial Navigation Program
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(*)(!!) IA_BMH_4:** Depression screening
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_ PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **(!!) IA_PSPA_21:** Implementation of fall screening and assessment programs

B.22: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP

Table B.22a represents the proposed MIPS core measures for the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP. The B.22b table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP (90 FR 50451 through 50453) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP focuses on providing care for patients experiencing some of the most common otolaryngology conditions such as, but not limited to: otologic conditions, chronic rhinosinusitis (CRS), age-related hearing loss (ARHL), and otitis media. This MVP would be most applicable to clinicians who treat patients within the practice of otolaryngology, including NPPs such as audiologists, nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement

activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[545], we are proposing the following measures as MIPS core measures for the Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP:

- **Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)
- **Q357:** Surgical Site Infection (SSI)
- **TBD:** Age-Related Hearing Loss: Comprehensive Audiometric Evaluation

We are proposing to add one new MIPS quality measure that is relevant to this MVP:

- **TBD:** Age-Related Hearing Loss: Comprehensive Audiometric Evaluation: This proposed MIPS quality measure assesses patients with hearing loss or tinnitus for completion of a comprehensive audiometric evaluation.

For the reasons stated in the introduction of this appendix[546], we are proposing to remove **Q332:** Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use). We are proposing to remove one duplicative QCDR measure and one QCDR measure proposed to transition to a MIPS measure:

- **AAO16:** Age-Related Hearing Loss: Audiometric Evaluation (proposed as a MIPS measure)
- **AAO21:** Otitis Media with Effusion (OME): Comprehensive Audiometric Evaluation for Chronic OME > or = 3 months (duplicative measure)

Modifications are being considered for the following QCDR measures:

- **AAO16:** Age-Related Hearing Loss: Audiometric Evaluation: If the measure is not finalized for removal in the CY 2027 PFS final rule, this QCDR measure would undergo modifications to update the description, denominator, and numerator to reflect the addition of a tinnitus diagnosis and clarifying that a hearing screening does not meet the measure's intent. Expanding the measure to include patients diagnosed with tinnitus will help capture a broader group of individuals who may have underlying or undiagnosed hearing loss.
- **AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation: This QCDR measure is undergoing modifications to update the description, denominator, and instructions to remove the otitis media with effusion (OME) diagnosis and expand the eligible population to include all patients undergoing tympanostomy tube insertion. This would increase the measure's applicability and case volume. This change reflects that preoperative hearing evaluation is an important component of care for any patient receiving tubes, not just those with OME.

Improvement Activities

We are proposing to add eight improvement activities relevant to this MVP, several of which include an advancing health and wellness component:

- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_CC_7:** Regular training in care coordination
- **IA_CC_8:** Implementation of documentation improvements for practice/process

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[545] See MVP Development: Quality Measure and Improvement Activity Updates

[546] Ibid.

improvements
- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_17:** Patient Navigator Program
- **IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PM_17:** Participation in Population Health Research
- **IA_PSPA_12:** Participation in private payer CPIA

For the reasons stated in the introduction of this appendix[547], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family, and Caregivers in Developing a Plan of Care.

Symbol Key:
Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): proposed new measure or improvement activity.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.22a: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP MIPS Core Measures

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP MIPS Core Measures
Q331: Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse)
Q357: Surgical Site Infection (SSI)
TBD: Age-Related Hearing Loss: Comprehensive Audiometric Evaluation

TABLE B.22b: Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP Clinical Groupings

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP		
Clinical Grouping	**Quality**	**Cost**
Otology	**(*) AAO20:** Tympanostomy Tubes: Comprehensive Audiometric Evaluation (Collection Type: QCDR)	**N/A**
Sleep Disorders	**Q277:** Sleep Apnea: Severity Assessment at Initial Diagnosis (Collection Type: MIPS CQM)	**N/A**
General Otolaryngology	**(!) Q331:** Adult Sinusitis: Antibiotic Prescribed for Acute Viral Sinusitis (Overuse) (Collection Type: MIPS CQM)	**N/A**
	(!)(^)(+) TBD: Age-Related Hearing Loss: Comprehensive Audiometric Evaluation	

[547] See MVP Development: Quality Measure and Improvement Activity Updates

Quality Care for the Treatment of Ear, Nose, and Throat Disorders MVP		
Clinical Grouping	**Quality**	**Cost**
	(Collection Type: MIPS CQM)	
Surgical	**Q355:** Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	

Quality Care for the Treatment of Ear, Nose, and Throat Disorders Improvement Activities

- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(+) IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(+) IA_CC_7:** Regular training in care coordination
- **(+)(*) IA_CC_8:** Implementation of documentation improvements for practice/process improvements
- **(+)(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(+) IA_CC_17:** Patient Navigator Program
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(+) IA_PM_14:** Implementation of methodologies for improvements in longitudinal care management for high risk patients
- **IA_PM_16:** Implementation of medication management practice improvements
- **(+) IA_PM_17:** Participation in Population Health Research
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **(+) IA_PSPA_12:** Participation in private payer CPIA

B.23: Quality Care in Mental Health and Substance Use Disorders MVP

Table B.23a represents the proposed MIPS core measures for the Quality Care in Mental Health and Substance Use Disorders MVP. The B.23b table, followed by a list of improvement activities, represents the measures and activities finalized within the Quality Care in Mental Health and Substance Use Disorders MVP (90 FR 50453 through 50456) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Quality Care in Mental Health and Substance Use Disorders MVP focuses on clinical actions promoting prevention of and quality care in behavioral health, including mental health and substance use disorders (SUD). This MVP would be most applicable to clinicians who treat patients with mental health and substance use disorders within the practices of mental/behavioral health and psychiatry, including NPPs such as clinical social workers, nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[548], we are proposing the following measures as MIPS core measures for the Quality Care in Mental Health and Substance Use Disorders MVP:

- **Q305:** Initiation and Engagement of Substance Use Disorder Treatment
- **Q370:** Depression Remission at Twelve Months
- **Q383:** Adherence to Antipsychotic Medications For Individuals with Schizophrenia

Improvement Activities

We are proposing to add one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_BMH_4:** Depression screening, treatment, and prevention.

For the reasons stated in the introduction of this appendix[549], we are proposing to remove **IA_BMH_5:** MDD prevention and treatment interventions.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.23a: Quality Care in Mental Health and Substance Use Disorders MVP MIPS Core Measures

Quality Care in Mental Health and Substance Use Disorders MVP MIPS Core Measures
Q305: Initiation and Engagement of Substance Use Disorder Treatment
Q370: Depression Remission at Twelve Months
Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia

TABLE B.23b: Quality Care in Mental Health and Substance Use Disorders MVP Clinical Groupings

Quality Care in Mental Health and Substance Use Disorders MVP		
Clinical Grouping	**Quality**	**Cost**
Mental Health—General	**Q009:** Anti-Depressant Medication Management (Collection Type: eCQM)	**COST_DEP_1**: Depression
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

[548] See MVP Development: Quality Measure and Improvement Activity Updates
[549] Ibid.

Quality Care in Mental Health and Substance Use Disorders MVP		
Clinical Grouping	**Quality**	**Cost**
	Q366: Follow-Up Care for Children Prescribed ADHD Medication (Collection Type: eCQM)	**N/A**
	(!) Q370: Depression Remission at Twelve Months (Collection Type: eCQM, MIPS CQM)	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	(!)(*) Q383: Adherence to Antipsychotic Medications For Individuals with Schizophrenia (Collection Type: MIPS CQM)	**COST_PRC_1:** Psychoses/Related Conditions
	MBHR2: Anxiety Response at 6-months (Collection Type: QCDR)	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	MBHR7: Posttraumatic Stress Disorder (PTSD) Outcome Assessment for Adults and Children (Collection Type: QCDR)	**N/A**
Mental Health—Suicide	**Q382:** Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment (Collection Type: eCQM)	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions
	Q504: Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk (Collection Type: MIPS CQM)	
	(*) Q505: Reduction in Suicidal Ideation or Behavior Symptoms (Collection Type: MIPS CQM)	
Substance Use Disorder	**(!) Q305:** Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM)	**N/A**
	Q468: Continuity of Pharmacotherapy for Opioid Use Disorder (OUD) (Collection Type: MIPS CQM)	
Experience of Care	**Q502:** Improvement or Maintenance of Functioning for Individuals with a Mental and/or Substance Use Disorder (Collection Type: MIPS CQM)	**COST_DEP_1:** Depression **COST_PRC_1:** Psychoses/Related Conditions **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician

Mental Health and Substance Use Disorders Improvement Activities

- **(!!) IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **(!!) IA_BE_23:** Integration of patient coaching practices between visits
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!!) IA_BMH_2:** Tobacco use
- **(+)(*)(!!) IA_BMH_4:** Depression screening and follow-up plan
- **IA_BMH_7:** Implementation of Integrated Patient Centered Behavioral Health Model
- **(!!) IA_BMH_14:** Behavioral/Mental Health and Substance Use Screening and Referral for Pregnant and Postpartum Women
- **(!!) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_7:** Enhance Engagement of Medicaid and Other Underserved Populations

- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(!!) IA_PSPA_32:** Use of CDC Guideline for Clinical Decision Support to Prescribe Opioids for Chronic Pain via Clinical Decision Support

B.24: Rehabilitative Support MVP

Table B.24a represents the proposed MIPS core measures for the Rehabilitative Support MVP. The B.24b table, followed by a list of improvement activities, represents the measures and activities finalized within the Rehabilitative Support for Musculoskeletal Care MVP (90 FR 50457 through 50461) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years, including an MVP title update to Rehabilitative Support MVP to more closely reflect the measures and activities included in the MVP. The Rehabilitative Support MVP focuses on clinical actions promoting quality rehabilitative care for patients. This MVP would be most applicable to clinicians who specialize in providing rehabilitative support such as chiropractic, physiatry, physical therapy and occupational therapy, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[550], we are proposing the following measures as MIPS core measures for the Rehabilitative Support MVP:

- **Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older
- **Q155:** Falls: Plan of Care
- **TBD:** Functional Improvement for Patients with Back Impairments

We are proposing to add five new MIPS quality measures relevant to this MVP:

- **TBD:** Functional Improvement for Patients with Neck Impairments: This proposed MIPS quality measure assesses functional improvement for patients with neck impairments after completing an episode of care, excluding surgical interventions. This measure is proposed to replace Q478: Functional Status Change for Patients with Neck Impairments.
- **TBD:** Functional Improvement for Patients with Upper Extremity Impairments: This proposed MIPS quality measure assesses functional improvement for patients with upper extremity impairments after completing an episode of care, excluding surgical interventions. This measure is proposed to replace Q222: Functional Status Change for Patients with Elbow, Wrist or Hand Impairments.
- **TBD:** Functional Improvement for Patients with Lower Extremity Impairments: This MIPS quality measure assesses functional improvement for patients with lower extremity impairments after completing an episode of care, excluding surgical interventions. This measure is proposed to replace Q218 Functional Status Change for Patients with Hip Impairments and Q219: Functional Status Change for Patients with Lower Leg, Foot or Ankle Impairments.
- **TBD:** Functional Improvement for Patients with Knee Impairments: This proposed MIPS quality measure assesses functional improvement for patients with knee impairments after completing an episode of care, excluding surgical interventions. This measure is proposed to replace Q217: Functional Status Change for Patients with Knee Impairments.
- **TBD:** Functional Improvement for Patients with Back Impairments: This proposed MIPS

[550] See MVP Development: Quality Measure and Improvement Activity Updates

quality measure assesses functional improvement for patients with back impairments after completing an episode of care, excluding surgical interventions. This measure is proposed to replace Q220: Functional Status Change for Patients with Low Back Impairments.

For the reasons stated in the introduction of this appendix[551], we are proposing to remove **Q217:** Functional Status Change for Patients with Knee Impairments, **Q218:** Functional Status Change for Patients with Hip Impairments, **Q219:** Functional Status Change with Lower Leg, Foot or Ankle Impairments, **Q220:** Functional Status Change for Patients with Low Back Impairments, **Q221:** Functional Status Change for Patients with Shoulder Impairments, **Q222:** Functional Status Change for Patients with Elbow, Wrist or Hand Impairments, and **Q478:** Functional Status Change for Patients with Neck Impairments.

Improvement Activities

We are proposing to add one improvement activity that is relevant to this MVP and includes an advancing health and wellness component:

- **IA_CC_9:** Implementation of practices/processes for developing regular individual care plans

For the reasons stated in the introduction of this appendix[552], we are proposing to remove **IA_BE_15:** Engagement of Patients, Family and Caregivers in Developing a Plan of Care and **IA_CC_12:** Care coordination agreements that promote improvements in patient tracking across settings.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): proposed new measure or improvement activity.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.24a: Rehabilitative Support MVP MIPS Core Measures

Rehabilitative Support MVP MIPS Core Measures
Q050: Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older
Q155: Falls: Plan of Care
TBD: Functional Improvement for Patients with Back Impairments

[551] Ibid.
[552] See MVP Development: Quality Measure and Improvement Activity Updates

TABLE B.24b: Rehabilitative Support MVP Clinical Groupings

Rehabilitative Support MVP		
Clinical Grouping	**Quality**	**Cost**
Orthopedic	**Q182:** Functional Outcome Assessment (Collection Type: MIPS CQM)	**COST_LBP_1:** Low Back Pain
	(^)(+) TBD: Functional Improvement for Patients with Neck Impairments (Collection Type: MIPS CQM)	**N/A**
	(^)(+) TBD: Functional Improvement for Patients with Upper Extremity Impairments (Collection Type: MIPS CQM)	
	(^)(+) TBD: Functional Improvement for Patients with Lower Extremity Impairments (Collection Type: MIPS CQM)	
	(^)(+) TBD: Functional Improvement for Patients with Knee Impairments (Collection Type: MIPS CQM)	
	(!)(^)(+) TBD: Functional Improvement for Patients with Back Impairments (Collection Type: MIPS CQM)	**COST_LBP_1:** Low Back Pain
	MSK6: Patients Suffering From a Neck Injury who Improve Pain (Collection Type: QCDR)	**N/A**
	MSK7: Patients Suffering From an Upper Extremity Injury who Improve Pain (Collection Type: QCDR)	
	MSK8: Patients Suffering From a Back Injury who Improve Pain (Collection Type: QCDR)	**COST_LBP_1:** Low Back Pain
	MSK9: Patients Suffering From a Lower Extremity Injury who Improve Pain (Collection Type: QCDR)	**N/A**
Geriatric	**(!) Q050:** Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older (Collection Type: MIPS CQM)	**N/A**
Advancing Health and Wellness	**(**) Q128:** Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_LBP_1:** Low Back Pain
	(*) Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(!) Q155: Falls: Plan of Care (Collection Type: MIPS CQM)	

Rehabilitative Support Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **(!!) IA_BE_16:** Promote Self-management in Usual Care
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **(!!) IA_BMH_12:** Promoting Clinician Well-Being
- **(!!) IA_BMH_15:** Behavioral/Mental Health and Substance Use Screening and Referral for Older Adults
- **(*) IA_CC_8**: Implementation of documentation improvements for practice/process improvements
- **(+)(*)(!!) IA_CC_9:** Implementation of practices/processes for developing regular individual care plans
- **IA_EPA_2:** Use of telehealth services that expand practice access

- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **(!) IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(*) IA_PSPA_16:** Use decision support—ideally platform-agnostic, interoperable clinical decision support (CDS) tools —and standardized treatment protocols to manage workflow on the care team to meet patient needs
- **(!!) IA_PSPA_21:** Implementation of fall screening and assessment programs

B.25: Surgical Care MVP

Table B.25a represents the proposed MIPS core measures for the Surgical Care MVP. The B.25b table, followed by a list of improvement activities, represents the measures and activities finalized within the Surgical Care MVP (90 FR 50461 through 50464) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Surgical Care MVP focuses on the clinical theme of surgery. This MVP would be most applicable to clinicians who specialize in general surgery, neurosurgery, and cardiothoracic surgery, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the improvement activities inventory and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[553], we are proposing the following measures as MIPS core measures for the Surgical Care MVP:

- **Q047:** Advance Care Plan
- **Q164:** Coronary Artery Bypass Graft (CABG): Prolonged Intubation
- **Q354:** Anastomotic Leak Intervention
- **Q357:** Surgical Site Infection (SSI)
- **Q358:** Patient-Centered Surgical Risk Assessment and Communication
- **Q459:** Back Pain After Lumbar Surgery

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.25a: Surgical Care MVP MIPS Core Measures

Surgical Care MVP MIPS Core Measures
Q047: Advance Care Plan
Q164: Coronary Artery Bypass Graft (CABG): Prolonged Intubation
Q354: Anastomotic Leak Intervention
Q357: Surgical Site Infection (SSI)
Q358: Patient-Centered Surgical Risk Assessment and Communication
Q459: Back Pain After Lumbar Surgery

[553] See MVP Development: Quality Measure and Improvement Activity Updates

TABLE B.25b: Surgical Care MVP Clinical Groupings

Surgical Care MVP		
Clinical Grouping	**Quality**	**Cost**
Cardiothoracic Surgery	**(!) Q164:** Coronary Artery Bypass Graft (CABG): Prolonged Intubation (Collection Type: MIPS CQM)	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q167: Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure (Collection Type: MIPS CQM)	
	(*) Q168: Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration (Collection Type: MIPS CQM)	
	Q445: Risk-Adjusted Operative Mortality for Coronary Artery Bypass Graft (CABG) (Collection Type: MIPS CQM)	
General Surgery	**(!) Q354:** Anastomotic Leak Intervention (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q355: Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQM)	**COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	**COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1**: Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Neurosurgical	**(!) Q459:** Back Pain After Lumbar Surgery (Collection Type: MIPS CQM)	**COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q461: Leg Pain After Lumbar Surgery (Collection Type: MIPS CQM)	
	Q471: Functional Status After Lumbar Surgery (Collection Type: MIPS CQM)	
Advancing Health and Wellness	**Q226:** Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-

Surgical Care MVP		
Clinical Grouping	**Quality**	**Cost**
		3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Experience of Care	**(!) Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_NECABG_1:** Non-Emergent Coronary Artery Bypass Graft (CABG) **COST_LSFDD_1:** Lumbar Spine Fusion for Degenerative Disease, 1-3 Levels **COST_LPMSM_1:** Lumpectomy, Partial Mastectomy, Simple Mastectomy **COST_CRR_1:** Colon and Rectal Resection **COST_FIHR_1:** Femoral or Inguinal Hernia Repair **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	

Surgical Care Improvement Activities

- **(!!) IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_15:** PSH Care Coordination
- **IA_CC_17:** Patient Navigator Program
- **(!!) IA_CC_18:** Relationship-Centered Communication
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PSPA_7:** Use of QCDR data for ongoing practice assessment and improvements
- **IA_PSPA_8:** Use of Patient Safety Tools

B.26: Value in Primary Care MVP

Table B.26a represents the proposed MIPS core measures for the Value in Primary Care MVP. The B.26b table, followed by a list of improvement activities, represents the measures and activities finalized within the Value in Primary Care MVP (90 FR 50465 through 50467) with modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Value in Primary Care MVP focuses on the clinical theme of promoting quality care for patients to reduce the risk of diseases, disabilities, and death. This MVP would be most

applicable to clinicians who specialize in preventive medicine, internal medicine, family medicine, and geriatrics, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[554], we are proposing the following measures as MIPS core measures for the Value in Primary Care MVP:

- **Q001:** Diabetes: Glycemic Status Assessment Greater Than 9%
- **Q134:** Preventive Care and Screening: Screening for Depression and Follow-up Plan
- **Q236:** Controlling High Blood Pressure

We are proposing to add one new MIPS quality measure:

- **TBD:** Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management: This proposed intermediate outcome MIPS quality measure ensures lipid monitoring in patients with atherosclerotic cardiovascular disease (ASCVD) and assesses target goal achievement of an LDL-C less than 70mg/dl.

For the reasons stated in the introduction of this appendix[555], we are proposing to remove **Q483:** Person-Centered Primary Care Measure Patient Reported Outcome Performance Measure (PCPCM PRO-PM).

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Caret symbol (^): proposed new measure or improvement activity.
Plus sign (+): measures and improvement activities proposed for addition to a previously finalized MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.26a: Value in Primary Care MVP MIPS Core Measures

Value in Primary Care MVP MIPS Core Measures
Q001: Diabetes: Glycemic Status Assessment Greater Than 9%
Q134: Preventive Care and Screening: Screening for Depression and Follow-Up Plan
Q236: Controlling High Blood Pressure

TABLE B.26b: Value in Primary Care MVP Clinical Groupings

[554] See MVP Development: Quality Measure and Improvement Activity Updates
[555] Ibid.

Value in Primary Care MVP		
Clinical Grouping	**Quality**	**Cost**
Chronic Conditions	**(!)(*) Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_D_1:** Diabetes **TPCC_1:** Total Per Capita Cost
	(!)(*) Q236: Controlling High Blood Pressure (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1:** Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **TPCC_1:** Total Per Capita Cost
	Q305: Initiation and Engagement of Substance Use Disorder Treatment (Collection Type: eCQM)	**N/A**
	(*) Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	**TPCC_1:** Total Per Capita Cost
	Q504: Initiation, Review, and/or Update to Suicide Safety Plan for Individuals with Suicidal Thoughts, Behavior, or Suicide Risk (Collection Type: MIPS CQM)	**COST_DEP_1:** Depression **TPCC_1:** Total Per Capita Cost
	(^)(+) TBD: Low Density Lipoprotein Cholesterol (LDL-C) Monitoring and Management (Collection Type: MIPS CQM)	**TPCC_1:** Total Per Capita Cost
Advancing Health and Wellness	**(!)(*) Q134:** Preventive Care and Screening: Screening for Depression and Follow-Up Plan (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1:** Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **TPCC_1:** Total Per Capita Cost
	(*) Q475: HIV Screening (Collection Type: eCQM)	
	Q493: Adult Immunization Status (Collection Type: MIPS CQM)	
	(*) Q497: Preventive Care and Wellness (composite) (Collection Type: MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_ACOPD_1:** Asthma/ Chronic Obstructive Pulmonary Disease (COPD) **COST_D_1:** Diabetes **COST_DEP_1:** Depression **COST_HF_1:** Heart Failure **TPCC_1:** Total Per Capita Cost
	Q321: CAHPS for MIPS Clinician/Group Survey (Collection Type: CMS-approved Survey Vendor)	

Value in Primary Care Improvement Activities

- **(!!) IA_AHW_1:** Chronic Care and Preventative Care Management for Empaneled Patients
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **IA_BE_6:** Regularly Assess Patient Experience of Care and Follow Up on Findings
- **IA_BE_12:** Use evidence-based decision aids to support shared decision-making

- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_13:** Practice improvements to align with OpenNotes principles
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **IA_PM_11:** Regular review practices in place on targeted patient population needs
- **IA_PM_16:** Implementation of medication management practice improvements
- **(!!) IA_PM_22:** Improving Practice Capacity for Human Immunodeficiency Virus (HIV) Prevention Services
- **(!!) IA_PM_23:** Use of Computable Guidelines and Clinical Decision Support to Improve Adherence for Cervical Cancer Screening and Management Guidelines
- **(!!) IA_PM_25:** Save a Million Hearts: Standardization of Approach to Screening and Treatment for Cardiovascular Disease Risk

B.27 Vascular Surgery MVP

Table B.27a represents the proposed MIPS core measures for the Vascular Surgery MVP. The B.27b table, followed by a list of improvement activities, represents the measures and activities finalized within the Vascular Surgery MVP (90 FR 50400 through 50405) with proposed modifications for the CY 2027 performance period/2029 MIPS payment year and future years. The Vascular Surgery MVP focuses on the clinical theme of providing high quality care for patients treated under vascular surgery. This MVP would be most applicable to clinicians who treat patients within the surgical setting of vascular surgery, including NPPs such as nurse practitioners, clinical nurse specialists, and physician assistants. We reviewed the MIPS quality measure and improvement activities inventories and considered feedback received during the 2026 MVP maintenance period to determine which measures and activities to include in this MVP. We request public comment on the proposed modifications included in this MVP.

Quality Measures

For the reasons stated in the introduction of this appendix[556], we are proposing the following measures as MIPS core measures for the Vascular Surgery MVP:

- **Q344:** Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)
- **Q356:** Unplanned Hospital Readmission within 30 Days of Principal Procedure
- **Q358:** Patient-Centered Surgical Risk Assessment and Communication

Improvement Activities

For the reasons stated in the introduction of this appendix[557], we are proposing to remove **IA_PM_2:** Anticoagulant Management Improvements.

Symbol Key:

Exclamation point (!): MIPS core measure within an MVP.
Single asterisk (*): existing measures and improvement activities with proposed revisions.
Double asterisk (**): measures and improvement activities only available when included in an MVP.
Double exclamation point (!!): improvement activities with an advancing health and wellness component.

TABLE B.27a: Vascular Surgery MVP MIPS Core Measures

[556] See MVP Development: Quality Measure and Improvement Activity Updates
[557] Ibid.

Vascular Surgery MVP MIPS Core Measures
Q344: Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2)
Q356: Unplanned Hospital Readmission within 30 Days of Principal Procedure
Q358: Patient-Centered Surgical Risk Assessment and Communication

TABLE B.27b: Vascular Surgery MVP Clinical Groupings

Vascular Surgery MVP		
Clinical Grouping	**Quality**	**Cost**
Interventional	**Q259:** Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Infrarenal Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q344: Rate of Carotid Endarterectomy (CEA) or Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2) (Collection Type: MIPS CQM)	
Surgical	**Q355:** Unplanned Reoperation within the 30-Day Postoperative Period (Collection Type: MIPS CQM)	**COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(!) Q356: Unplanned Hospital Readmission within 30 Days of Principal Procedure (Collection Type: MIPS CQM)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q357: Surgical Site Infection (SSI) (Collection Type: MIPS CQM)	**COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Dialysis-Related	**RCOIR12:** Tunneled Hemodialysis Catheter Clinical Success Rate (Collection Type: QCDR)	**MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician **COST_HAC_1:** Hemodialysis Access Creation
	RCOIR13: Percutaneous Arteriovenous Fistula for Dialysis - Clinical Success Rate (Collection Type: QCDR)	
	RPAQIR14: Arteriovenous Graft Thrombectomy Clinical Success Rate (Collection Type: QCDR)	
	RPAQIR15: Arteriovenous Fistulae Thrombectomy Clinical Success Rate (Collection Type: QCDR)	
General Vascular Surgery	**(*) Q374:** Closing the Referral Loop: Receipt of Specialist Report (Collection Type: eCQM, MIPS CQM)	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia

Vascular Surgery MVP		
Clinical Grouping	**Quality**	**Cost**
		COST_HAC_1: Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
Advancing Health and Wellness	**(*) Q001:** Diabetes: Glycemic Status Assessment Greater Than 9% (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia **COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	(*) Q130: Documentation of Current Medications in the Medical Record (Collection Type: eCQM, MIPS CQM)	
	Q226: Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention (Collection Type: Medicare Part B Claims, eCQM, MIPS CQM)	
	(*) Q438: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (Collection Type: eCQM, MIPS CQM)	
Experience of Care	**Q047:** Advance Care Plan (Collection Type: Medicare Part B Claims, MIPS CQM)	**COST_CCLI_1:** Revascularization For Lower Extremity Chronic Critical Limb Ischemia **COST_HAC_1:** Hemodialysis Access Creation **MSPB_1:** Medicare Spending Per Beneficiary (MSPB) Clinician
	Q321: CAHPS for MIPS Clinician/Group Survey (Collection Type: CMS-approved Survey Vendor)	
	(!) Q358: Patient-Centered Surgical Risk Assessment and Communication (Collection Type: MIPS CQM)	

Vascular Surgery Improvement Activities

- **IA_BE_1:** Use of certified EHR to capture patient reported outcomes
- **IA_BE_4:** Engagement of Patients through Implementation of New Patient Portal
- **(!!) IA_BE_12:** Use evidence-based decision aids to support shared decision-making
- **(!!) IA_BE_26:** Promote Use of Patient-Reported Outcome Tools
- **IA_CC_15:** PSH Care Coordination
- **IA_EPA_2:** Use of telehealth services that expand practice access
- **IA_EPA_3:** Collection and use of patient experience and satisfaction data on access
- **IA_EPA_8:** Provide Education Opportunities for New Clinicians
- **(**) IA_MVP:** Practice-Wide Quality Improvement in MIPS Value Pathways
- **(!!) IA_PM_5:** Engagement of community for health status improvement
- **IA_PM_11:** Regular Review Practices in Place on Targeted Patient Population Needs
- **IA_PM_15:** Implementation of episodic care management practice improvements
- **IA_PM_16:** Implementation of medication management practice improvements
- **IA_PM_21:** Advance Care Planning
- **IA_PSPA_1:** Participation in an AHRQ-listed patient safety organization</EXTRACT>

<FRDOC> [FR Doc. 2026–14327 Filed 7–14–26; 4:15 pm]

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Part V

Nuclear Regulatory Commission

10 CFR Parts 2, 50, 51 et al.
Modernizing Reactor Licensing, Safety Oversight, and Siting Practices; Proposed Rule

NUCLEAR REGULATORY COMMISSION

10 CFR Parts 2, 50, 51, 52, 53, 54, 71, and 100

[NRC–2025–0975]

RIN 3150–AL44

Modernizing Reactor Licensing, Safety Oversight, and Siting Practices

AGENCY: Nuclear Regulatory Commission.

ACTION: Proposed rule and guidance; request for comment.

SUMMARY: Consistent with Executive Order 14300, ''Ordering the Reform of the Nuclear Regulatory Commission,'' the U.S. Nuclear Regulatory Commission (NRC) is conducting a review and wholesale revision of its regulations. This proposed rule aims to modernize reactor licensing, safety oversight, and siting practices addressing sections 5(f), 5(h), and 5(i) of Executive Order 14300, and additional items that contribute to adding additional generation to the electrical grid. Additionally, as part of the NRC's overarching review of all of its regulations, the agency identified a number of further changes to the NRC's regulations that will improve the efficiency and efficacy of its licensing process that are also included in this rulemaking.

DATES: Comments must be submitted electronically using *https://www.regulations.gov* by 11:59 p.m. eastern time on August 31, 2026. Comments received after this date will be considered if it is practical to do so, but the Commission is able to ensure consideration of only comments received before this date.

ADDRESSES: Submit your comments, identified by Docket ID NRC–2025–0975, at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

Do not include any personally identifiable information (such as name, address, or other contact information) or confidential business information that you do not want publicly disclosed. All comments are public records; they are publicly displayed exactly as received, and will not be deleted, modified, or redacted. Comments may be submitted anonymously.

Follow the search instructions on *https://www.regulations.gov* to view public comments.

You can read a plain language description of this proposed rule at *https://www.regulations.gov/docket/NRC-2025-0975.* For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Doyle, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–3748, email: *Daniel.Doyle@nrc.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

A. Need for the Regulatory Action

On May 23, 2025, President Donald J. Trump signed Executive Order (E.O.) 14300, ''Ordering the Reform of the Nuclear Regulatory Commission.'' Section 5, ''Reforming and Modernizing the NRC's Regulations,'' requires the NRC to undertake a review and wholesale revision of its regulations in title 10 of the *Code of Federal Regulations* (10 CFR) and guidance documents as guided by the policies set forth in section 2 of the E.O. This rulemaking addresses section 5(f) of E.O. 14300, which directs the NRC to ''[e]stablish stringent thresholds for circumstances in which the NRC may demand changes to reactor design once construction is underway''; section 5(h) of E.O. 14300, which directs the NRC to ''[a]dopt revised and, where feasible, determinate and data-backed thresholds to ensure that reactor safety assessments focus on credible, realistic risks''; and section 5(i) of E.O. 14300, which directs the NRC to ''[r]econsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.'' Additionally, as part of the NRC's overarching review of all of its regulations, the agency identified a number of additional changes to the NRC's regulations that will improve the efficiency and efficacy of its licensing process that are also included in this rulemaking.

These changes are the culmination of decades of combined experience, feedback from nuclear experts, lessons learned by the NRC and industry, international experience, and prior efforts to modernize the regulatory framework. They have undergone thoughtful preparation and internal vetting by the NRC technical experts. While some changes in this rule had not been advanced as regulatory priorities, the direction in the E.O. catalyzed agency efforts to accelerate modernization of 10 CFR part 50, ''Domestic Licensing of Production and Utilization Facilities,'' and 10 CFR part 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants,'' and make conforming changes to 10 CFR part 53, ''Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants.'' Therefore, this proposed rule aims to modernize reactor licensing, safety oversight, and siting practices addressing sections 5(f), 5(h), and 5(i) of E.O. 14300 and additional items that would contribute to adding generation to the electrical grid. In developing the proposed changes, the NRC has considered the benefits of increased availability of, and innovation in, nuclear power to our economic and national security consistent with section 501(a) of the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act) and section 3 of E.O. 14300.

B. Major Provisions

Major provisions of this proposed rule include changes in the following areas:

Expedited Construction of Certain Structures, Systems, and Components

The NRC is proposing to amend its regulations applicable to the definition of construction in 10 CFR 50.10, ''License required; limited work authorization,'' 10 CFR 51.4, ''Definitions,'' and 10 CFR 53.020, ''Definitions,'' in order to focus the scope of activities that are considered construction on structures, systems, and components (SSCs) for which construction can affect attributes of the SSC material to the SSC's capability to perform a safety-significant function and thereby reduce the cost impact of the current definition of construction. Additionally, the NRC proposes to include new paragraphs in 10 CFR 50.10(h) and 53.1130(e), which would issue a general license for beginning construction upon docketing an application for a license that would authorize construction of a nuclear plant, subject to conditions that ensure safety, security, and appropriate environmental review.

Determinate and Data-Backed Thresholds for Reactor Safety Assessments

The NRC is proposing to amend its regulations by revising 10 CFR 50.2, ''Definitions,'' to add the terms ''design basis event'' (DBE) and ''beyond design basis event'' (BDBE). The proposed changes also include a conforming revision to the definition of DBE in 10 CFR 50.49, ''Environmental

qualification of electric equipment important to safety for nuclear power plants.'' In parallel with the proposed changes, the NRC has developed draft regulatory guidance (DG)-1454, ''Implementation of Determinate and Data-Backed Thresholds for Reactor Safety Assessments,'' which (1) establishes determinate and data-backed thresholds for categorizing events into defined bins, (2) outlines graded assessment approaches for DBEs and BDBEs, and (3) clarifies the process for selecting ''design bases'' controlling parameters used as reference bounds in the design of SSCs.

Removal of IEEE–323–1974 Reference in Footnote 3 of 10 CFR 50.49

The NRC is proposing to revise the regulations in 10 CFR 50.49 to delete footnote 3, which clarifies that safety-related electric equipment is referred to as Class 1E equipment in Institute of Electrical and Electronics Engineers (IEEE) Standard 323–1974. The reference in this footnote is now unnecessary because the NRC has established the connection between ''safety-related'' electric equipment and ''Class 1E'' equipment elsewhere.

Expanded Alternative Requests Under 10 CFR 50.55a(z)

The NRC is proposing to amend its regulations to allow licensees to request a broader scope of alternatives to the requirements in 10 CFR 50.55a, ''Codes and standards.'' Currently, alternatives under 10 CFR 50.55a(z), ''Alternatives to codes and standards requirements,'' are limited to the requirements in 10 CFR 50.55a(b), ''Use and conditions on the use of standards,'' through (h), ''Protection and safety systems.'' Expanding the scope of alternatives permitted under 10 CFR 50.55a to all requirements in 10 CFR 50.55a would allow for added flexibility without requiring exemptions, while relying on the well-understood existing criteria of acceptable level of quality and safety (10 CFR 50.55a(z)(1)) and hardship without a compensating increase in quality or safety (10 CFR 50.55a(z)(2)) for consistent and predictable regulatory outcomes. This proposed action would allow nuclear power plant licensees and applicants for construction permits (CP), operating licenses (OL), combined licenses (COL), standard design certifications, standard design approvals, and manufacturing licenses (ML) to request authorization of voluntary alternatives to a broader scope of requirements in 10 CFR 50.55a.

Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods

There are two proposed changes to 10 CFR 50.59, ''Changes, tests, and experiments.'' The first proposed change to the regulation would allow the use of quantitative risk results to demonstrate a change to the facility does not result in a ''more than minimal increase'' as the phrase is used in 10 CFR 50.59(c)(2)(i) and (ii). The second proposed change would allow licensees to make changes to methods that would previously have required NRC review under 10 CFR 50.59(c)(2)(viii) or 53.1550(a)(2)(iv), provided the licensee adopts an acceptable verification, validation, and uncertainty quantification (VVUQ) program in accordance with a proposed new 10 CFR 50.221, ''Credibility requirements for modeling and simulation.'' This shift would enable licensee-led evaluations and allow for the evaluation of advanced modeling methods through structured processes rather than fixed requirements.

Minimum Decommissioning Funding Assurance for Non-Large Light-Water Reactors

The NRC is proposing rule changes in 10 CFR 50.75, ''Reporting and recordkeeping for decommissioning planning,'' to allow certain new reactor applicants and licensees to submit a design-specific decommissioning cost estimate that is less than the approved table of minimum amounts (*i.e.,* ''formula'') values in 10 CFR 50.75(c). The current regulations restrict minimum funding assurance for decommissioning to the table of minimum amounts values or greater. The NRC is proposing similar changes to 10 CFR part 53, which currently only allows for a site-specific decommissioning cost estimate as the certification amount. These changes would more broadly accommodate new reactor technologies.

Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

This proposed rule would incorporate an appendix T, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' to 10 CFR part 50. The proposed appendix T to 10 CFR part 50 would provide a voluntary alternative to appendix B, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' to 10 CFR part 50 that applicants, who meet certain conditions, could use in their respective applications. This action would support implementation of E.O. 14300, section 5, through (1) the establishment of performance-based quality assurance (QA) criteria that provide explicit direction on the use of a graded approach for applying QA requirements to SSCs relative to their safety and risk contributions to the overall nuclear facility; (2) the incorporation of QA terminology and methodologies used across various industries; (3) enhanced regulatory certainty during the application process; and (4) the removal, when appropriate, of NRC oversight of suppliers and vendors of products and services related to nuclear power plant and fuel reprocessing plant SSCs subject to this proposed rule.

Updates to Construction Permit Requirements and Related Licenses

The proposed rule would revise the content of applications relevant to technical information required for CPs in 10 CFR 50.34, ''Contents of applications; technical information,'' to remove some overly-prescriptive wording; clarify that the level of detail provided in a preliminary safety analysis report should be sufficient to permit the NRC to make the findings in 10 CFR 50.35(a), 10 CFR 50.40, ''Common standards,'' and 10 CFR 50.50, ''Issuance of licenses and construction permits''; and adjust some of the light-water reactor (LWR)-centric language to be more technology-inclusive. Conforming changes to parallel sections in 10 CFR part 52 are also proposed.

Alternative Risk-Informed and Performance-Based Acceptance Criteria for 10 CFR Parts 50 and 52

The NRC is proposing to amend its regulations by adding new, standalone provisions in 10 CFR 50.220 and 10 CFR 52.220, entitled ''Use of risk-informed and performance-based alternatives to acceptance criteria.'' These provisions would allow licensees and applicants to voluntarily submit and use technology-inclusive, risk-informed or performance-based acceptance criteria as alternatives to existing prescriptive requirements.

In addition, the NRC is proposing revisions to appendix A to 10 CFR part 50 to update and clarify its regulations for General Design Criteria (GDC). The proposed changes would explicitly allow deviations from the GDCs without requiring exemptions and would revise GDC 28, ''Reactivity limits,'' to remove the prescriptive requirement to evaluate control rod ejection and drop accidents. Instead, applicants would be permitted to propose an alternative design basis accident for reactivity control systems.

Establishing Thresholds for Changes to Reactor Designs During Construction and Operation Under 10 CFR Parts 52 and 53

In response to E.O. 14300, section 5(f), the NRC is proposing to amend its regulations related to reactor design changes made during construction and operation under the 10 CFR parts 52 and 53 licensing approaches. These changes would impact licensees that reference a certified design or manufacturing license under 10 CFR part 52 or 53. The objectives of these proposed changes are to establish appropriate thresholds for NRC-initiated changes as well as provide additional flexibility and reduce unnecessary regulatory burden for licensee-initiated changes.

Revision of the Emergency Preparedness Regulations for Nuclear Power Reactors

The NRC is proposing to amend its regulations to create adaptable licensing pathways for emergency preparedness (EP). Consistent with E.O. 14300, the NRC's objectives for this proposed rule are to streamline the licensing process, provide regulatory certainty for the deployment of new reactor technologies, and remove prescriptive language of lesser safety significance for licensed facilities. Central to these proposed changes is a strengthened, more risk-informed approach to EP for providing reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

Optional Submittal of Operational Programs

This rulemaking would allow a developer the option to voluntarily submit operational programs for NRC review and approval with an ML application. The intent is to allow construction permit/operating license (CP/OL) and COL applicants the flexibility to reference the standardized programs approved in the ML, use their own approved programs, or use a combination of both. Early review of these programs would support streamlined CP/OL or COL reviews.

Early Site Permit for Nuclear Power Plants

The NRC is proposing to amend its regulations by revising the provisions applicable to early site permit (ESP) licensing and approval processes for nuclear power plants. These amendments would eliminate the requirement for an ESP expiration date, clarify the applicability of various requirements to ESPs, and propose necessary conforming amendments throughout the NRC's regulations to enhance the NRC's necessary regulatory effectiveness and efficiency in implementing its licensing and approval processes.

Manufacturing License Term Extension

The NRC is proposing to amend the regulations in 10 CFR 52.173, ''Duration of manufacturing license,'' and 52.181, ''Duration of renewal,'' to change the duration of an ML to 40 years and the duration of the renewed ML to 40 years. By amending the regulations with these proposed changes, the ML would be consistent with the durations for certified designs, thereby increasing efficiency in building new reactors.

Nuclear Power Plant License Renewal

The NRC is proposing to amend its regulations for renewing nuclear power plant OLs. The revisions would extend the duration of renewed licenses, allow applicants to voluntarily propose alternative risk-informed and performance-based criteria, and remove several prescriptive requirements related to the application process and post-approval recordkeeping. These changes would enhance regulatory flexibility and efficiency to facilitate operational extensions for the current nuclear fleet.

Enhancing Flexibility of Reactor Site Criteria

The existing regulatory framework requires all stationary power reactor applications submitted after January 10, 1997, to follow the siting criteria in subpart B to 10 CFR part 100, ''Evaluation Factors for Stationary Power Reactor Site Applications on or After January 10, 1997,'' without consideration of reactor type, size, output, radiological consequence, or other factors that can widely vary given the breadth of power reactor designs considered for future construction and deployment in the United States. Subpart A, ''Evaluation Factors for Stationary Power Reactor Site Applications Before January 10, 1997 and for Testing Reactors,'' to 10 CFR part 100, ''Reactor Site Criteria,'' provides less prescriptive regulatory requirements for reactor siting but only applies to power reactor applications submitted prior to January 10, 1997, or an application for a testing reactor, as defined in 10 CFR 50.2. To increase the flexibility of regulatory requirements for the full spectrum of prospective reactor technologies, including non-stationary reactors, this proposed change would (1) revise subpart A to 10 CFR part 100 to include Tier 1 power reactors, as defined in proposed 10 CFR 100.3, ''Definitions,'' and DG–4036, ''Graded Approach to Site Characterization for New Reactor Applications,'' in addition to testing reactors; (2) remove appendix A to 10 CFR part 100 that applies to subpart A to 10 CFR part 100; and (3) revise subpart B to 10 CFR part 100 to include Tier 2 power reactors, which are those reactors that do not meet the entry criteria for subpart A to 10 CFR part 100. This proposed change will be accompanied by draft guidance on application content, including the entry criteria for subpart A to 10 CFR part 100, a clarification on site parameters to be included in a site parameter envelope, and an explanation of a graded approach to site characterization for all external hazards to be considered under both subparts A and B to 10 CFR part 100. In addition, the NRC proposes to revise 10 CFR part 100 to maintain the agency's long-standing preference for siting reactors in areas of low population density, while providing flexibility to allow siting reactors in areas of greater population density when justified by an assessment comparing the societal risks and societal benefits of siting reactors in those areas. Implementing guidance for these assessments will be developed.

Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors

The NRC is proposing to amend its regulations related to the use of conventional and accident tolerant LWR fuel designs. The NRC's goal is to establish effective and efficient licensing of the use of fuels enriched to greater than 5.0 weight percent uranium-235 while continuing to provide reasonable assurance of adequate protection of public health and safety. The new requirements also would address fuel fragmentation, relocation, and dispersal in relation to the key accident tolerant fuel components of increased enrichment and burnup limits.

C. Cost and Benefits

The NRC prepared a draft regulatory analysis to determine the expected quantitative and qualitative costs of the proposed rule and associated guidance. The draft regulatory analysis concluded that the proposed rule and associated guidance would result in undiscounted total net savings of $1.86 billion to the NRC and industry ($802.10 million using a 7 percent discount rate and $1.26 billion using a 3 percent discount rate).

The draft regulatory analysis also considers qualitative factors to be considered in the NRC's rulemaking decision. Qualitative factors include

regulatory efficiency. The proposed rule would enable the NRC to better maintain and administer the new reactor licensing process and ensure that the requirements for the licensing of new reactors are clear and appropriate.

For more information, the draft regulatory analysis is available as indicated in the ''Availability of Documents'' section of this document.

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I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2025–0975 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2025–0975.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin ADAMS Public Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section of this document.

• *NRC's PDR:* The PDR, where you may examine and order copies of publicly available documents, is open by appointment. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

• *Technical Library:* The Technical Library, which is located at Two White Flint North, 11545 Rockville Pike, Rockville, Maryland 20852, is open by appointment only. Interested parties may make appointments to examine documents by contacting the NRC Technical Library by email at *Library.Resource@nrc.gov* between 8 a.m. and 4 p.m. Eastern Time, Monday through Friday, except Federal holidays.

• *Public Meeting:* The NRC will conduct public meetings to describe the proposed amendments and answer questions from the public on the proposed rule. The NRC will publish a notice of the location, time, and agenda of the meetings on the NRC's public meeting website within 10 calendar days of the meetings. Stakeholders should monitor the NRC's public meeting website for information about the public meetings at: *https://www.nrc.gov/public-involve/public-meetings/index.cfm.*

B. Submitting Comments

Comments must be submitted using *https://www.regulations.gov* by 11:59 p.m. Eastern Time on August 31, 2026. Please include Docket ID NRC–2025–0975 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Executive Order 14300: Ordering the Reform of the Nuclear Regulatory Commission

On May 23, 2025, President Donald J. Trump signed Executive Order (E.O.) 14300, ''Ordering the Reform of the Nuclear Regulatory Commission.'' Section 5, ''Reforming and Modernizing the NRC's Regulations,'' requires the Nuclear Regulatory Commission (NRC) to undertake a review and wholesale revision of its regulations and guidance documents as guided by the policies set forth in section 2 of the E.O. This rulemaking addresses section 5(f), which directs the NRC to ''[e]stablish stringent thresholds for circumstances in which the NRC may demand changes to reactor design once construction is underway''; section 5(h), which directs the NRC to ''[a]dopt revised and, where feasible, determinate and data-backed thresholds to ensure that reactor safety assessments focus on credible, realistic risks''; and section 5(i), which directs the NRC to ''[r]econsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.'' Additionally, as part of the NRC's overarching review of all of its regulations, the agency identified a number of additional changes to the NRC's regulations that will improve the efficiency and efficacy of its licensing process that are also included in this rulemaking. In developing the proposed changes, the NRC has considered the benefits of increased availability of, and innovation in, nuclear power to our economic and national security consistent with section 501(a) of the Accelerating Deployment of Versatile, Advanced Nuclear for Clean Energy Act of 2024 (ADVANCE Act) and section 3 of E.O. 14300.

III. Background—Expedited Construction of Certain Structures, Systems, and Components

A. Definition of Construction

Section 185 of the Atomic Energy Act of 1954, as amended (AEA), requires that the NRC grant construction permits (CPs) to applicants for licenses to construct or modify production or utilization facilities, if the applications for such permits are acceptable to the NRC. However, the term ''construction'' is not defined anywhere in the AEA. Instead, construction is defined within section 50.10, ''License required; limited work authorization'' of part 50, ''Domestic Licensing of Production and Utilization Facilities,'' in title 10 of the *Code of Federal Regulations* (10 CFR). The Commission last updated this definition in 2007 as part of the limited work authorization (LWA) final rule, ''Limited Work Authorizations for Nuclear Power Plants'' (72 FR 57416; October 9, 2007).

In developing this definition of construction in the 2007 LWA final rule, the Commission concluded that the definition of construction should parallel the agency's jurisdiction because activities outside the definition of construction would not require prior authorization. Therefore, the Commission ''determined that construction should include all of the activities that have a reasonable nexus to radiological health and safety, or common defense and security'' (72 FR 57429; October 9, 2007). For the 2007 LWA final rule, the scope of structures, systems, and components (SSCs) falling within the definition of construction was derived from the scope of SSCs that are included in the program for monitoring the effectiveness of maintenance at nuclear power plants, as defined in 10 CFR 50.65(b), because ''the definition is well understood and there is good agreement on its implementation'' (72 FR 57429–30; October 9, 2007). The SSCs were supplemented with those necessary to comply with emergency preparedness and security regulations because they also have a reasonable nexus to radiological safety or are required for the common defense and security.

New reactor designs and deployment strategies, as well as lessons learned from previous examples, warrant a fresh look at how application of the 10 CFR 50.10 definition of construction may unnecessarily restrict construction of nuclear power plants using modern construction techniques on optimized schedules. Additionally, some prospective applicants to construct a nuclear power reactor have indicated

the desire to construct portions of the facility, such as permanent materials left in an excavation, or even balance of plant systems, in advance of a CP or combined license (COL), and without an LWA, based on their business needs and the lack of the SSCs' safety significance. The Commission recognizes that the activities undertaken to build or install some facility SSCs will not affect the safety-significant functions of those SSCs, even though the 2007 rule could have been understood to require a license to build or install them, and the NRC need not authorize such activities before they occur. Moreover, the NRC has considered and granted exemptions from the current definition of construction to allow an applicant to build SSCs over which the NRC exercises authority but for which construction is not material to the safety function of the SSC.

B. General Licenses

In regard to general licenses for utilization facilities, section 109 of the AEA, ''Component and Other Parts of Facilities,'' authorizes the Commission to ''issue general licenses for domestic activities required to be licensed under section 101 [of the AEA]'' with respect to those utilization facilities determined by the Commission under section 11cc.(2) of the AEA. Section 11cc.(2) of the AEA defines such facilities as ''any important component part especially designed for [a utilization facility as defined under sec. 11cc.(1) of the AEA] as determined by the Commission.'' Under section 109 of the AEA, the Commission may issue a general license authorizing construction of such ''important component parts'' if it ''determines in writing that such general licensing will not constitute an unreasonable risk to the common defense and security.''

In order to accommodate the business models for new reactor designs some prospective vendors are proposing and to enable rapid deployment strategies for advanced reactor technologies, the NRC plans to revise its regulations to allow the use of general licenses for construction of important component parts of a utilization facility.

IV. Discussion—Expedited Construction of Certain Structures, Systems, and Components

A. Definition of Construction

The NRC is proposing to revise its regulations to update the definition of ''construction'' in 10 CFR 50.10, 10 CFR 51.4, ''Definitions,'' and 10 CFR 53.020, ''Definitions,'' to facilitate the safe construction of nuclear power plants using modern construction techniques on optimized schedules.

Specifically, this proposed rule would revise the definition of construction to include SSCs for which construction can affect the SSC's capability to perform a safety-related or safety-significant function and will, therefore, require NRC approval before commencing construction. An additional purpose of this change is to afford license applicants, when justified, additional flexibility to build or install SSCs whose safety-related or safety-significant functions are not significantly affected by those activities at a site prior to the issuance of a license. Those SSCs that are constructed without NRC authorization may still be subject to additional operational requirements as part of any subsequent operating license (OL) that would be issued.

B. Safety Review

Since the issuance of the 2007 LWA final rule, the NRC has observed that prospective advanced reactor applicants have designed their facilities with separation between nuclear and balance of plant SSCs in mind, such that many of the criteria in the current definition for a construction activity are not met for certain SSCs. Some stakeholders have maintained that such SSCs do not have a reasonable nexus to safety and therefore the unmet criteria are not necessary to provide reasonable assurance of adequate protection to the health and safety of the public; therefore, those unmet criteria are not needed or do not serve the underlying purpose of the rule. Lacking a revision to the definition, the remaining unmet criteria prevent prospective applicants from constructing such components without first obtaining an LWA, CP, a COL, or an exemption.

The proposed construction definition would be limited to those SSCs for which construction activities may have a significant impact on radiological health and safety. For other SSCs, even those that may have a nexus to radiological health and safety during operation, operational requirements should suffice, and the NRC need not license the construction of those SSCs.

The flexibility afforded by this proposed change would rely on an applicant-performed analysis and categorization of the SSCs of the facility to those that do and those that do not meet the definition of construction.

The set of SSCs that would meet the definition of construction should include only those SSCs that perform safety-related functions or that perform safety-significant functions and the successful completion of those functions may be impacted by construction. For those SSCs, prior NRC approval for construction would be required because inadequate design or construction of those SSCs could have a substantial contribution to radiological risk during operation.

Activities undertaken to build onsite emergency facilities necessary to comply with either 10 CFR 50.160, ''Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities,'' or 10 CFR 50.47, ''Emergency plans,'' and appendix E to 10 CFR part 50, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' or 10 CFR 53.855, ''Emergency preparedness,'' as applicable, would not be considered SSCs that meet the definition of construction. Historically, emergency response facilities (ERF) were included due to their reasonable nexus to radiological health and safety, but they would not fall under the criteria in proposed 10 CFR 50.10(a)(1)(i) through (iii) or 10 CFR 53.020. Instead, applicants would comply with the requirements of 10 CFR 50.160, or 10 CFR 50.47 and appendix E to 10 CFR part 50, or 10 CFR 53.855, as applicable. The applicant would need to be aware of all functional requirements of 10 CFR 50.160, or 10 CFR 50.47 and appendix E to 10 CFR part 50, or 10 CFR 53.855 for ERFs. These functional requirements would need to be validated in a preoperational exercise, which would satisfy the historical reasons why ERFs were previously included in the construction definition.

For license applicants under 10 CFR parts 50 and 52, ''Licenses, Certifications, and Approvals for Nuclear Power Plants,'' the proposed revisions to the definition of construction would also support use of the SSC categorization methodology for designs licensed under the technology-inclusive, risk-informed, and performance-based methodology described in regulatory guide (RG) 1.233, ''Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' dated June 2020. Under this framework, the applicant would use its probabilistic risk assessment (PRA) of the design to analyze the function of the SSCs. As explained in RG 1.233, the applicant's analysis would result in the classification of SSCs into one of four categories: ''safety-related,'' ''non-safety-

related with special treatment,'' ''non-safety-related with no special treatment,'' and ''all other SSCs'' (with no special treatment required). Within the RG 1.233 methodology, ''safety-significant'' SSCs include all those SSCs classified as ''safety-related'' or ''non-safety-related with special treatment.'' Those SSCs whose construction could impact their safety-significant function, and thus would fall under the definition of construction in the amended 10 CFR 50.10(a)(1)(i) and (ii), would likely include only those SSCs that were analyzed and classified as safety-related or non-safety-related with special treatment. It is possible that a subset of some non-safety-related with special treatment SSCs could have no safety functions which would be impacted by the construction of the SSC. For these cases, an applicant could provide further information that justifies the exclusion of the SSC from the definition of construction. All SSCs classified as either ''non-safety-related with no special treatment'' or ''all other SSCs,'' would likely not be included in the definition of construction under those criteria because, as demonstrated in the PRA, their impact on safety as evaluated under the methodology would be negligible. Consequently, the proposed amendments to 10 CFR 50.10 would enable applicants referencing RG 1.233 greater flexibility to undertake preconstruction activities.

Applicants under 10 CFR part 50 or 52, when determining whether SSCs fall under the criteria in proposed 10 CFR 50.10(a)(1)(i) through (iii), would confirm that other considerations do not require that the resulting list of SSCs should otherwise be subject to NRC quality assurance (QA) requirements for design in appendix B to 10 CFR part 50, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.'' Criterion III of appendix B to 10 CFR part 50 sets forth requirements for design control, and appendix B to 10 CFR part 50 includes other requirements (*e.g.,* for records and audits) that apply to the design of SSCs subject to appendix B to 10 CFR part 50.

In addition, applicants under 10 CFR parts 50 and 52 would also confirm that other considerations would not require that any other SSC should be subject to general design criterion (GDC) 1, ''Quality standards and records,'' in appendix A to 10 CFR part 50. Criterion 1 of appendix A to 10 CFR part 50 also imposes corresponding requirements for SSCs important to safety but not safety-related to the extent such requirements are commensurate with an SSC's importance to safety. Safety-related SSCs are subject to all requirements in appendix B to 10 CFR part 50, including QA requirements applicable to facility operation.

Application of the QA requirements for design in proposed appendix T, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' to 10 CFR part 50 (see section XVI of this document), could also affect the definition of construction for applicants under 10 CFR part 50, 52, or 53, ''Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants.'' Specifically, the definition of construction proposed in this rule would include SSCs subject to the requirements of proposed appendix T to 10 CFR part 50, and, in certain instances, the structures built for those SSCs.

Applicants under 10 CFR parts 50 and 52 must comply with criterion 1 of appendix A to 10 CFR part 50. This criterion requires that ''SSCs important to safety be designed, fabricated, erected, and tested'' to QA standards commensurate with the importance of the safety functions to be performed. However, an SSC could be subject to performance requirements for operation but would not warrant the application of QA measures under GDC 1 such as QA for design. Specifically, the SSC could be commercial grade but also subject to specified operational performance requirements. Such an SSC could be constructed without a license. The rationale for the approach rests on the fact that if no NRC QA requirement for design, fabrication, erection, and testing applies to an SSC, then there is nothing uniquely related to nuclear safety for the NRC to approve with respect to construction of the SSC. Further, design limits on the *operation* of the SSCs that do perform safety functions would prevent or mitigate the safety effects of the failure of SSCs not subject to NRC QA requirements applicable to construction. Accordingly, construction of such SSCs would not have a reasonable nexus to nuclear safety, even if operation of the SSC did have a reasonable nexus to nuclear safety.

The failure of an SSC that has an effect on the safety of operation could warrant operational requirements with respect to SSCs that perform safety functions in response to such failures and possibly operational requirements with respect to the SSCs themselves.

An applicant's designation of an SSC as something that does not meet the definition of construction would not restrict the NRC from imposing such operational requirements to address radiological health and safety.

The NRC encourages pre-application engagement when licensees plan to undertake significant preconstruction activities to assist the NRC staff to further understand which SSCs have a reasonable nexus to radiological health and safety at the construction phase. An applicant may communicate its plan to comply with the regulations, including an SSC classification methodology to the NRC as part of preapplication interactions. The NRC staff will provide feedback as appropriate. Alternatively, one or more prospective license applicants could propose a generic SSC classification methodology, which the NRC staff could review and endorse as acceptable guidance outside a particular licensing action. The approved methodology could then be referenced by multiple applicants.

Similar to the existing regulations, if an applicant under the proposed rule determines that an SSC falls within the scope of the definition of construction in the proposed 10 CFR 50.10 or 53.020, an exemption request or an LWA would need to be submitted to the NRC to allow for this construction activity to occur prior to issuance of a CP or COL. Similar to the existing processes, the LWA would be granted if the underlying requirements of 10 CFR 50.10(d) and (e) or 10 CFR 53.1130, ''Limited work authorizations, general licenses,'' as applicable, are met.

C. Environmental Review

As explained in section IV.A., ''Definition of Construction,'' of this document, a CP, COL, or LWA applicant does not need to obtain an NRC license to build SSCs that do not meet the definition of construction in 10 CFR 51.4. As long as there is no other Federal action authorizing these activities, under 10 CFR 51.20 through 51.22, an environmental review under the National Environmental Policy Act (NEPA) is not required. Activities undertaken to build SSCs excluded from the definition of construction are not part of an NRC licensing action because such construction activities do not have a reasonable nexus to nuclear safety, even if operation of a particular SSC does have a reasonable nexus to nuclear safety. An applicant's classification of an SSC as not safety-significant, that is built prior to issuance of a license, would not restrict the NRC from imposing operational requirements on those SSCs through a later action.

For SSCs that do meet the definition of construction where the NRC would authorize construction, the NRC must perform an environmental review in accordance with 10 CFR 50.10 or 53.610, ''Construction,'' as applicable,

and the application requirements of 10 CFR part 51, ''Environmental Protection Regulations for Domestic Licensing and Related Regulatory Functions.''

D. General Licenses and Generic Finality

The NRC proposes to add new 10 CFR 50.10(h) and 53.1130(e), which would implement the authority in section 109 of the AEA to create a general license allowing construction of an important component part of a specified class of commercial nuclear plants. The specified class of plants would be those plants of a design the NRC previously approved in a licensing action in which the NRC also granted ''generic finality,'' as discussed later, and for which operation has been authorized. The important component part defined as a utilization facility under Section 11cc.(2) of the AEA and subject to the general license would be the portion of the plant constructed on site except for the reactor vessel, the reactor coolant system, and associated reactivity control and heat removal systems. The general license would authorize construction of the important component part upon docketing of an application for a license that would authorize construction of the nuclear plant, subject to conditions. The conditions would provide reasonable assurance of adequate protection of the health and safety of the public and common defense and security, and would also ensure an appropriate level of environmental review. The NRC also proposes a conforming change to 10 CFR 50.10(c) and 53.610(b) to provide that construction may occur under the general licenses issued in 10 CFR 50.10(h) and 53.1130(e), respectively.

The construction activities authorized by the general license would be limited to those SSCs for which a previously approved design was provided generic finality, but would not include the reactor vessel, the reactor coolant system, and associated reactivity control and heat removal systems. The NRC expects that the construction of SSCs approved through a general license would be for those SSCs that are not inherently sensitive to the site-specific characteristics of a proposed deployment site. Although construction of many SSCs in a particular design could conceptually be approved through a general license, the NRC cannot approve the construction of an entire utilization facility through this provision.

The proposed new regulations would enable future applicants to reference previously reviewed and approved information only when significant safety and environmental issues related to design, construction, and operation are generically resolved in a manner that applies to the intended use of the information. For example, to qualify for a general license, an applicant would have to reference a nuclear reactor design that was afforded generic finality by the NRC and successfully constructed under NRC oversight and placed into operation. Also, the applicant's proposed site would have to fall within the corresponding site parameter envelope that was provided in the request for generic finality. Therefore, an application that satisfies the proposed new regulation would provide reasonable assurance of adequate protection of public health and safety and common defense and security equivalent to satisfaction of existing regulations, and there would have been a prior hearing opportunity on the reactor design being referenced. Further, the proposed regulation would require the general licensee to allow for NRC inspections that the Commission deems necessary related to activities performed under the general license.

The general license regulation would also include conditions to address environmental considerations. The OL or COL (as applicable) of the plant for which generic finality was approved would either have met the criteria for categorical exclusion or had a finding of no significant impact after preparation of an environmental assessment. Provided that the environmental characteristics of the proposed plant fall within the environmental parameters for the plant for which generic finality was approved, the environmental effects of a subsequent plant would not exceed those of the approved plant and would be acceptable. In addition, the applicant proposing to use the general license would have to propose a plan for redress of any adverse environmental impact from conduct of activities under the general license should such redress be necessary. This proposed requirement would be similar to the requirements in 10 CFR 50.10(d)(3)(iii), which requires a redress plan as part of an application for an LWA, and 10 CFR 50.12(b)(2), which requires the Commission to consider redress of adverse environmental impacts in determining whether to grant an exemption permitting the conduct of construction activities prior to the issuance of a CP.

The proposed general license regulation would also require that the general licensee has notified the NRC that all applicable permits, licenses, approvals, and other entitlements in connection with the proposed action that the general licensee was responsible for obtaining have been obtained. In addition, the proposed general license would require that applicable Federal environmental consultations have been completed. This would ensure that construction activities would not begin unless the NRC has the information it would need to fulfill its obligations for environmental review under the AEA, NEPA, and other relevant laws.

In addition, the proposed general license regulation would clarify that any activities undertaken by the general licensee or on its behalf under the general license would be entirely at the risk of the general licensee and would have no bearing on the issuance of a license with respect to the requirements of the AEA, and rules, regulations, or orders issued under the AEA. However, the general licensee would be able to mitigate this additional regulatory risk through careful site selection to ensure that site characteristics are within the bounds of the postulated site parameters and by performing construction activities following appropriate QA and fitness-for-duty programs.

Based on the proposed general license requirements in 10 CFR 50.10(h) and 53.1130(e), the Commission has determined that such general licensing would be for only parts of utilization facilities, not constitute an unreasonable risk to the common defense and security, and, therefore, be consistent with the authority provided to the Commission by section 109a. of the AEA.

In addition, in order to facilitate the use of the general licensing concept, the NRC proposes to add conforming changes to the following regulations.

The NRC proposes to add new 10 CFR 50.34(b)(14) which would require an OL application for those 10 CFR part 50 applicants that request the NRC to make a finding on generic finality, to include applicable site parameters postulated for the design, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters. Similarly, the NRC proposes to add new paragraph (bb) to 10 CFR 53.1369, ''Contents of applications for operating licenses; technical information,'' for 10 CFR part 53, ''Risk-Informed, Technology-Inclusive Regulatory Framework for Commercial Nuclear Plants,'' OLs for the same purpose. For COL applications under 10 CFR part 52 or 53, this application content requirement would be included in a new 10 CFR 52.79(a)(48) and 53.1416(i), respectively. The site parameters may be the same as or more severe than the site

characteristics established for the site of the reactor proposed in the OL or COL application that proposed generic finality.

The NRC also proposes to add a new 10 CFR 50.58(b)(7), which would require the Commission to include the request for generic finality as a proposed action in the notice of proposed action required by 10 CFR 2.105 for OL applications. Similarly, the NRC also proposes to add a new paragraph (b)(2) to 10 CFR 53.1375, ''Review of applications,'' which would require the Commission to include the request for generic finality as a proposed action in the notice of proposed action for a 10 CFR part 53 OL, required by 10 CFR 2.105. For COL applications, the NRC proposes to add a new 10 CFR 52.85(b) and 53.1422(b)(2), which would require the Commission to include the request for generic finality as a proposed action in the notice of hearing required by 10 CFR 2.104 for COL applications under 10 CFR parts 52 and 53, respectively. These changes would provide a hearing opportunity to the public on the request for generic finality. In addition, the Commission's ruling on a request for hearing or petition for leave to intervene under 10 CFR 2.309(d)(2) would consider that a petitioner may have an interest in the application if matters resolved in the licensing proceeding were to be afforded generic finality. This would enable petitioners whose property, financial, or other interests would not be directly affected by the issuance of the OL or COL for a particular reactor to have an opportunity to intervene on generic aspects of the design that would be afforded finality and would therefore not be subject to hearing if referenced in a later application that would affect the petitioner's property, financial, or other interest.

Consistent with the previous discussion, the NRC proposes to add new 10 CFR 50.57(d), which would permit the Commission to afford generic finality to generic aspects of the design of a utilization facility licensed under 10 CFR part 50, including postulated site parameters submitted pursuant to 10 CFR 50.34(b)(14), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design. For the same reason and with the same conditions, the NRC proposes to add new paragraph (e) to 10 CFR 53.1387, ''Issuance of operating licenses,'' which would permit the Commission to afford generic finality to generic aspects of the design of a commercial nuclear plant licensed under 10 CFR part 53, including postulated site parameters submitted pursuant to 10 CFR 53.1369(bb).

Similarly, the NRC proposes to add new 10 CFR 52.97(d) which would permit the Commission to afford generic finality to generic aspects of the design of a utilization facility licensed under 10 CFR part 52, including postulated site parameters submitted pursuant to 10 CFR 52.79(a)(48), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design. For the same reason and with the same conditions, the NRC proposes to add new paragraph (d) to 10 CFR 53.1440, ''Issuance of combined licenses,'' which would permit the Commission to afford generic finality to generic aspects of the design of a commercial nuclear plant licensed under 10 CFR part 53, including postulated site parameters submitted pursuant to 10 CFR 53.1416(i).

The regulations in 10 CFR 50.59, ''Changes, tests and experiments,'' that establish requirements for making changes to portions of the facility as described in the final safety analysis report (FSAR) for an OL are applicable to generic aspects of the design of a utilization facility that have been afforded generic finality because that design information would be included in the FSAR for the OL. Similarly, the regulations in 10 CFR 50.59 are applicable to generic aspects of the design of a utilization facility that are described in a COL FSAR and have been afforded generic finality.

Similarly, the regulations in 10 CFR part 53 that establish requirements for making changes to portions of the facility as described in the FSAR are applicable to generic aspects of the design of a utilization facility that have been afforded generic finality.

The NRC proposes to add new 10 CFR 50.58(b)(8) and 52.98(h) to include requirements to address finality for portions of 10 CFR part 50 OLs and 10 CFR part 52 COLs with respect to NRC reviews and hearings. Proposed 10 CFR 50.58(b)(8) would require the Commission to treat as resolved any issues referenced in following proceedings or in enforcement hearings (other than ones under 10 CFR 2.202(e)(1)) that were afforded finality pursuant to 10 CFR 50.57(d). The proposed 10 CFR 50.58(b)(8) would ensure that issues resolved in an approved request for generic finality (including, if applicable, the adequacy of a reactor design) are not re-adjudicated in the license proceedings where such information is referenced in the license applications. The proposed 10 CFR 52.98(h) would include substantially the same provisions for COLs with generic finality.

To address generic finality in 10 CFR part 53, the NRC proposes to add similar provisions to new paragraph (b) to 10 CFR 53.1390, ''Finality of operating licenses,'' and new paragraph (g) to 10 CFR 53.1443, ''Finality of combined licenses.''

Proposed 10 CFR 53.1390(b) would require the Commission, in the proceedings for issuance of a CP, an OL, or a COL or in any enforcement hearing (other than one initiated under 10 CFR 53.1390(a)), to treat as resolved those matters resolved in the proceedings on the application or renewal of the referenced OL, including, if applicable, the adequacy of a reactor design where the referenced OL was afforded finality pursuant to 10 CFR 53.1387(e).

Proposed 10 CFR 53.1443(g) would require the Commission, in the proceedings for issuance of a CP, an OL, or a COL or in any enforcement hearing (other than one initiated under 10 CFR 53.1443(a)), to treat as resolved those matters resolved in the proceedings on the application or renewal of the referenced COL, including, if applicable, the adequacy of a reactor design where the referenced COL was afforded finality pursuant to 10 CFR 53.1440(d).

As written, the proposed generic finality provisions would allow the NRC to take appropriate action under the applicable backfitting or issue finality provision if the NRC determines that the generic finality approval or associated technical information presents safety concerns that warrant NRC action. As stated above, the generic finality that would be afforded under the proposed rule provisions would *not* apply to certain enforcement hearings. For example, proposed 10 CFR 50.58(d)(8) provides that finality would apply, in part, to ''any enforcement hearing *other than one initiated by the Commission under § 2.202(e)(1) of this chapter*'' (emphasis added). Enforcement hearings under 10 CFR 2.202(e)(1) are those which involve a backfit to modify a 10 CFR part 50 license, and 10 CFR 50.109 must be followed for such orders and the associated proceedings. Thus, generic finality would not apply in such cases so that the NRC could take appropriate action if the backfitting requirements in 10 CFR 50.109 are satisfied. Similarly, the proposed generic finality provisions in 10 CFR 52.98(h), 53.1390(b), and 53.1443(g) would provide that generic finality applies except in enforcement hearings initiated under the issue finality

provisions in 10 CFR 52.98(a), 53.1390(a), and 53.1443(a), respectively.

V. Background—Determinate and Data-Backed Thresholds for Reactor Safety Assessments

Section 5(h) of E.O. 14300 directs the NRC to ''[a]dopt revised and, where feasible, determinate and data-backed thresholds to ensure that reactor safety assessments are focused on credible, realistic risks.''

The NRC evaluated ''reactor safety assessments,'' focusing on assessments conducted to (1) demonstrate the capability of safety-related SSCs during design basis events (DBEs) (*e.g.,* as described in Chapter 15, ''Transient and Accident Analysis,'' of NUREG–0800, ''Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition''), and (2) verify the ability of SSCs to withstand certain design basis conditions, including natural phenomena and environmental conditions (*e.g.,* high winds, seismic events, and conditions during normal operation and accident scenarios). To effectively address the direction in E.O. 14300, the NRC concluded that the most appropriate approach would be to clarify the terminology in 10 CFR 50.2, ''Definitions,'' to ensure that safety assessments are focused on credible, realistic risks.

The selection of DBEs and associated design basis parameters is a critical prerequisite for determining the safety of a nuclear facility. DBEs serve to identify the subset of SSCs subject to more stringent QA requirements and to establish the performance capabilities those SSCs must demonstrate under normal operation, anticipated operational events, and accident conditions. For example, 10 CFR 50.46, ''Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors,'' requires analysis of postulated loss-of-coolant accidents to verify the adequacy of emergency core cooling system (ECCS) designs. In addition to the general requirement to analyze SSC performance during DBEs, other regulations specify additional, event-specific accident analyses, often referred to as beyond design basis events (BDBEs). For example, 10 CFR 50.63, ''Loss of all alternating current power,'' provides requirements related to plants' abilities to withstand for a specified duration and recover from a station blackout (SBO).

The technical information required in applications for CPs and OLs, including the content of preliminary and FSARs, is outlined in 10 CFR 50.34, ''Contents of applications; technical information.'' Among other requirements, an applicant is required to evaluate siting considerations and the design and performance of SSCs that are intended to prevent accidents and mitigate their consequences. The regulatory processes described in 10 CFR part 52 include similar technical information requirements for the content of applications (*e.g.,* as specified in 10 CFR 52.17, ''Contents of applications; technical information,'' 52.47, ''Contents of applications; technical information,'' 52.79, ''Contents of applications; technical information in final safety analysis report,'' 52.137, ''Contents of applications; technical information,'' and 52.157, ''Contents of applications; technical information in final safety analysis report'').

The technical information associated with the performance of safety assessments is documented in the preliminary or FSAR for CPs or OLs and COLs, respectively. The FSAR describes the evaluation methods used to establish design bases and perform safety analyses, the design and performance requirements for SSCs, and the methods used to demonstrate that those SSCs can perform their intended safety functions. Accordingly, the FSAR serves as an essential component of the licensing basis for a nuclear facility. It is also used to determine the appropriate regulatory process for licensing basis changes, such as those governed by 10 CFR 50.59, ''Changes, tests and experiments,'' or 10 CFR 50.90, ''Application for amendment of license, construction permit, or early site permit.''

Within the power reactor licensing framework, the term ''safety-related'' is used to identify SSCs that require special treatment, including QA controls, environmental qualification, and compliance with applicable industry codes and standards. The current definition of ''safety-related SSCs,'' provided in 10 CFR 50.2, uses the term ''design basis events'' to define the scope of safety assessments needed to identify safety-related SSCs. However, 10 CFR 50.2 does not include a corresponding definition of ''design basis event'' or provide criteria for selecting events to be considered in the design basis. While 10 CFR 50.49, ''Environmental qualification of electric equipment important to safety for nuclear power plants,'' includes a definition of DBEs, that definition does not explicitly apply to the definition of safety-related SSCs in 10 CFR 50.2 and does not reference the use of determinate, data-backed thresholds.

Traditionally, the spectrum of DBEs used to identify safety-related SSCs, as defined in 10 CFR 50.2, has been based on information contained in Chapter 15 of NUREG–0800. While this approach had been effective for licensing large light-water reactors (LWRs) with designs similar to the currently operating power reactor fleet, the DBEs described in NUREG–0800 can have limited applicability to evolutionary LWR designs and non-LWR designs. For example, the lack of a more technology-inclusive definition for the term DBE in the current definition has created challenges with respect to clarity and reliability on the subset of SSCs that warrant special treatment. Furthermore, it has created the potential to require safety assessments that may not be focused on credible, realistic risks. Therefore, clarifying what constitutes a DBE based on determinate, data-backed thresholds would enhance the efficiency and consistency of future power reactor licensing reviews. Consequently, the NRC proposes to provide a definition for DBE in 10 CFR part 50.

Nonetheless, the NRC has not identified a need to propose a corresponding revision to the term ''design bases'' in 10 CFR 50.2. The term ''design bases'' is defined in 10 CFR 50.2 as information which identifies the specific functions to be performed by a structure, system, or component of a facility, and the specific values or ranges of values chosen for controlling parameters as reference bounds for design. The definition further clarifies that design basis values may be (1) constraints derived from generally accepted ''state-of-the-art'' practices for achieving functional goals or (2) requirements based on analyses of the effects of postulated accidents for which an SSC must meet specified functional goals. Design bases are connected to safety assessments in two ways: (1) the performance capabilities of SSCs, as established through evaluations of DBEs and BDBEs, and (2) the design parameters for SSCs, which are derived from the operational context in which the function is to be performed, including considerations of natural phenomena and environmental factors. The NRC has determined that the existing definition of design bases in 10 CFR 50.2 provides sufficient flexibility to support the use of determinate, data-backed thresholds. In practice, the NRC has already applied determinate and data-backed thresholds for the selection of design bases attributes in several areas, including high winds, flooding, and seismic hazards. Therefore, a rulemaking to revise the definition of design bases is not necessary. However, the NRC is issuing draft guidance (DG)

that will provide additional detail within DG–1454, ''Implementation of Determinate and Data-Backed Thresholds for Reactor Safety Assessments,'' to support consistent application in this area.

The term BDBE has not previously been defined in 10 CFR 50.2. However, lessons learned from ongoing studies of nuclear plant risks, as well as operational experience, have historically led the NRC to identify and address plant events and conditions beyond the originally defined set of DBEs that could result in the release of radioactive material sufficient to pose a hazard to public health and safety. Accordingly, the NRC has imposed additional requirements to address such events when risk insights emerged from operational experience (*e.g.,* SBO in 10 CFR 50.63 and anticipated transients without scram (ATWS) in 10 CFR 50.62, ''Requirements for reduction of risk from anticipated transients without scram (ATWS) events for light-water-cooled nuclear power plants''). These requirements extended regulatory attention beyond the traditional scope of DBEs. When developing this proposed rulemaking, the NRC initially considered a framework where these types of events were included in the DBE category. However, experience with regulating events such as SBO and ATWS has demonstrated that these types of events can be adequately addressed without the same regulatory treatment as DBEs. Therefore, the formal inclusion of the BDBE category in this proposed rule would provide a framework for applying graded regulatory treatment to such events. It would enable the NRC to address risks to public health and safety that do not warrant mitigation exclusively through safety-related SSCs or conservative safety assessments. Consequently, the NRC proposes to provide a definition for BDBE in 10 CFR part 50.

VI. Discussion—Determinate and Data-Backed Thresholds for Reactor Safety Assessments

The proposed changes would revise 10 CFR 50.2 to add definitions for the terms ''design basis events'' and ''beyond design basis events.'' The proposed changes would include a conforming revision to the definition of ''design basis event'' in 10 CFR 50.49(b)(1)(ii). These changes would apply to future 10 CFR part 50 and 52 applications submitted on or after the date that would be 180 days after the effective date of a final rule if this proposed rule were issued as a final rule; however, existing applicants, licensees, and approval holders under 10 CFR part 50 or 52 could voluntarily choose to adopt them. In parallel with the proposed changes, the NRC has developed DG–1454, which would (1) describe determinate and data-backed thresholds for categorizing events as DBEs or BDBEs, (2) outline graded assessment approaches for each event category, and (3) clarify the process for selecting design bases controlling parameters used as reference bounds in the design of SSCs. This guidance would use initiating event frequencies and qualitative criteria for categorizing events, maintaining consistency with the current safety assessment framework described in 10 CFR part 50 (and referenced in 10 CFR part 52). In addition, this guidance would describe acceptable approaches for identifying, grouping, and quantifying initiating events to ensure they are binned into appropriate categories. While alternate approaches, such as defining thresholds in terms of event sequences could be used, they would typically require the development of a full risk assessment or other systematic risk evaluation to determine sequence frequencies. To avoid imposing additional requirements not currently included in 10 CFR part 50, anchoring event selection to initiating event frequencies would provide a determinate and data-backed approach without adding regulatory burden.

Adding generally applicable definitions for DBE and BDBE would improve regulatory clarity and enable the use of objective criteria in selecting initiating events. Establishing threshold criteria, graded assessment approaches, and the selection process for design basis parameters within guidance would ensure that applicants and licensees are provided with an approach acceptable to the NRC, while ensuring flexibility for applicants to justify unique approaches, if desired, without the need for an exemption.

The addition of a definition of BDBE and corresponding thresholds would allow a reduction in unnecessary conservatism applied in the safety assessments of lower frequency events. The NRC concluded that reactor safety assessments associated with BDBEs are within the scope of the existing contents of application requirements of 10 CFR 50.34 and analogous sections of 10 CFR part 52. Specifically, requirements related to analysis and evaluation of the design and performance of SSCs of the facility with the objective of assessing the risk to public health and safety include consideration of BDBEs. Several existing regulations already address specific events not originally considered in the licensing basis or considered BDBEs (examples include but are not limited to ATWS, loss of all alternating current power events resulting in SBOs, and combustible gas control). For current applicants, licensees, or approval holders who may opt to adopt the proposed definitions for DBE and BDBE, as well as future applicants who would be mandated to use the proposed definitions, this rulemaking would not change the treatment of BDBEs specifically addressed by regulation such as ATWS and SBO. However, adoption of the BDBE definition could eliminate some events not specifically addressed by regulation from consideration that are determined to be non-credible.

Similarly, evaluations that assume substantial release of fission products would still be performed in accordance with 10 CFR 50.34(a) and 10 CFR 50.67, ''Accident source term.'' For LWRs, the release would be into containment. For other designs, it may be expressed as releases to the environment considering expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of accidents. These evaluations would address the safety features that are engineered into a facility and those barriers that must be breached as a result of an accident before a radiological release to the environment can occur. Evaluations required to comply with 10 CFR 50.34(a) and 10 CFR 50.67 rely on conservative modeling assumptions. For example, as described in RG 1.183, ''Alternative Radiological Source Terms for Evaluating Design Basis Accidents at Nuclear Power Reactors,'' source term fission product release fractions are derived from a set of accident sequences and many physical processes and phenomena are represented by bounding assumptions rather than being modeled directly. In addition, these evaluations credit only safety-related features in providing mitigation capability. Therefore, this evaluation is generally included in the spectrum of DBEs analyzed in Chapter 15 of NUREG–0800 (*e.g.,* Sections 15.0.1 or 15.0.3).

The current definition of design bases in 10 CFR 50.2 provides that controlling parameters may be derived either from accepted ''state-of-the-art'' practices or from analysis (based on calculations or experiments). The NRC has determined that this definition is sufficiently broad to accommodate the use of determinate, data-backed thresholds as implemented through guidance without the need for a rulemaking change. Design bases are identified through two primary means:

(1) the functional performance capabilities required to mitigate DBEs and BDBEs; and (2) the design parameters derived from the operational context in which the function is to be performed, including natural hazards and environmental conditions. The first element is addressed through the addition of proposed definitions of DBE and BDBE in 10 CFR 50.2 that would focus safety assessments on credible and realistic risks. With regard to the second element, the NRC has gained substantial experience in developing appropriate determinate and data-backed thresholds to address protection against natural phenomena and environmental conditions. Examples include assessment of tornado winds (RG 1.76, ''Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants''), hurricane winds (RG 1.221, ''Design-Basis Hurricane and Hurricane Missiles for Nuclear Power Plants''), and seismic hazards (RG 1.208, ''A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion''). The NRC has developed DG–1454 to leverage existing practices in this area and further clarify the selection of design bases.

VII. Background—Removal of IEEE–323–1974 Reference in Footnote 3 of 10 CFR 50.49

Safety-related structures, systems and components are defined in 10 CFR 50.2, ''Definitions.'' The relationship between safety-related electric equipment and Class 1E equipment was initially established through footnote 3 of 10 CFR 50.49, ''Environmental Qualification of Electric Equipment Important to Safety for Nuclear Power Plants.'' The final rule promulgating 10 CFR 50.49, including footnote 3 of 10 CFR 50.49, (48 FR 2733; January 21, 1983) stated, in part: ''The scope of the final rule covers that portion of equipment important to safety commonly referred to as ''safety-related'' (which the Commission interprets as essentially ''Class 1E'' equipment defined in [Institute of Electrical and Electronics Engineers (IEEE)]–323–1974).''

The connection between ''safety-related'' and ''Class 1E'' is now established in a more up-to-date standard—IEEE Standard 308, ''IEEE Standard Criteria for Class 1E Power Systems for Nuclear Power Generating Stations,'' which the NRC endorsed in RG 1.32, ''Criteria for Power Systems for Nuclear Power Plants.''

VIII. Discussion—Removal of IEEE–323–1974 Reference in Footnote 3 of 10 CFR 50.49

The proposed action would remove footnote 3 of 10 CFR 50.49. Footnote 3 references an old standard that is no longer utilized as the sole means to establish the connection between ''safety-related'' and ''Class 1E.'' Instead, this connection is established in the more up-to-date IEEE Standard 308, which the NRC endorsed in RG 1.32. Removal of this footnote would improve regulatory clarity and would be consistent with the NRC modernizing and improving its regulations to reflect best practices and the maturity of the nuclear industry.

In addition, a minor editorial change is proposed to redesignate the current footnote 4 of 10 CFR 50.49 as footnote 1 given the previous and proposed deletions of the preceding footnotes.

IX. Background—Expanded Alternative Requests Under 10 CFR 50.55a(z)

In 10 CFR 50.55a, ''Codes and standards,'' the NRC incorporates by reference certain parts of editions and addenda of specified codes and standards through rulemaking. Upon incorporation by reference of these specified codes and standards into 10 CFR 50.55a, the provisions of these codes and standards are legally-binding NRC requirements as delineated in 10 CFR 50.55a, subject to the conditions on certain specific provisions that are set forth in 10 CFR 50.55a. Currently, in paragraph (z), ''Alternatives to codes and standards requirements,'' of 10 CFR 50.55a, an applicant or licensee may request authorization of alternatives to the requirements of paragraphs (b), ''Use and conditions on the use of standards,'' through (h), ''Protection and safety systems,'' of 10 CFR 50.55a, if the applicant or licensee demonstrates either that the proposed alternative would provide an acceptable level of quality and safety or that compliance with the specified requirements would result in hardship or unusual difficulty without a compensating increase in the level of quality and safety. Since its initial promulgation in 1971 (36 FR 11423; June 12, 1971), 10 CFR 50.55a has allowed for the consideration of proposed alternatives under these same two criteria. Over the years, 10 CFR 50.55a has been periodically updated to reflect revised and updated codes and standards for nuclear power plants.

On March 15, 1984 (49 FR 9711), the NRC issued a final rule that made procedural changes by, among other things, clarifying the procedures for alternatives, expressly noting that alternatives can be authorized by the Director of the Office of Nuclear Reactor Regulation. In the November 5, 2014, final rule, ''Approval of American Society of Mechanical Engineers' [ASME] Code Cases'' (79 FR 65776), the NRC restructured 10 CFR 50.55a to align with the Office of the Federal Register's guidelines for incorporation by reference and to allow proposed alternatives to NRC-approved Code Cases rather than only to ASME Code provisions. In this restructuring, the proposed alternatives provisions were moved from their prior location in paragraph (a)(3) of 10 CFR 50.55a to a newly designated paragraph (z) of 10 CFR 50.55a. However, these rulemakings addressed only procedural clarifications and a restructuring of existing regulations, not changes in the scope of opportunities for alternatives. In the July 17, 2024, final rule, ''American Society of Mechanical Engineers Code Cases and Update Frequency'' (89 FR 58039), the NRC added paragraph (y), ''Definitions,'' to 10 CFR 50.55a. These definitions provide consistency and clarity throughout 10 CFR 50.55a and accommodate new opportunities to change code of record intervals. However, these definitions were added outside the scope of paragraph (z) of 10 CFR 50.55a because the Commission had not approved the use of 10 CFR 50.55a(z) for definitions or the newly defined intervals.

X. Discussion—Expanded Alternative Requests Under 10 CFR 50.55a(z)

Currently, the proposed alternative provisions of paragraph (z) of 10 CFR 50.55a apply to the codes and standards requirements in paragraphs (b) through (h) of 10 CFR 50.55a. The addition of paragraph (y) to 10 CFR 50.55a in the July 17, 2024, final rule, without an associated expansion of the scope of paragraph (z), has resulted in unanticipated exemptions under 10 CFR 50.12, ''Specific exemptions,'' to use alternate definitions to those included in paragraph (y) of 10 CFR 50.55a. Moreover, the criteria of paragraph (z)(1), ''Acceptable level of quality and safety,'' or (z)(2), ''Hardship without a compensating increase in quality and safety,'' of 10 CFR 50.55a provide appropriate controls for requested alternatives to all requirements in 10 CFR 50.55a, so there is no need to restrict the application of 10 CFR 50.55a(z) to only some paragraphs in 10 CFR 50.55a. Therefore, the NRC proposes to remove the restriction limiting proposed alternatives to paragraphs (b) through (h) of 10 CFR 50.55a so that proposed alternatives

would now be permitted for all regulatory requirements in 10 CFR 50.55a using the existing criteria in paragraphs (z)(1) and (2) of 10 CFR 50.55a. The proposed removal of this scope restriction would also allow for the use of the proposed alternatives provision in paragraph (z) of 10 CFR 50.55a for any future additions or modifications to 10 CFR 50.55a without the need for further revision to paragraph (z).

In addition to creating paragraph (y) of 10 CFR 50.55a, the revisions in the July 17, 2024, final rule provided more flexibility to licensees by expanding the code of record interval from 10 years to two consecutive inservice testing and inservice inspection intervals. In that final rule's preamble, the Commission stated, in part, that licensees may request future alternatives based upon the code of record interval. This revision, coupled with the staff position in SECY–23–0061, ''Clarification of the Staff's Position on Certain American Society of Mechanical Engineers Code Alternatives for More Than One 10-Year Inservice Inspection Interval Under Title 10 of the *Code of Federal Regulations* 50.55a,'' dated July 21, 2023, clarified that, when appropriately justified, the duration of an alternative need not be limited to the length of a single inservice testing or inservice inspection interval. Rather, the NRC may approve specific alternatives for longer durations when the technical bases supporting the requested alternative ensure that an acceptable level of quality and safety will be maintained. These existing flexibilities would be unchanged by this proposed rule.

The proposed change would provide additional flexibility to a licensee or applicant, while maintaining the same requirements for an acceptable level of quality and safety or the presence of a hardship without a compensating increase in quality and safety, which have been foundational to proposed alternatives since their initial promulgation.

XI. Background—Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods

A. Use of Quantitative Risk Results

The AEA requires a licensee to seek an amendment for significant changes to its facility or procedures. The Commission possesses substantial discretion to define, by rule, the threshold that constitutes a change significant enough to require a license amendment.

The current regulation in 10 CFR 50.59 was developed in response to issues involving inconsistency in how licensees applied the previous criteria to determine whether changes, tests, or experiments require prior NRC approval. The NRC is proposing to amend 10 CFR 50.59 to allow licensees to consider risk insights from PRAs when applying the criteria in that provision. The statements of consideration for the 10 CFR 50.59 final rule, ''Changes, Tests, and Experiments'' (64 FR 53582; October 4, 1999), did not allow licensees to use PRA insights at that time, but the Commission recognized the possibility that the NRC could one day develop the regulatory infrastructure to support the use of PRAs in 10 CFR 50.59 analyses.

The NRC now proposes to incorporate the use of quantitative risk results, like Core Damage Frequency (CDF) and Large Early Release Frequency (LERF), to evaluate changes under 10 CFR 50.59(c)(2)(i) and (ii).

The current state of practice in the nuclear fleet for quantitative risk assessment is the use of Level 1/limited Level 2 PRAs. The quantitative risk metrics output by these PRAs are CDF and LERF, and they, along with their changes (*i.e.,* ΔCDF and ΔLERF), are the metrics used as part of risk-informed decision-making processes. As described in RG 1.174, Revision 3, ''An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,'' dated January 2018, these risk metrics are based on the Commission's safety goals and the associated quantitative health objectives. Similarly, the NRC proposes to use the small changes in CDF and LERF jointly as means to determine the importance of the effect of the proposed change on accident frequency and SSC malfunction rate under 10 CFR 50.59.

B. Improved Flexibility for Changes to Methods of Evaluation

Currently, 10 CFR 50.59 allows licensees to make certain changes to their facility or procedures without prior NRC approval, provided those changes do not meet specific thresholds that would require a license amendment. One of those thresholds, stated in 10 CFR 50.59(c)(2)(viii), requires NRC review of any change in a methodology that results in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analysis. As explained in the preamble of the 10 CFR 50.59 final rule in 1999, this language was chosen to ensure NRC oversight of the safety margins and conservatisms that form the basis of the NRC's licensing decision. The Commission stated that the language of 10 CFR 50.59(c)(2)(viii) was selected ''to allow licensees only a small degree of flexibility in methods where the results are tending in the non-conservative direction'' (64 FR 53598; October 4, 1999).

In SECY–97–035, ''Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, and Experiments),'' dated February 12, 1997, which transmitted proposed 10 CFR 50.59 guidance to the Commission ahead of the proposed rulemaking, the staff recognized that, ''as the knowledge base increases and computing power increases, new methods of analysis will more accurately predict the actual plant response.'' However, the staff found that a comparison of the analytical results from two different methodologies was not valid to make a 10 CFR 50.59 determination. To make the 10 CFR 50.59 determination using a new methodology, the new methodology must be valid (*e.g.,* previously approved by the NRC) and the analysis in question must be performed for the situation before the change and the situation after the change using the same methodology.

In the decades since the original rule was written, there have been substantial advancements in computational capabilities and modeling practices. New data, improved understanding, and increased computing power now allow for faster iteration and refinement of methods used in safety analyses. Due to this substantial increase in computational power and the rapid growth in the use of modeling and simulation, other industries are beginning to shift away from model-by-model reviews and are instead focusing on the processes by which organizations establish the credibility of their models—specifically through verification, validation, and uncertainty quantification (VVUQ) programs. The U.S. Food and Drug Administration has taken the most prominent step in this direction by issuing new guidance centered on credibility assessments (FDA–2021–D–0980; November 17, 2023). The aviation industry is actively developing a VVUQ standard through an industry-led, Federal Aviation Administration-supported initiative.

The existing requirements of 10 CFR 50.59(c)(2)(viii) mandate a license amendment for any departure from a method of evaluation described in the FSAR. As defined in the regulation, a departure is a change to any element of a methodology, unless the results are

''conservative or essentially the same,'' or any change from one method to another method, unless the method has been previously approved by the NRC for the specific application. Paragraph (a)(2)(iv) of 10 CFR 53.1550 limits changes to methods similarly to 10 CFR 50.59, allowing changes without NRC review and approval only when results are conservative or essentially the same, the revised method of evaluation has been previously approved by the NRC for the intended application, or the revised method of evaluation can be used under an NRC-approved consensus code or standard. The rapid advancement in computational modeling and simulation can offer more realistic and accurate safety analyses than the legacy methods documented in many plants' original FSARs. Thus, the current regulations can create an unnecessary regulatory burden by requiring licensees to seek amendments to use superior analytical tools, since these new tools would constitute a departure from a method of evaluation described in the FSAR as contemplated in the existing regulatory frameworks. This can disincentivize the adoption of better technology and expend both licensee and NRC resources on reviewing license amendment requests that ultimately enhance, rather than degrade, safety analysis quality. The purpose of the proposed rule change, therefore, would be to increase regulatory efficiency and flexibility, consistent with the objectives of the 1999 rule revision, the ADVANCE Act, and the Executive orders.

XII. Discussion—Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods

A. Use of Quantitative Risk Results

The NRC proposes rulemaking to establish an alternative pathway that would allow the use of quantitative risk metrics, like CDF and LERF, along with consideration of safety margins and defense in depth, to evaluate a proposed change, test, or experiment against the criteria of 10 CFR 50.59(c)(2)(i) and (ii), while leaving all other criteria in 10 CFR 50.59(c)(2) in place. New proposed 10 CFR 50.59(e) would establish a risk-informed alternative to the existing regulation and would not alter or impede the current practice for evaluating proposed changes against the text of 10 CFR 50.59(c)(2)(i) and (ii), as written. A licensee could continue to use qualitative assessments, engineering judgement, and other existing practices and techniques to evaluate a proposed change, test, or experiment.

Under the proposed 10 CFR 50.59(e), a licensee could demonstrate that a change would not result in a ''more than a minimal increase'' under 10 CFR 50.59(c)(2)(i) and (ii) by using quantitative risk results based on a PRA of appropriate scope and quality that provides appropriate risk metrics. The change would also need to maintain defense-in-depth and safety margins. ''Appropriate scope and quality'' in this context would mean that the licensee's model fully encompasses the proposed change and that the model has been found to be acceptable for use in a previous NRC-approved application. ''Appropriate risk metrics'' in this context would mean quantitative results that demonstrate the effects on the proposed change and can provide a baseline for judging facility risk. For traditional PRAs, these metrics are CDF, LERF, and the changes (Δs) to CDF and LERF. Extensive discussion of maintaining defense in depth and safety margins can be found in RG 1.174, Revision 3. The NRC has proposed guidance for 10 CFR 50.59(e) in DG–1466, draft Revision 4 to RG 1.187, ''Guidance for Implementation of 10CFR50.59, 'Changes, Tests, And Experiments.'''

The use of PRA would not replace or supplant the deterministic licensing basis but would supplement it with a powerful analytical tool. Since the initial licensing of the current fleet, the NRC and the industry have developed and matured PRA methodologies, which provide a holistic, integrated assessment of plant safety. PRA can identify contributors to risk and potential vulnerabilities that may not be apparent from a purely deterministic analysis.

Incorporating CDF and LERF into the 10 CFR 50.59 process would not be an attempt to re-license plants on a probabilistic basis. Instead, it would provide an alternative methodology licensees could voluntarily choose for conducting analyses under 10 CFR 50.59. It would use risk insights to inform the judgment of the safety significance of changes to the existing deterministic design. A change that results in a very small, quantifiable increase in calculated risk could be reasonably judged not to undermine the fundamental safety basis established through deterministic principles. This approach would allow for a more consistent, predictable, and efficient screening process, directly fulfilling the original purpose of 10 CFR 50.59 to differentiate between changes that require prior NRC review and those that do not.

This integration would be consistent with decades of evolving NRC policy and practice. The agency has successfully used risk-informed approaches in many other regulatory applications, including 10 CFR 50.65, ''Requirements for monitoring the effectiveness of maintenance at nuclear power plants''; 10 CFR 50.48(c), ''National Fire Protection Association Standard NFPA 805''; the Reactor Oversight Process; and RG 1.174. Using quantitative risk results, such as from a PRA, in the 10 CFR 50.59 process would be a logical evolution that would enhance the existing framework by leveraging modern analytical tools to better focus licensee and agency resources on issues of genuine safety significance.

B. Improved Flexibility for Changes to Methods of Evaluation

The NRC proposes two regulatory amendments, which would work in concert to allow licensees greater flexibility to implement changes to analytical methods described in the FSAR.

First, the NRC proposes a targeted revision to 10 CFR 50.59(c)(2)(viii) and 53.1550(a)(2)(iv). This change would allow licensees to implement certain changes to analytical methods described in the FSAR (as updated) without prior NRC approval, provided those changes are undertaken pursuant to an NRC-approved VVUQ program under 10 CFR 50.221, ''Credibility requirements for modeling and simulation.'' Proposed guidance for compliance with proposed 10 CFR 50.221 is in DG–1468, ''Guidance for Implementation of 10 CFR 50.221, 'Credibility requirements for modeling and simulation.''' This revision would clarify that appropriate changes made using a risk-informed and graded VVUQ framework would be permissible under 10 CFR 50.59 without prior NRC approval. The proposed rule would allow such changes without prior NRC approval only if the VVUQ program were approved by the NRC for the method of evaluation in question, and the new method of evaluation met the credibility criteria established in the approved VVUQ. These measures would maintain safety and ensure appropriate controls over licensee changes to methods or evaluations while affording flexibility through reliance on the NRC-approved VVUQ program.

Second, the NRC proposes to adopt an optional regulation on VVUQ at 10 CFR 50.221 that would establish the requirements a VVUQ program must meet. The new regulation would establish clear requirements and structure for VVUQ activities used to support regulatory decisions. Specifically, the proposed 10 CFR

50.221 would specify that licensees and applicants could voluntarily establish a VVUQ program and determine the scope of the models and simulations the VVUQ program would cover. Licensees and applicants that establish a VVUQ program would be required to establish a process under the VVUQ program for demonstrating the credibility of models and simulations through VVUQ activities and assessments and could use only models and simulations within the scope of the program for which the licensee or applicant has successfully completed VVUQ activities and assessments. Additionally, the licensee or applicant adopting a VVUQ program would need to ensure that the VVUQ activities and assessments were commensurate with the overall risk from the model or simulation. The NRC has prepared guidance in DG–1468 on an acceptable approach for a VVUQ program that would conform to the proposed regulation. This approach would provide a consistent, technology-neutral framework for demonstrating model credibility across the NRC's regulatory structure.

Via these proposed changes, the NRC would shift focus away from evaluating each individual model or simulation directly and toward evaluating the process by which models are determined to be credible—specifically through structured VVUQ programs. In this context, credibility would refer to the level of trust in a model's ability to produce accurate and appropriate predictions for its intended use. An NRC-approved VVUQ program would establish a new licensing basis that focuses on how methods are selected and applied, rather than the characteristics of the specific method and the inherent conservatisms. Where appropriate, VVUQ-based credibility assessments could serve as a viable alternative to full NRC review of each new or revised model. However, a single generic VVUQ process would not be appropriate due to the significant variability in physical phenomena, modeling assumptions, numerical techniques, and uncertainties across different reactor technologies and methods of evaluation. A tailored VVUQ process approved by the NRC for the intended application would be required for each method of evaluation to provide the necessary specificity to ensure credible, defensible assessments of model performance for each unique application for all possible reactor technologies and their vastly different physical domains.

This approach could be particularly beneficial for new and advanced reactor designs. Unlike the current fleet, which has decades of operational data and analytical stability, advanced reactors often lack extensive experimental databases at the time of initial licensing. Requiring them to demonstrate method maturity at the level of existing plants would demand significant upfront testing and analysis, delaying deployment and increasing cost. Many of these designs are being developed as test reactors specifically to generate such data. A rule change would provide a clear, structured mechanism for these reactors to update their methods over time, based on data collected during operation, without needing to go through repeated full NRC reviews—so long as the updates are made through an approved VVUQ process.

XIII. Background—Minimum Decommissioning Funding Assurance Requirements for Non-Large Light-Water Reactors

The regulation in 10 CFR 50.75, ''Reporting and recordkeeping for decommissioning planning,'' establishes requirements for indicating to the NRC how an applicant or licensee will provide reasonable assurance that funds will be available for the decommissioning process. During the operational phase of a reactor facility, an applicant or licensee must certify that funding is being provided in an amount that may be more, but not less, than the amount described in 10 CFR 50.75(c)(1) and (2) (also known as the table of minimum amounts, minimum funding assurance, or ''formula'' amount). As the NRC stated in the 1988 decommissioning rule (53 FR 24018–24030; June 27, 1988), the ''formula'' amount in 10 CFR 50.75(c) does not represent the actual cost of decommissioning for specific reactors but rather serves as a reference level established to ensure that the bulk of the funds necessary for a safe decommissioning is being considered and planned for early in facility life by licensees. This provides assurance that the facility will not become a risk to public health and safety when it is decommissioned.

The table of minimum amounts and the associated adjustment factors were developed and designed specifically for the large light-water reactor technologies (boiling water reactors and pressurized water reactors) that make up the current commercial power reactor fleet in the U.S. However, new reactors may incorporate different technologies and output capacities that may not require the amount of decommissioning funding assurance described in 10 CFR 50.75(c). In order to address different decommissioning funding needs for these new technologies without requiring an exemption from NRC regulations, the NRC is proposing updates to its regulations to allow certain new reactor applicants and licensees the flexibility to certify adequate decommissioning funding assurance during operations through the use of either the table of minimum amounts or the submission of a design-specific decommissioning cost estimate. Allowing for the use of a design-specific decommissioning cost estimate that may be less than the table of minimum amounts would provide a path for certain new reactor applicants and licensees to demonstrate financial responsibility for safe decommissioning based on factors specific to the reactor facility.

XIV. Discussion—Minimum Decommissioning Funding Assurance Requirements for Non-Large Light-Water Reactors

The NRC proposes an amendment to 10 CFR 50.75 to allow certain new reactor applicants and licensees to submit a design-specific decommissioning cost estimate to demonstrate minimum decommissioning funding assurance during operations that may be less than the table of minimum amounts provided in 10 CFR 50.75(c). The values in the current table of minimum amounts are based on funding assumptions associated with the decommissioning of large light-water reactor facilities. This proposed rule would allow certain new reactor applicants and licensees to certify financial assurance for decommissioning through the use of either the minimum formula amount or through the submission of a design-specific decommissioning cost estimate. Thus, the proposed rule would provide flexibility for new reactor applications that represent smaller output and size considerations than large light-water reactor designs.

Specifically, the NRC is proposing to add a new paragraph (b)(2) to 10 CFR 50.75 that describes the certification amount process and minimum requirements, including reliance on design-specific decommissioning cost estimates, for new reactor applicants and licensees seeking to use the alternative pathway. Additionally, the NRC is proposing to delete language in the table of minimum amounts in 10 CFR 50.75(c)(1) that requires reactors of less than 1200 megawatts thermal (MWt) to use the certification amount for a 1200 MWt reactor. It is conceivable that new LWR designs could have an output less than 1200 MWt. Therefore, requiring a new reactor applicant or

licensee to assure to an amount well above what is needed to establish decommissioning funding assurance could be financially limiting and unnecessary to meet the intent of decommissioning funding assurance regulations.

A certification relying on a design-specific decommissioning cost estimate would be required to include a description of the factors used to develop the design-specific decommissioning cost estimate, including generic activities performed in the major decommissioning phases of a decommissioning project (*e.g.,* pre-decommissioning engineering and planning, reactor deactivation, and dismantlement). Similar to the table of minimum amounts for large light-water reactor designs, design-specific decommissioning cost estimates should represent the bulk of funds necessary to safely decommission a facility, as applicable to the specific reactor technology being utilized and the design of the facility. Additionally, similar to the table of minimum amounts for large light-water reactor designs, the design-specific decommissioning cost estimate would have to be adjusted annually at a rate at least equal to the formula in 10 CFR 50.75(c)(2). This certification process would include NRC review and approval. However, once an initial design-specific decommissioning cost estimate is approved by the agency as a sufficient certification amount for financial assurance for decommissioning, other applicants or licensees using similar technology could reference and justify use of this amount (escalated in accordance with NRC regulations and guidance) as the certification amount required by proposed 10 CFR 50.75(b) for a different application. Once a licensee nears permanent cessation of operations, a site-specific decommissioning cost estimate that encompasses the design-specific cost as well as costs associated with the site and operational period of the facility, would be required for funding assurance purposes, as described in current regulations in 10 CFR 50.82, ''Termination of license.'' Finally, the NRC is proposing to revise 10 CFR 50.75(e)(1)(i) and (ii) to allow reactor licensees that have prepaid or collected funds based on a design-specific estimate to take credit for projected earnings on the prepaid or collected decommissioning funds using up to a 2-percent annual real rate of return up to the time of permanent termination of operations.

The NRC is proposing a similar change to 10 CFR part 53. Currently, 10 CFR part 53 only allows for a site-specific decommissioning cost estimate as the certification amount. Therefore, the NRC is proposing to add conforming language to 10 CFR 53.1010, ''Financial assurance for decommissioning,'' and 53.1020, ''Cost estimates for decommissioning,'' to allow new reactor applicants and licensees to submit a design-specific decommissioning cost estimate to demonstrate minimum decommissioning funding assurance during operations. Finally, the NRC is proposing to add conforming language to 10 CFR 53.1040, ''Methods for providing financial assurance for decommissioning,'' to allow new reactor applicants and licensees that have prepaid or collected funds based on a design-specific estimate to take credit for projected earnings on the prepaid or collected decommissioning funds using up to a 2-percent annual real rate of return up to the time of permanent termination of operations.

Additionally, conforming changes would be made to 10 CFR 50.75(e) to include references to the requirements of proposed 10 CFR 50.75(b)(2), where appropriate. In addition, this proposed rule would revise 10 CFR 50.75(e) to include ''applicant or'' in all appropriate places where currently only ''licensee'' is referenced, as directed by the Commission in staff requirements memorandum (SRM)-SECY–23–0021: Enclosure 4, ''Table of Typographical errors and Inconsistencies,'' dated March 4, 2024. Similar changes are proposed in 10 CFR 53.1040 and 10 CFR 53.1050, ''NRC oversight'' for consistency. Collectively, these changes would clarify that applicants and licensees would be subject to the requirements under 10 CFR 50.75(e), 53.1040, and 53.1050, as applicable.

This proposed rule also would make minor editorial changes in 10 CFR 50.75(e), (g), and (h) by removing errant commas, correcting capitalization errors, correcting references by indicating paragraphs instead of sections, and removing ''of this part,'' where necessary.

XV. Background—Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

A. Historic Quality Assurance Requirements Perspectives and Emergent Issues

During the early days of nuclear power (1950s-1960s), the Atomic Energy Commission (AEC), the NRC's predecessor agency, focused on developing and licensing nuclear reactors. As the nuclear industry grew, it became clear that systematic quality assurance (QA) was essential to ensure nuclear safety, especially given the complexity and potential hazards of nuclear technology. By the 1960s, nuclear power plants were becoming more complex, and the consequences of failures were more severe. Incidents and near-misses highlighted the need for formalized QA programs to prevent design, fabrication, and construction errors. Appendix B was added to 10 CFR part 50 by the AEC in 1970 (35 FR 10498; June 27, 1970) to (1) establish minimum QA requirements for safety-related structures, systems, and components (SSCs) and (2) ensure that these SSCs are designed, fabricated, constructed, and tested to perform their intended safety functions.

Applicants for CPs, OLs, early site permits (ESPs), COLs, design certifications, standard design approvals, and manufacturing licenses (MLs) must include in their respective application a description of the QA program that discusses how the applicable requirements of appendix B to 10 CFR part 50 are satisfied.

Although appendix B to 10 CFR part 50 is foundational to nuclear safety, commenters have expressed concerns over its implementation, flexibility, and alignment with modern practices. These concerns include the following topics.

- *Inflexibility:* Appendix B to 10 CFR part 50 (1) is prescriptive and has not been substantively updated since 1970; (2) lacks risk-informed or performance-based flexibility, which modern quality systems increasingly emphasize; and (3) does not facilitate tailoring of QA programs to low-risk activities or innovative technologies.
- *Outdated Language:* The language in appendix B to 10 CFR part 50 is reflective of technologies from the 1970s and does not explicitly address digital systems, software QA, and additive manufacturing. As a result, applicants must rely on guidance, which could result in inconsistent implementation across applicants due to applicants interpreting the guidance differently based on their specific technologies.
- *Vendor and Supply Chain Challenges:* Many suppliers, especially non-nuclear vendors, are unfamiliar with appendix B to 10 CFR part 50, and thus applicants and licensees have challenges in procuring products and services for the nuclear power plants.
- *Lack of Harmonization with International Standards:* Appendix B to 10 CFR part 50 is United States-specific and not aligned with international standards and best practices and, thus, creates challenges for international collaboration and global supply chains.

In light of these considerations, commenters have advocated for a modernized, risk-informed QA framework that retains the safety rigor of appendix B to 10 CFR part 50 while allowing for graded application based on safety significance that is integrated with modern quality systems.

B. NRC Responses to These Issues

As a result of these issues, the NRC is proposing to add appendix T to 10 CFR part 50 as a voluntary alternative to appendix B to 10 CFR part 50. The proposed appendix T would draw on international QA standards to incorporate the following elements:

- Performance-based QA criteria that provide explicit direction on use of a graded approach for applying QA requirements to SSCs relative to their safety and risk contributions to the overall nuclear facility.
- Quality assurance requirements specific to software used in digital items and for design and analysis.
- Quality assurance terminology and methodologies used across various safety critical industries and in international standards for quality management, thus allowing applicants to leverage cross-industry and global supply chains.

XVI. Discussion—Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

This proposed rule would add a new appendix T to 10 CFR part 50 to provide streamlined QA criteria that could be used for applications of COLs, CPs, and OLs under certain eligibility requirements.

A. Introduction and Scope

As discussed in section XV, ''Background—Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' of this document, NRC stakeholders have expressed interest in utilizing a streamlined approach to QA that better aligns with international standards. Therefore, the NRC has developed a proposed appendix T to 10 CFR part 50 that would provide an alternative to the current QA requirements in appendix B to 10 CFR part 50 based on International Standard, ISO 19443, ''Quality management systems—Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety [ITNS],'' (2018–05). The International Standard Organization collaborated closely with the International Atomic Energy Agency in developing ISO 19443.

The proposed section I, ''Introduction and Scope,'' of appendix T to 10 CFR part 50 would provide the eligibility requirements for using appendix T to 10 CFR part 50 as a voluntary alternative to appendix B to 10 CFR part 50. Specifically, applicants for CPs, OLs, and COLs would have the option to use appendix T to 10 CFR part 50 as an alternative to appendix B to 10 CFR part 50, provided that the three conditions in section I are met.

Proposed condition I.A would require that the application is for an nth-of-a-kind (NOAK) plant and would require the application to identify the first-of-a-kind (FOAK) reference plant.

Proposed condition I.B would require that any departures from the FOAK reference plant in the application of the NOAK plant would not result in a change to the classification, design, and method of manufacture, construction, and operation of SSCs identified in licensing basis of the referenced plant.

Proposed condition I.C would require the application to include procedures and work processes for implementing the requirements in proposed appendix T to 10 CFR part 50.

The NRC would define FOAK nuclear power plants and fuel reprocessing plants in proposed appendix T as the initial implementation of a new reactor design or technology or new fuel reprocessing plant design that has not been previously constructed and operated at commercial scale, either within the U.S. or internationally. The FOAK plant would serve as a reference plant for NOAK nuclear power plants and fuel reprocessing plants. The NRC would define NOAK nuclear power plants and fuel reprocessing plants in proposed appendix T to be any subsequent implementation of a FOAK reactor design or technology or fuel reprocessing plant design after the FOAK plant has been designed, constructed, and operated.

Proposed conditions I.A, I.B, and I.C would limit the use of proposed appendix T to 10 CFR part 50 to those applications that could potentially leverage the following:

- the design maturity of the FOAK completed plant design information;
- standardized components and systems to streamline procurement and construction;
- skilled labor and contractors from the FOAK projects;
- FOAK operational data to help NOAK commissioning procedures, standard operating procedures, emergency operating procedures, training, design, and operational programs; and
- established processes and procedures for implementing the requirements in proposed appendix T to 10 CFR part 50, including an established mechanism to ensure deviations from FOAK reliability in NOAK would be identified and promptly corrected.

In recent cases, the NRC has noticed that design details and QA procedures are not available during the licensing review of a CP, OL, or COL for a FOAK plant. Therefore, during licensing and construction for FOAK plants, the NRC conducts vendor inspections to confirm the detailed design and as-built SSCs meet the technical and quality requirements committed to by the applicant. However, because a NOAK applicant could reference design details and QA procedures developed during the FOAK licensing, these additional QA activities, such as vendor inspections, may be unnecessary, especially for vendors previously inspected by the NRC. Therefore, when the conditions I.A, I.B, and I.C are met, the proposed appendix T to 10 CFR part 50 may eliminate the need for NRC oversight of suppliers and vendors who supply applicants with approved appendix T to 10 CFR part 50 compliant QA programs because (1) the list of SSCs that would be governed by proposed appendix T to 10 CFR part 50 would be standardized and verified to be acceptable using information from the reference FOAK plant; (2) the design of these SSCs would be complete and verified to be acceptable using information from the reference FOAK plant; and (3) the manufacturing and construction methods for these SSCs would be established and verified to be acceptable during oversight of manufacturing and construction processes for the referenced FOAK plant.

B. Definitions

The proposed section II, ''Definitions,'' of proposed appendix T to 10 CFR part 50, would include definitions for terms used in the proposed appendix.

The NRC would define ''first-of-a-kind'' nuclear power plants and fuel reprocessing plants as the initial implementation of a new reactor design or technology or new fuel reprocessing plant design that has not been previously constructed and operated at commercial scale.

The NRC would define ''nth-of-a-kind'' nuclear power plants and fuel reprocessing plants as any subsequent implementation of a reactor design or technology or fuel reprocessing plant

design after the FOAK has been designed, constructed, and operated.

The NRC would define ''quality assurance'' as all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those actions related to the physical characteristics of a material, structure, component, or system that provide a means to ensure the material, structure, component, or system meets predetermined requirements. This proposed definition is equivalent to the definition used in appendix B to 10 CFR part 50.

The NRC would define ''quality assurance program'' as the overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work necessary to achieve QA.

The NRC would define ''quality management system'' (QMS) as a structured framework that documents an organization's processes, procedures, and responsibilities for ensuring quality. This term and definition are used broadly by other safety-critical industries, nuclear regulatory bodies and industry abroad, and vendors and third-party suppliers to these industries. The QMS is different from the terminology ''quality assurance program description'' (QAPD) used in appendix B to 10 CFR part 50 in that the QMS has a broader scope and is a system framework that includes quality planning, controls, assurance, and improvement; whereas a QAPD is a descriptive document that is narrowly focused on QA.

The NRC would define ''functional design criteria'' as metrics for the performance of SSCs. For safety-related SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in 10 CFR 53.210, ''Safety criteria for design-basis accidents.'' For non-safety-related but safety-significant SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in 10 CFR 53.220, ''Safety criteria for licensing-basis events other than design-basis accidents.'' This proposed definition would be added to proposed appendix T to 10 CFR part 50 to align with the definition and use of this term in 10 CFR part 53.

The NRC would define ''non-safety-related but safety-significant SSCs'' as those SSCs that are not safety-related but are relied on to achieve adequate defense in depth or perform risk-significant functions and warrant special treatment. This proposed definition would be added to proposed appendix T to 10 CFR part 50 to align with the definition and use of this term in 10 CFR part 53.

C. General Requirements

The proposed section III, ''General Requirements,'' of proposed appendix T to 10 CFR part 50 would provide general requirements for establishing and maintaining a QA program for applicants that choose to meet proposed appendix T.

Proposed section III.A, ''Integrated Quality Assurance Program,'' of proposed appendix T to 10 CFR part 50 would require that the integrated QA program ensures that safety-related and non-safety-related but safety-significant SSCs are designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions those SSCs perform. Proposed section III.A of in proposed appendix T to 10 CFR part 50 would include the following seven items that any application using in proposed appendix T to 10 CFR part 50 would be required to identify and explain in the integrated QA program:

- Responsibilities (1) are properly assigned to specific individuals or teams in charge of executing QA activities and (2) ensure any delegated responsibilities are properly identified and controlled.
- The design requirement of SSCs are sufficiently captured in corresponding documents; the design bases requirements are adequately translated into specifications, drawings, procedures, and instructions; outputs reflect the correct design inputs; the design is properly verified and validated; the as-built and as-operated SSC properly meet the intended function and safety margin.
- Means and methods are established to communicate relevant technical, quality, and regulatory requirements, expectations, and concerns between the applicant and its vendors and third-party suppliers.
- Measures are established to (1) ensure that procured SSCs and related services meet technical and quality requirements and (2) assess the capability of vendors or third-party suppliers that supply the SSCs and related services.
- Measures are established to (1) verify and validate that products and services meet the technical and quality requirements of the procured products and services, and (2) audit the vendors or third-party suppliers that are providing the products and services.
- Processes are implemented to address reoccurrence of issues and failures.
- Recordkeeping and documentation protocols for the QA program are established.

Proposed section III.B.1 of proposed appendix T to 10 CFR part 50 would require the applicant document the QA program in the QMS and submit the QMS to the NRC for review and approval. Proposed section III.B.1 would require the QA program, as documented in the QMS, to contain a graded approach for implementing the requirements of the QA program.

Proposed section III.B.2 of proposed appendix T to 10 CFR part 50 would require the QMS to describe how the requirements in section IV of the appendix would be met. Proposed section IV of appendix T to 10 CFR part 50 would identify general QA criteria and software QA criteria. Proposed section III.B.3 of appendix T to 10 CFR part 50 would require the applicant to invoke the applicant's QA requirements in procurement documents to all relevant contractors, vendors, suppliers, and third-parties.

Proposed section III.B.4 of proposed appendix T to 10 CFR part 50 would require the applicant to select the appropriate industry standards that are used to achieve quality consistent with regulatory requirements and the NRC's policies. This proposed section would state that the applicant would need to document the selection of ASME Nuclear Quality Assurance (NQA)–1, ''Quality Assurance Requirements for Nuclear Facility Applications'' or another appropriate industry standard. Proposed section III.B.4 of appendix T to 10 CFR part 50 would also require that gaps between the selected industry standards and the proposed section IV, ''Quality Assurance Requirements,'' of appendix T to 10 CFR part 50 are addressed within the QMS.

D. Quality Assurance Requirements

Proposed section IV.A, ''Quality Assurance Criteria,'' of proposed appendix T to 10 CFR part 50, identifies QA criteria that would be applicable to all applications that reference proposed appendix T to 10 CFR part 50. This proposed section would include 11 criteria that cover topical areas in management, performance, and assessment. The proposed requirements in these topical areas are consistent with International Standards for QMSs such as ISO 9001, ''Quality Management System—Requirements,'' which are used by many safety-critical industries, and ASME NQA–1, ''Quality Assurance Requirements for Nuclear Facility

Applications,'' which is used by the nuclear industry.

(i) Management

Proposed section IV.A.1, ''Criterion 1—Management: Program,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to define the organizational structure, functional responsibilities, levels of authority, and interfaces for performing the work necessary to implement the QA program, and develop management processes to plan, schedule, and assign resources to perform this work.

Proposed section IV.A.2, ''Criterion 2—Management: Personnel Training and Qualifications,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to develop processes for indoctrination and continuous training of employees for performing the work necessary to implement the QA program.

Proposed section IV.A.3, ''Criterion 3—Management: Quality Improvement,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement a process for identifying and controlling issues and failures that could adversely impact quality, safety, and regulatory compliance. The proposed section IV.A.3 would also require applicants to include prevention of recurrence of issues as part of corrective actions and implement processes for continuous improvement of the QA program.

Proposed section IV.A.4, ''Criterion 4—Management: Documents and the Associated Records,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to prepare, review, approve, issue, use, and revise documents that prescribe processes, specify requirements, or establish the design of the SSC, and maintain these documents as records for the QA program.

(ii) Performance

Proposed section IV.A.5, ''Criterion 5—Performance: Work Processes,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to perform work, including hazard controls. Hazard controls are systematic measures designed to prevent, detect, and correct issues that could compromise quality, safety, and regulatory compliance. Examples of hazard controls applicable to QA programs include:

- embedded work processes to ensure quality such as inspection and testing protocols, hold points and witness points, and nonconformance reporting protocols;
- monitoring and detection programs to ensure detection of deviations and malfunctions in real time such as surveillance and audits;
- structured approaches to identify quality issues and implement corrective and preventive actions.

Proposed section IV.A.5 of proposed appendix T to 10 CFR part 50, would also require the applicant to establish and implement work processes for identifying and controlling items to ensure proper use; maintain items to prevent damage, loss, or deterioration; and calibrate and maintain equipment used for activities affecting quality.

Proposed section IV.A.6, ''Criterion 6—Performance: Design,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement measures for controlling the design of SSCs, including requirements for controlling design changes, design interfaces, and verifying and validating the adequacy of the design. Verify in the context of design control means to perform the set of activities to demonstrate that design conforms to specifications and occurs during the design and development process. Examples include reviews, inspections, and unit tests. Validate in the context of design control means to perform the set of activities to demonstrate that the as-developed or as-built SSC performs the intended safety-functions and occurs after the development process. Examples include integrated tests, analysis, and simulations.

Proposed section IV.A.7, ''Criterion 7—Performance: Procurement,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement processes for procurement of items and services, including processes to verify that procured items and services meet established requirements, evaluate and select prospective suppliers, and verify that the approved suppliers continue to provide acceptable items and services.

Proposed section IV.A.8, ''Criterion 8—Performance: Inspection and Acceptance Testing,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement processes for performing inspection and acceptance testing for procured items and services.

Proposed section IV.A.9, ''Criterion 9—Performance: Maintenance of Structures, Systems, and Components,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement processes to control the storage of SSCs in accordance with cleanliness and environmental standards. These requirements would ensure that a process is used to prevent foreign material from being introduced to the SSC during storage and to store SSCs in accordance with the required environmental conditions (*e.g.,* humidity, temperature).

(iii) Assessment

Proposed section IV.A.10, ''Criterion 10—Assessment: Management Assessment,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement processes for management of the organization to assess the continued effectiveness of the QA program.

Proposed section IV.A.11, ''Criterion 11—Assessment: Independent Assessment,'' of proposed appendix T to 10 CFR part 50, would include requirements for the applicant to establish and implement processes for independent assessment of each aspect of the QA program. These requirements would ensure that those performing these assessments have sufficient authority and freedom from their management and are technically qualified and knowledgeable to perform the assessment.

E. Quality Assurance for Software Used in Design and Analysis, and Digital Items Important to Safety

Proposed section IV.B, ''Quality Assurance for Software Used in Design and Analysis, and Digital Items Important to Safety,'' of proposed appendix T to 10 CFR part 50, would identify QA criteria for software used for design and analysis of SSCs and for digital items important to safety.

Proposed section IV.B.1 of proposed appendix T to 10 CFR part 50, would require that applicants establish and implement processes within the QA program to ensure that (1) software used in digital items that perform a safety function, (2) software used for design verification for any SSC, and (3) software used for design analysis for any SSC, are documented, managed, and controlled throughout the software life cycle to ensure that the related SSCs perform their intended safety function.

Proposed section IV.B.2 would require the applicant to use appropriate national or internal software engineering standards. Examples of such standards include ASME, Institute for Electrical and Electronics Engineers (IEEE), National Institutes of Standards and Technology (NIST), and American Nuclear Society (ANS).

F. Proposed Conforming Changes to 10 CFR 50.4, 50.34, 50.54, 50.55, 52.79, 53.020, 53.040, 53.460, 53.500, 53.865, 53.1309, 53.1369, 53.1416, and 53.1565

Proposed conforming changes to 10 CFR 50.34(a)(7) would allow a CP applicant who meets the eligibility requirements included in proposed section I of appendix T to 10 CFR part 50, to include in its application for a CP, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 50.34(a)(7) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 50.34(b)(6)(ii) would allow an OL applicant who meets the eligibility requirements included in proposed section I of appendix T to 10 CFR part 50, to include in its application for an OL, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 50.34(b)(6)(ii) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 50.34(f)(3)(ii) would add a reference to the proposed appendix T to 10 CFR part 50 for the requirement on ensuring all SSCs important to safety are included in the QA list.

Proposed conforming changes to 10 CFR 50.54(a)(1) would incorporate requirements for:

- Each nuclear power plant or fuel reprocessing plant licensee subject to the QA criteria in proposed appendix T of 10 CFR part 50, to implement, under 10 CFR 50.34(b)(6)(ii) or 52.79, the QMS described or referenced in the safety analysis report, including changes to that report.
- For holders of a COL under 10 CFR part 52, to implement the QMS described or referenced in the safety analysis report applicable to operation 30 days prior to the scheduled date for initial loading of the fuel.

The proposed conforming addition of 10 CFR 50.54(a)(5) would include requirements for changes to a QMS to be submitted to the NRC and receive NRC approval prior to implementation.

Proposed conforming changes to 10 CFR 50.55(f)(1) would incorporate requirements for nuclear power plant or fuel reprocessing plant CP holders subject to the QA criteria in proposed appendix T of 10 CFR part 50, to implement, pursuant to 10 CFR 50.34(a)(7), the QMS described or referenced in the safety analysis report, including changes to that report.

The proposed conforming addition of 10 CFR 50.55(f)(5) would add requirements for changes to a QMS to be submitted to the NRC and receive NRC approval prior to implementation.

The proposed conforming addition of paragraph (b)(7)(iii) to 10 CFR 50.4, ''Written communications,'' would require a change to the safety analysis report QMS under the proposed 10 CFR 50.54(a)(5) or 10 CFR 50.55(f)(5), or a change to a licensee's NRC-accepted QMS topical report under 10 CFR 50.54(a)(5) or 10 CFR 50.55(f)(5), to be submitted to the NRC's Document Control Desk, with a copy to appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility.

Proposed conforming changes to 10 CFR 52.79(a)(25) and (27) would allow a COL applicant who meets the eligibility requirement included in proposed section I of appendix T to 10 CFR part 50, to include in its application for COL, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 52.79(a)(25) and (27) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.020 would modify the definition of QA to align with the definition of QA in the proposed appendix T to 10 CFR part 50.

The proposed conforming addition of paragraph (b)(7)(iii) to 10 CFR 53.040, ''Written communications,'' would require a change to the safety analysis report QMS under the proposed 10 CFR 53.1565, ''Evaluating changes to programs included in licensing-basis information,'' or a change to a licensee's NRC-accepted QMS topical report under 10 CFR 53.1565, to be submitted to the NRC's Document Control Desk, with a copy to appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility.

Proposed conforming changes to paragraphs (b)(1) and (2) of 10 CFR 53.460, ''Safety categorization and special treatments,'' would allow, for applicants that meet the eligibility requirements included in proposed section I of appendix T to 10 CFR part 50, the special treatments for safety-related SSCs (under proposed 10 CFR 53.460(b)(1)), and non-safety-related safety-significant SSCs and safety-related SSCs beyond 10 CFR 53.460(b)(1) (under proposed 10 CFR 53.460(b)(2)), to meet applicable QA requirements from proposed appendix T to 10 CFR part 50, as an alternative to these SSCs having to meet the applicable QA requirement in appendix B to 10 CFR part 50.

Proposed conforming changes to paragraph (b) of 10 CFR 53.500, ''General siting and siting assessment,'' would allow, for applicants that meet the eligibility requirements included in proposed section I of appendix T to 10 CFR part 50, activities performed to identify site characteristics or otherwise needed to determine site-specific contributors to functional design criteria or analysis assumptions under subpart C of 10 CFR part 53 to satisfy the QA requirements from proposed appendix T to 10 CFR part 50, as an alternative for these activities to meet the applicable QA requirement in appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.865, ''Quality assurance,'' for holders of an OL or COL under 10 CFR part 53 that meet the eligibility requirements included in proposed section I of appendix T to 10 CFR part 50, to develop, implement, and maintain a QA program in accordance with proposed appendix T to 10 CFR part 50, as an alternative to appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.1309(a)(2)(i) would allow a CP applicant under 10 CFR part 53 who meets the eligibility requirement included in proposed section I of appendix T to 10 CFR part 50, to include in its application for a CP, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 53.109(a)(2)(i) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.1369(l) would allow an OL applicant under 10 CFR part 53 who meets the eligibility requirement included in proposed section I of appendix T to 10 CFR part 50, to include in its application for an OL, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 53.1369(l) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.1416(a)(12) would allow a COL applicant under 10 CFR part 53 who meets the eligibility requirement included in proposed section I of appendix T to 10 CFR part 50, to include in its application for a COL, a QMS that meets proposed appendix T to 10 CFR part 50, as an alternative to satisfying the requirement in 10 CFR 53.1416(a)(12) for submittal of a description of the QA program that meets appendix B to 10 CFR part 50.

Proposed conforming changes to 10 CFR 53.1565(d)(1)(i) would clarify the applicability of QA criteria of appendix B of 10 CFR part 50 for each holder of an OL or COL under 10 CFR part 53, after the Commission makes the finding under 10 CFR 53.1452(g).

Proposed conforming addition of 10 CFR 53.1565(d)(1)(iii) would include requirements for changes to a QMS to be submitted to the NRC and receive NRC approval prior to implementation for each holder of an OL or COL under 10 CFR part 53, after the Commission makes the finding under 10 CFR 53.1452(g).

Proposed conforming changes to10 CFR 53.1565(d)(2) would modify the numbering scheme and clarify the applicability of QA criteria of appendix B to 10 CFR part 50 for each holder of a CP or COL under 10 CFR part 53, before the Commission makes the finding under 10 CFR 53.1452(g).

The proposed conforming addition of 10 CFR 53.1565(d)(2)(ii) would include requirements for changes to a QMS to be submitted to the NRC and receive NRC approval prior to implementation for each holder of a CP or COL under 10 CFR part 53, before the Commission makes the finding under 10 CFR 53.1452(g).

XVII. Background—Updates to Construction Permit Requirements and Related Licenses

The regulations in 10 CFR 50.34 specify the requirements for technical information to accompany an application for a CP or an OL. These regulations were amended in 1968 (33 FR 18610; December 17, 1968) to add paragraph (a) of 10 CFR 50.34 to require an applicant for a CP to submit a preliminary safety analysis report. Paragraph (a) of 10 CFR 50.34 specifies the minimum technical information in the preliminary safety analysis report, including preliminary design information and a description and safety assessment of the site on which the facility is to be located. As stated in the 1968 final rule, the preliminary safety analysis report requirement was ''intended to provide early and adequate information which is expected to expedite the processing of CP applications by reducing the time-consuming exchanges between the applicant and the AEC staff required to fill information gaps.'' Subsequent changes to 10 CFR 50.34 from 2007 to the present were additions due to new requirements, as well as clarifications and relaxations, but the majority of 10 CFR 50.34 is unchanged since 1968.

The NRC may issue the CP if the agency makes the findings specific to a CP that are listed in paragraph (a) of 10 CFR 50.35, ''Issuance of construction permits,'' as well as the more general findings for issuance of licenses and permits in 10 CFR 50.40, ''Common standards,'' and 10 CFR 50.50, ''Issuance of licenses and construction permits.'' The findings in 10 CFR 50.35(a) stem from the early practices of the AEC, when a ''provisional'' CP would be issued when an applicant had not submitted all the technical information necessary to complete the application and to approve all proposed design features. Since almost all issued ''provisional'' CPs were never converted to a ''final'' CP, the AEC proposed codifying this practice (34 FR 6540; April 16, 1969). The final amendment to the regulations in 10 CFR 50.35 eliminated the term ''provisional'' CP, but the criteria in 10 CFR 50.35(a) for issuing a CP remained the same as those previously required for a ''provisional'' CP (35 FR 5317; March 31, 1970). The current regulations for issuing a CP in 10 CFR 50.35(a) have not been modified since 1970.

The NRC issued 10 CFR part 52 on April 18, 1989 (54 FR 15372), to reform the NRC's licensing process for future nuclear power plants. The rule established new approval processes in 10 CFR part 52 for ESPs, standard design certifications, and COLs that were additions to the two-step licensing process that already existed in 10 CFR part 50. This 10 CFR part 52 rule also included processes for standard design approvals and MLs. On August 28, 2007 (72 FR 49352), the NRC issued a final rule with changes to 10 CFR part 52 to clarify the applicability of various requirements to each of the 10 CFR part 52 approval processes.

XVIII. Discussion—Updates to Construction Permit Requirements and Related Licenses

This proposed rule would include updates to the language in 10 CFR 50.34(a) to more clearly link the level of detail required to be submitted with a CP application to the findings the NRC is required to make in 10 CFR 50.35(a), 50.40, and 50.50 to issue a CP. During its review of recent CP applications, the NRC has noted that applicants may provide a higher level of detail for some of the technical areas listed in 10 CFR 50.34(a), and a lower level of detail for others, while still providing sufficient information for the NRC to make the findings required by 10 CFR 50.35(a), 50.40, and 50.50 to issue the CP. The proposed revisions to footnote 1 of 10 CFR 50.34(a) would clarify that the level of detail provided in a preliminary safety analysis report to satisfy the minimum technical requirements in 10 CFR 50.34(a) would be deemed sufficient if the provided information allows the NRC to make the findings required by 10 CFR 50.35(a), 50.40, and 50.50.

This proposed rule would also remove a sentence in 10 CFR 50.34(a)(4) specifying in detail the need to perform loss of coolant accident (LOCA) analyses required in 10 CFR 50.46 and the need for high-point vents in proposed 10 CFR 50.46b, ''Acceptance criteria for reactor coolant system venting systems.'' The NRC considers that these requirements are already implicitly included in the preceding sentence of 10 CFR 50.34(a)(4), which specifies the need to include an evaluation of ''the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.'' These requirements are also referred to in 10 CFR 50.34(b)(4), and the NRC proposes to remove a sentence from 10 CFR 50.34(b)(4) that similarly specifies in detail the need to perform LOCA analyses required in 10 CFR 50.46.

Conforming changes are also proposed to the similar regulatory text and footnotes in each subpart of 10 CFR part 52 to ensure consistency between the power reactor licensing and approval pathways. These changes would be made in 10 CFR 52.47, which applies to standard design certifications; 10 CFR 52.79, which applies to COLs; 10 CFR 52.137, which applies to standard design approvals; and 10 CFR 52.157, which applies to MLs. This change would reflect a more technology-inclusive approach and remove prescriptive language that could be read to mean that a LOCA analysis methodology is fully developed and validated at the CP stage.

The proposed rule would also adjust the wording in 10 CFR 50.34(a)(1)(ii)(D) to be meaningful for designs with functional containments which are evaluated as a release barrier or series of barriers taken together to perform the containment safety function. Specifically, with the proposed changes, the regulation would no longer prescriptively state that the assumed fission product release be ''from the core into the containment'' and would be replaced with technology-inclusive language that refers to ''leakage rates from potential flow paths'' rather than a ''containment leak rate.'' Light-water reactor designs would continue to use fission product release paths from the core into the containment and containment leak rates. The proposed rule would also revise footnotes 3 and

6—which provide additional information on the fission product release to be used in the analyses described in 10 CFR 50.34(a)(1)(ii)(D) and in several items in 10 CFR 50.34(f)(1)—to be more technology-inclusive and allow for evaluation of designs with mechanistic source terms and functional containments. In addition, the proposed rule would revise footnote 4, which discusses the use of 25 roentgen equivalent man (rem) (0.25 sieverts (Sv)) total effective dose equivalent (TEDE) in 10 CFR 50.34(a)(1)(ii)(D)(*1*) as a reference value to remove outdated information regarding recommendations included in a 1959 National Bureau of Standards handbook.

Conforming changes would be made to the similar regulatory text and footnotes in each subpart of 10 CFR part 52 to ensure consistency between the power reactor licensing and approval pathways. Specifically, these proposed changes would be made in 10 CFR 52.17, which applies to ESPs, 10 CFR 52.47, 52.79, 52.137, and 52.157. These changes would reflect a more technology-inclusive approach, eliminate unnecessary exemptions that may otherwise be needed for some designs, and ensure consistency in power reactor applications.

XIX. Background—Alternative Risk-Informed and Performance-Based Acceptance Criteria for 10 CFR Parts 50 and 52

A. Need for Regulatory Flexibility

Many existing NRC regulations include prescriptive acceptance criteria expressed as specific numerical limits (*e.g.,* temperature, pressure, dose). These criteria were developed based on the state of knowledge and technology at the time the rules were promulgated and do not always reflect the significant advancements in nuclear safety analysis, PRA, and reactor design that have occurred in the decades since. Additionally, the codification of these criteria has limited the ability of licensees and applicants to propose alternative approaches without seeking exemptions, which can introduce cost and regulatory uncertainty.

Licensees and applicants have consistently identified unduly prescriptive requirements as a deterrent to innovation. This has been particularly challenging for U.S. companies developing new reactor designs and seeking to compete in global markets. Nonetheless, the NRC has determined that a top-down approach—modifying individual prescriptive requirements throughout 10 CFR parts 50 and 52—would be resource-intensive and could have unintended consequences, especially for the licensing bases of currently operating reactors. Therefore, instead of a top-down approach, the NRC is proposing to expand the use of risk-informed and performance-based alternatives to existing prescriptive requirements.

B. Enabling Risk-Informed and Performance-Based Alternatives

The NRC has long supported the use of risk-informed and performance-based approaches in its regulatory decision-making, as reflected in the Commission's policy statements and strategic goals, particularly, SRM–SECY–98–144, ''Staff Requirements—SECY–98–144—White Paper on Risk-Informed and Performance-Based Regulation,'' dated March 1, 1999. Since then, the agency has encouraged the use of such approaches to improve regulatory decision-making, enhance safety, and reduce unnecessary regulatory burden.

The proposed rule would build on this foundation by providing a structured pathway for licensees and applicants to propose alternative acceptance criteria that would be tailored to demonstrate the safety of their specific technologies without the need for exemptions. Additionally, the proposed rule would further utilize risk-informed and performance-based methodologies to update appendix A to 10 CFR part 50 to clarify the application of general design criteria (GDCs) during the licensing of new LWR designs.

XX. Discussion—Alternative Risk-Informed and Performance-Based Acceptance Criteria for 10 CFR Parts 50 and 52

The NRC is proposing to add new, standalone regulations, 10 CFR 50.220 and 10 CFR 52.220, entitled ''Use of risk-informed and performance-based alternatives to acceptance criteria,'' to allow licensees and applicants to voluntarily submit and use technology-inclusive, risk-informed, or performance-based acceptance criteria as alternatives to existing prescriptive requirements. These new provisions would support the expanded and accelerated use of acceptance criteria reflective of innovative nuclear technologies without the need for exemptions, while continuing to ensure reasonable assurance of adequate protection of public health and safety.

In addition, the NRC is proposing to update appendix A to 10 CFR part 50 to clarify that (1) deviations from GDCs could be identified and justified within licensing submittals, with no need for a separate exemption request; and (2) demonstrating compliance with Criterion 28, ''Reactivity limits'' (GDC 28), of appendix A to 10 CFR part 50 could be based on a different design basis accident than the control rod ejection or control rod drop accident.

The proposed 10 CFR 50.220 and 10 CFR 52.220 would address regulatory inefficiencies and foster innovation by offering a flexible, voluntary alternative to the current approach, which in many instances relies on prescriptive requirements that applicants must seek exemptions from when proposing to adopt innovative methodologies. The NRC has identified several cases in which this type of framework could have enabled more timely and efficient regulatory decisions. These experiences highlight the value of reducing the number of exemptions and rulemakings required, thereby improving efficiency and supporting the deployment of new technologies. The proposed rule would also provide opportunities for increased operational flexibility at existing facilities that choose to propose and adopt alternative criteria.

The proposed approach would enhance regulatory flexibility, efficiency, and reliability by providing a voluntary pathway for the use of alternative criteria. This approach would maintain the existing licensing basis for currently operating reactors and potential restart units, thereby avoiding unintended impacts associated with a broad, top-down revision of regulatory requirements. Additionally, the proposed rule would establish a more transparent and structured process for NRC review and acceptance of alternative criteria.

This approach would be consistent with the NRC's commitment to enabling the safe use of nuclear technology for the benefit of society, while maintaining reasonable assurance of adequate protection of public health and safety. It would also be consistent with the approach of previous NRC rulemakings that provided voluntary pathways for risk-informed and performance-based alternatives to existing requirements, such as the promulgation of 10 CFR 50.69, ''Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors'' (69 FR 68008; November 22, 2004) and 10 CFR part 53 (91 FR 15696; March 30, 2026).

The NRC recognizes that successful implementation of this proposed approach would require broad and flexible guidance to accommodate the range of potential alternative criteria. As a result, NRC encourages the increased

use of pre-application engagement by applicants and licensees who would wish to exercise the flexibility provided by the proposed 10 CFR 50.220 and 52.220. Draft guidance on the content of applications submitted under this proposed rule is provided in DG–1464, ''Guidance for Content of Applications Under 10 CFR 50.220 and 52.220 Proposing Risk-Informed and Performance-Based Alternative Acceptance Criteria,'' which accompanies this rulemaking.

Looking forward, the NRC would maintain a record of NRC-approved alternative acceptance criteria, along with references to the associated bases for approval to support streamlined use of approved alternative acceptance criteria by potential applicants and serve as a means of regulatory recordkeeping for the agency.

The proposed changes would include revising appendix A to 10 CFR part 50 to clarify that exemptions are not required for deviations from the GDCs. Instead, such deviations could be identified and justified directly within the licensing application. While this clarification would not change the NRC's review of the justification itself, it would reduce regulatory burden for applicants proposing innovative designs in which certain GDCs may be tailored to be better risk-informed.

In addition, the NRC is proposing to revise GDC 28 of appendix A to 10 CFR part 50 to allow applicants to propose and justify alternative design basis accidents for reactivity control, rather than prescriptively requiring evaluation of control rod ejection or control rod drop accidents. Although applicants and licensees may be able to accomplish this through the flexibilities in the proposed 10 CFR 50.220 and 52.220, this change would more explicitly enable the use of design-specific accident scenarios and support removal of unnecessary conservatism in safety analyses without the need to provide the information that would be required in proposed 10 CFR 50.220(b) and 52.220. The NRC is issuing, for public comment along with this proposed rule, DG–1464, ''Guidance for Content of Applications Under 10 CFR 50.220 and 52.220 Proposing Risk-Informed and Performance-Based Alternative Acceptance Criteria,'' which would be used to support applicants in determining appropriate design basis accidents based on credible, realistic risks.

XXI. Background—Establishing Thresholds for Changes to Reactor Designs During Construction and Operation Under 10 CFR Parts 52 and 53

Section 5(f) of E.O. 14300 directs the NRC to establish stringent thresholds for circumstances in which the NRC may demand changes to a reactor design once construction of the reactor is underway. In response, the NRC is proposing to raise the threshold for changes required during construction by eliminating ''increased standardization'' as a criterion for Commission-directed modification of design certification information on either a plant-specific or generic basis. In addition, this proposed rule would provide additional flexibility and reduce unnecessary regulatory burden in the regulations governing licensee-requested changes during construction under 10 CFR parts 52 and 53. The NRC is also proposing changes to 10 CFR parts 52 and 53 to provide flexibility and efficiencies for licensee-requested changes during operation.

A. Development of Tiers of Information and Processes for Changes and Departures in Design Certification Rules

In 1987, the NRC issued a policy statement on nuclear power plant standardization (52 FR 34884; September 15, 1987). In 1989, 10 CFR part 52 was issued (54 FR 15372; April 18, 1989), which established that design certification would be accomplished by rulemaking. The NRC ultimately adopted a two-tiered system for design information. These tiers are designated in a design control document (DCD), which the NRC incorporates by reference into its regulations, and each information tier is subject to a specified process for changes and departures from design certification information.

Tier 1 information is the portion of the DCD that is approved and certified. It includes definitions and general provisions; design descriptions; inspections, tests, analyses, and acceptance criteria (ITAAC); significant site parameters; and significant interface requirements. Tier 1 design descriptions were intended to be applicable for the life of the facility. Tier 2 and Tier 2* information is the portion of the DCD that is approved but not certified. Tier 2 includes information like that found in a final safety analysis report (FSAR) for 10 CFR part 50 licenses. Tier 2* was created to minimize information in Tier 1 while requiring that this information could not be changed without prior NRC approval. If the Tier 2* designation were not available, this information would have been designated Tier 1. While the Tier 2* category was used in the first five design certifications, from the U.S. Advanced Boiling Water Reactor (ABWR) to the Economic Simplified Boiling-Water Reactor (ESBWR), the later APR1400 and NuScale DCDs did not designate any information as Tier 2*.

Each design certification in appendix A, ''Design Certification Rule for the U.S. Advanced Boiling Water Reactor,'' appendix D, ''Design Certification Rule for the AP1000 Design,'' appendix E, ''Design Certification Rule for the ESBWR Design,'' appendix F, ''Design Certification Rule for the APR1400 Design,'' and appendix G, ''Design Certification Rule for NuScale,'' of 10 CFR part 52 includes a section VIII, ''Processes for Changes and Departures,'' that specifies processes to change Tier 1, Tier 2, and, where applicable, Tier 2* information. The requirements in section VIII of these appendices are essentially identical except for certain certified designs that do not have information designated as Tier 2*. Under these section VIII requirements, plant-specific changes or departures from Tier 1 require an exemption. Plant-specific departures from Tier 2* require NRC approval by license amendment. Changes or departures from Tier 2 information are evaluated using a process like the one provided for 10 CFR part 50 licensees in 10 CFR 50.59, which provides criteria for determining whether a licensee-initiated change requires prior NRC approval. This similar departure process for Tier 2 information is, therefore, often described as a 10 CFR 50.59-like process for COL holders referencing a design certification. The change processes in section VIII sought to balance standardization with flexibility and apply during both construction and operation.

For currently certified designs, Tier 2* is defined in section II.F of appendices A, D, and E to 10 CFR part 52. Appendices F and G to 10 CFR part 52 do not contain Tier 2* information. Tier 2* is the portion of Tier 2 information designated with brackets, italicized text, and an asterisk in the generic DCD. Per sections VIII.B.6.b and VIII.B.6.c of appendices A, D, and E to 10 CFR part 52, any licensee who references these appendices may not depart from Tier 2* matters without prior NRC approval and any request for such a departure will be treated as a request for a license amendment under 10 CFR 50.90. Sections VIII.B.6.b and VIII.B.6.c of appendices A, D, and E to 10 CFR part 52 list all of the Tier 2* matters for the respective designs. The Tier 2* matters listed in section

VIII.B.6.b of appendices A, D, and E to 10 CFR part 52 retain this Tier 2* designation for the lifetime of the facility, while the Tier 2* matters listed in section VIII.B.6.c of these appendices revert to Tier 2 after the plant first achieves full power.

Another key aspect of the standard design certification is finality. Issuance of the design certification rule allows the design to be incorporated by reference into a COL application. Issue finality rules limit the types of changes that may be imposed on the certification information. During the COL application review, design information codified by rule is not subject to NRC review, but the NRC staff would review applicant-requested departures from the certified design that require NRC approval. The scope of a hearing for a COL application that references a certified design does not include the design certified by NRC rule but would encompass any departures from the certified design requiring NRC approval.

The final rule promulgating 10 CFR part 53 established a risk-informed, performance-based, and technology-inclusive regulatory framework for commercial nuclear plants, including advanced reactor designs. Part 53 of 10 CFR dispensed with the Tier 1 and Tier 2 terminology. Rather, 10 CFR 53.1525, ''Revising certification information within a design certification rule,'' uses the term ''certification information'' in place of Tier 1. Information that is ''not certification information'' is equivalent to Tier 2 information under 10 CFR part 52. The change control processes for ''certification information'' and ''not certification information'' in 10 CFR part 53 are similar to those for Tier 1 and Tier 2 in 10 CFR part 52.

B. Licensing Experience and Improvement Initiatives Regarding Information Designation and Change Processes for Design Certifications

The NRC has periodically considered improvements to the effectiveness and efficiency of information designations for standard design certifications and associated change processes. Many of these improvements, developed through internal and external reviews and interactions, are addressed in this proposed rule.

The NRC staff internally reviewed and considered improvements to the content of Tier 2* and Tier 1 information. In SECY–17–0075, ''Planned Improvements in Design Certification Tiered Information Designations,'' dated July 24, 2017, the NRC staff examined license amendment requests (LARs) affecting Tier 2* information from AP1000 COL licensees to assess the effectiveness of the Tier 2* designation and the 10 CFR 50.59-like change process. While the NRC staff concluded that there was a benefit to maintaining the use of Tier 2* information in certified designs, it noted that for the AP1000 there were several non-safety significant Tier 2* changes requested in LARs that probably would not have triggered the 10 CFR 50.59-like criteria requiring prior NRC approval of the change. In SECY–19–0034, ''Improving Design Certification Content,'' dated April 8, 2019, the NRC staff refined the general principles for Tier 1 content so that in future design certifications, NRC approval would not be required for design changes of minimal safety significance. These refinements also apply to Tier 2*.

Through the experience from Vogtle Units 3 and 4, the NRC staff has gained insights into the Tier 2* information for the AP1000 design referenced in appendix D to 10 CFR part 52. These insights were summarized in the ''10 CFR part 52 Construction Lessons Learned Report,'' issued January 16, 2024.

The AP1000 design certification contained a significant amount of Tier 2* information, more than would be identified should the process be repeated today. The construction experience at Vogtle Units 3 and 4 showed that, in some cases, LARs were needed to change Tier 2* information that had minimal if any safety significance (*e.g.,* to make edits to a bibliography in a document that was identified as Tier 2* information in its entirety). In these cases, submittal of an LAR to change the information resulted in an inefficient use of resources for both the licensee and the NRC. The use of Tier 2* designations should be consistent with the approaches described in SECY–17–0075 and SECY–19–0034. When this designation is used in future licensing applications, the Tier 2* information should be carefully selected to minimize the potential to require LARs for non-safety-significant changes to this information.

Following the issuance of several 10 CFR part 52 COLs, the NRC engaged with industry representatives and members of the public to consider their perspectives while developing guidance for standardized ITAAC and corresponding Tier 1 information. The NRC considered a draft industry guideline developed by the Nuclear Energy Institute (NEI), dated May 27, 2015, which discussed ''first principles'' for developing Tier 1 information and a set of standard ITAAC that could be used in future design certification applications. While discussions between the NRC and the NEI continued, a final version of the guideline was never endorsed.

The NRC issued COLs to Southern Nuclear Operating Company (SNC) for Vogtle Units 3 and 4 on February 10, 2012. Vogtle Units 3 and 4 are currently the only two nuclear plants to be licensed and constructed and to enter into commercial operation using the 10 CFR part 52 licensing process. In the years following the issuance of the COLs, the NRC and SNC had a series of interactions regarding exemptions related to Tier 1 and Tier 2* information for Vogtle Units 3 and 4, including the challenges, lessons learned, and experience gained during licensing and construction.

During construction, SNC sought adjustments to the Tier 2* process on several occasions. By letter dated August 7, 2014, SNC submitted an amendment and exemption request to apply the existing departure evaluation process for Tier 2 changes to Tier 2* changes. SNC withdrew that request by letter dated December 15, 2014. Subsequently, on February 1, 2016, the NRC granted amendment and exemption requests to reclassify fire-protection related Tier 2* information as Tier 2. On December 21, 2017, SNC submitted LAR–17–037, and an associated exemption request, seeking changes to the Vogtle Units 3 and 4 COLs to add a license condition that would apply the change process for Tier 2 information for a proposed departure from Tier 2* information provided that specific criteria are not met. If one of the criteria were met for the proposed departure, then the proposed departure would continue to require prior NRC approval. In this request, SNC noted that LAR–17–037 ''arises from SNC's nearly six years' experience with the departure evaluation processes outlined in 10 CFR part 52, Appendix D'' and that ''SNC has identified an approach to alleviate some of the administrative burden for both the NRC and the Licensee.'' In addition, SNC stated that this proposal was intended to be in line with the Tier 2* lessons learned in SECY–17–0075. On September 20, 2018, the NRC granted the amendments and exemptions to Vogtle Units 3 and 4 that effectively replaced the Tier 2* change process with an alternative process (reflected in a license condition) that applied the Tier 2 change process along with nine additional criteria to determine whether a license amendment was required.

SNC submitted LARs, both during construction and after the start of commercial operation, proposing to change the contents of Tier 2 and Tier

2* information, and, where applicable, requested exemptions from Tier 1 information in accordance with the change processes specified in the design certification appendix. During construction, there were nearly 200 license amendments, some with related exemptions, and various ASME Code alternatives that required NRC review and approval. For each of the numerous Tier 1 exemption requests approved for Vogtle Units 3 and 4, the NRC determined that the special circumstances outweighed any decrease in safety from the reduction in standardization. Lessons learned from these licensing activities indicate that the need for the submittal and an evaluation of how standardization is maintained do not result in significant insights that support the implementation of the standardization policy; rather, experience shows that the requirement for maintaining standardization as a criterion for allowing changes is often burdensome to a licensee without significant benefit. The NRC has not imposed these changes on the certification information in appendix D of 10 CFR part 52 via rulemaking under 10 CFR 52.63, because these deviations from standardization are not significant reductions in safety. In addition, the NRC never found an exemption request submitted by SNC to be unacceptable based solely on the criterion that the special circumstances did not outweigh the decrease in safety from the reduction in standardization. During construction, SNC also sought efficiencies in the content of both Tier 1 and Tier 2* information. Specifically, SNC requested an amendment to consolidate several ITAAC, with corresponding changes to related Tier 1 information, in the plant-specific DCD to improve the efficiency of the ITAAC completion and closure process.

During a September 20, 2023, public meeting, SNC staff acknowledged that the ''existing Tier 2* requirements are not overly burdensome, but SNC would benefit from being able to implement a similar change process across its fleet of plants.''

After the start of commercial operation, SNC submitted a license amendment and exemption request dated July 25, 2024, for Vogtle Units 3 and 4 to remove all Tier 1 and Tier 2* information and associated requirements from its license. SNC proposed, in part, to convert Tier 1 and Tier 2* information to Tier 2, so that the Tier 2 change process would apply to all this information. At that time, the NRC communicated to SNC that the request contained significant questions of policy more appropriately addressed through the petition for rulemaking process and that revisions to the licensing documents SNC proposed were significant licensing changes that raised policy implications appropriate for Commission consideration. Subsequently, SNC withdrew the license amendment and exemption request on September 25, 2024. This proposed rulemaking would address the issue raised by SNC's request to convert Tier 1 and Tier 2* information to Tier 2.

On January 15, 2025, the NRC held another public meeting to seek feedback on preliminary options to provide regulatory flexibility in 10 CFR part 52 during construction and operational phases, including a change process for Tier 1 and Tier 2* information and the adjustment of tier designations. Members of the public who spoke at the meeting provided no adverse feedback and supported the NRC's approaches presented at the meeting.

In its rulemaking efforts to align the 10 CFR parts 50 and 52 licensing processes, the NRC staff proposed various changes regarding standardization and Tier 1 principles in SECY–22–0052, ''Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150–AI66),'' dated June 6, 2022. In SRM–SECY–22–0052, ''Staff Requirements—SECY–22–0052—Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150–AI66),'' dated November 20, 2024, the Commission approved publication of a revised proposed rule in the **Federal Register** that would eliminate requirements for evaluating the impact on standardization when approving departures from information in a design certification or ML. This proposed rule would incorporate that change.

In SECY–22–0052, the NRC staff also proposed to add a definition in 10 CFR part 52 for Tier 1 information that would have defined Tier 1 information as the qualitative and functional level portion of the design-related information in the generic DCD. This proposed rule also incorporates this change and would further include ITAAC in the definition of Tier 1. Relevant guidance documents would be updated to clarify that Tier 1 information should not include detail that could necessitate NRC approval for departures from certified designs that have minimal safety significance.

This proposed rule would also revise regulations governing licensee-requested changes during construction and operation under 10 CFR part 52 to provide additional flexibility and reduce unnecessary regulatory burden. This would be accomplished through changes in each of the certified designs described in appendices A, D, E, F, and G of 10 CFR part 52. Appendix B (System 80+) and appendix C (AP600) to 10 CFR part 52 have expired.

C. Severe Accidents

In SECY–12–0081, ''Risk-Informed Regulatory Framework for New Reactors,'' dated June 6, 2012, the NRC staff described a potential ''gap'' in the Tier 2 change process regarding severe accident features that are not related to ex-vessel severe accident prevention and mitigation. Unless such non-ex-vessel severe accident design features also happen to have a dual function such as also addressing design basis accidents or aircraft impacts, risk-significant Tier 2 changes (*e.g.,* information in Chapter 19 of Tier 2 of the DCD and FSAR related to prevention and mitigation of severe accidents other than those considered ''ex-vessel'') could be screened out altogether and not receive prior NRC approval. In SECY–12–0081, the NRC staff observed that Tier 1 descriptions usually have sufficient detail that necessitates prior NRC review for major changes to severe accident design features. However, the NRC staff also noted that (1) changes may be screened out or less appropriate criteria applied when determining if prior NRC approval is needed and (2) whether prior NRC approval is obtained may be highly dependent on the degree of detail in Tier 1, if any. The current change process does not address all of the severe accidents defined in 10 CFR 52.47(a)(23) and 52.79(a)(38). The current regulation and its implementation through the guidance in NEI 96–07, Appendix C, ''Guideline for Implementation of Change Processes for New Nuclear Power Plants Licensed under 10 CFR part 52,'' Revision 0-Corrected, issued March 2014, could result in the licensee screening out changes in Chapter 19 (and other sections) of Tier 2 of the DCD and FSAR that do not affect ex-vessel severe accident design features. In a worst-case scenario, significant Tier 2 changes to non-ex-vessel severe accident features, up to and including permanent removal from service, could be made without prior NRC approval.

In SRM–SECY–12–0081, ''Staff Requirements—SECY–12–0081—Risk-Informed Regulatory Framework for New Reactors,'' dated October 22, 2012, the Commission approved the NRC staff's plan to address the potential gap in the Tier 2 change process by (a) ensuring that there are sufficient details

on all key severe accident features in Tier 1 and (b) including a change process in future design certification rulemaking for non-ex-vessel severe accident features similar to the process for ex-vessel severe accident features. While no current certified designs include a change process for non-ex-vessel severe accident features, reverting Tier 1 information to Tier 2 information once the plant first achieves full power (a proposed change discussed in section XXII.B. of this document) may introduce a gap regarding changes to non-ex-vessel severe accident features. To address this potential gap, the proposed rule would revise the 10 CFR 50.59-like process in section VIII of appendices A, D, E, F, and G of 10 CFR part 52 to consider all severe accidents and not just ex-vessel severe accidents.

XXII. Discussion—Establishing Thresholds for Changes to Reactor Designs During Construction and Operation Under 10 CFR Parts 52 and 53

To respond to the direction in E.O. 14300 to ''establish stringent thresholds'' for changes required during construction, this proposed rule would revise the finality provisions for design certifications in 10 CFR 52.63, ''Finality of standard design certifications,'' and 10 CFR 53.1263, ''Finality of standard design certifications,'' to (1) eliminate ''increased standardization'' as a criterion for modifying design certification information on either a generic or plant-specific basis, and (2) eliminate whether special circumstances outweigh any decrease in safety that may result from a reduction in standardization as considerations for plant-specific orders and licensee requests for exemptions. Similarly, the proposed rule would revise finality provisions for MLs in 10 CFR 52.171, ''Finality of manufacturing licenses; information requests,'' and 10 CFR 53.1437, ''Exemptions, departures, and variances,'' to eliminate whether ''special circumstances outweigh any decrease in safety that may result from the reduction in standardization'' as a consideration for requests for departures from the applicant referencing or using the manufactured reactor. Further, the proposed rule would include other rule changes to provide additional flexibility and reduce unnecessary regulatory burden for licensee-initiated changes.

A. Standardization

The NRC is proposing to amend its regulations to remove unnecessary requirements to consider standardization as a criterion to justify generic changes to certified designs, plant-specific orders regarding information from a referenced standard design certification, or requested departures from a standard design certification or ML.

As explained in section XXI.B. of this document, recent reactor licensing experience with Vogtle Units 3 and 4 has shown that the requirement for maintaining standardization as a criterion for allowing requested changes is often burdensome to a licensee without significant offsetting benefit. With regard to changes imposed by the NRC, 10 CFR 52.63(a)(1), 52.63(a)(4), 53.1263(a)(1), and 53.1263(a)(4) set out criteria that must be met before the Commission modifies, rescinds, or imposes new requirements on certification information by rulemaking or plant-specific order. Sections 52.63(a)(1)(vii) and 53.1263(a)(1)(vii) of 10 CFR, which provide that changes contributing to increased standardization of certification information is an exception to finality that the Commission may use as a basis to impose new requirements on the certification information, would be deleted from the NRC's regulations. Before imposing new requirements by plant-specific order, 10 CFR 52.63(a)(4)(ii) and 53.1263(a)(4)(ii) require that special circumstances be present and the Commission consider whether these special circumstances outweigh any decrease in safety that results from the effects of decreased standardization. The criterion of whether the special circumstances outweigh any decrease in safety that results from a reduction in standardization, which apply to the Commission, would be deleted from the NRC's regulations. The criterion that special circumstances are present would remain in the regulations.

With regard to changes proposed by licensees and applicants, 10 CFR 52.63(b)(1) and 53.1263(b) permit an applicant or licensee that references a design certification rule to request an exemption from one or more elements of the certification information. These regulations require the Commission to consider whether the special circumstances that the exemption regulation requires to be present outweigh any decrease in safety that may result from the reduction in standardization caused by the exemption. However, as described in section XXI.B. of this document, experience has shown that for all cases, the required special circumstances outweigh any decrease in safety that may result from the reduction in standardization caused by the requested exemption. Therefore, the NRC is proposing to revise 10 CFR 52.63(b)(1) and 53.1263(b) to eliminate the requirements for the NRC to review the impact of the requested exemption on standardization.

For similar reasons, the NRC is also proposing to revise 10 CFR 52.93(c), 52.171(b)(2), and 53.1437(c) to remove the requirement to discuss the impact of the change on standardization as a criterion for the justification for departures from ML information.

On September 15, 1987, the NRC issued a revised policy statement on nuclear power plant standardization (52 FR 34884). The purpose of this policy statement was for the Commission to encourage standardization by providing a regulatory framework for the certification of nuclear power plant designs that can be referenced in individual plant applications. As stated in this policy, ''[t]he Commission believes that the use of certified standardized designs can benefit the public health and safety by concentrating resources on specific design approaches without stifling ingenuity; by stimulating standardized programs of construction practice, quality assurance, and personnel training; and by fostering more effective maintenance and improved operation.'' The use of certified designs would also improve the efficiency of NRC reviews and reduce uncertainty in the regulatory process.

The proposed rule changes would not be contrary to this policy goal. The policy goal of standardization along with the efficiencies and safety benefits associated with it would be maintained because the overall regulatory framework would still allow for certified designs to be referenced by applicants and licensees in CP applications or COL applications. The deletion of 10 CFR 52.63(a)(1)(vii) and 53.1263(a)(1)(vii) would ensure that changes to certified designs could not be imposed on licensees for the sole purpose of establishing or maintaining standardization among reactors referencing the same design. However, the Commission could still impose new requirements on certification information using one of the six other criteria that would remain in 10 CFR 52.63(a)(1) and 53.1263(a)(1). Since the design certification changes imposed by the NRC for reasons that meet these other criteria would apply to all plants referencing the certified design, standardization would still be achieved.

Regarding the proposed changes to the requirements in 10 CFR 52.63(b)(1), 52.93(c), 52.171(b)(2), 53.1263(b), and 53.1437(c) requiring an analysis of the effects of a change on standardization,

experience has shown that it is challenging for an applicant or the NRC to evaluate whether any one change proposed would decrease safety solely as a result of a reduction in standardization. The NRC recognizes that increased standardization remains a policy goal of 10 CFR parts 52 and 53, and requirements supporting that goal should be maintained when there is an appropriate benefit to doing so. The proposed changes to the NRC's regulations that remove the requirement to justify requested changes to the design, based on the changes' effects on standardization, would eliminate unnecessary burden on applicants and licensees while maintaining beneficial aspects of the NRC's policy on standardization. The proposed changes to 10 CFR 52.63(a)(4) and 53.1263(a)(4) would eliminate similar requirements for the NRC to consider whether special circumstances outweigh any decrease in safety that results from a reduction in standardization before issuing a plant-specific order.

Even though the proposed rule revisions described in section XXII.C, ''Processes for Changes and Departures,'' of this document would provide licensees with additional flexibility to make plant-specific changes to certified designs, the NRC does not expect the scope and extent of plant-specific changes to result in such drastic and significant differences that would negate the advantages and safety benefits of standardization. The regulatory structure and change control processes in 10 CFR parts 52 and 53 would continue to support the policy goal of standardization.

B. Definitions

The NRC is proposing to change its regulations to add the definitions of tier information to 10 CFR 52.1, ''Definitions,'' and to make the definitions consistent with the principles in SECY–19–0034. The terms ''Tier 1,'' ''Tier 2,'' and ''Tier 2*'' are defined in section II, ''Definitions,'' of each design certification in appendices A, D, E, F and G to 10 CFR part 52. A design certification applicant is free to define this information. For example, an application can define no tier information, include more than three tiers of information, or define tiers with definitions that are different than those in current 10 CFR part 52 design certification appendices. This flexibility can lead to inconsistencies and increased burden for design certification and COL applicants in preparing applications and increased burden to the NRC in reviewing applications. Recent reactor licensing experience has shown that some applications have included more information in Tier 1 than is necessary for the purpose of Tier 1. This has resulted in the need for licensees to request NRC review and approval of Tier 1 departures from information that, because of its minimal safety significance, could more appropriately have been handled under the 10 CFR 50.59-like change process currently applicable to Tier 2 information.

To address these problems, the NRC is proposing to change its regulations to add a definition of ''Tier 1'' to 10 CFR 52.1 that would state that Tier 1 information is the qualitative and functional-level portion of the design-related information in the generic DCD and also includes ITAAC. Relevant guidance documents would be updated to clarify that Tier 1 information should not include detail that could necessitate NRC approval for departures from the certified design that have minimal safety significance. The NRC proposes the same refinements to the proposed 10 CFR 52.1 definition of Tier 2* information because information should be designated as Tier 2* only if it qualifies for inclusion in Tier 1.

The NRC also notes the following regarding the definitions of ''Tier 2'' and ''Tier 2*'' proposed to be added to 10 CFR 52.1:

- The definition of ''Tier 2'' in section II of appendices A, D, E, F and G to 10 CFR part 52 goes on to list specific information that is included in Tier 2. The proposed definition of ''Tier 2'' in 10 CFR 52.1 would not contain this listed information.
- The definition of ''Tier 2*'' in section II of appendices A, D, E, F and G to 10 CFR part 52 states, ''This designation expires for some Tier 2* information under paragraph VIII.B.6.'' The proposed definition of ''Tier 2*'' in 10 CFR 52.1 would state, in part, that after the plant first achieves full power, the Tier 2* designation reverts to Tier 2 status for all Tier 2* matters.

These proposed 10 CFR 52.1 definitions of Tier 1, Tier 2, and Tier 2* would apply to design certifications issued after the effective date of the final rule.

For currently certified designs, the NRC is proposing to clarify its definitions of Tier 1 information in section II.D of appendices A, D, E, F, and G to 10 CFR part 52. Currently, section II.D in each of these appendices states that Tier 1 is the portion of the design-related information in the generic DCD that is approved and certified and includes: definitions and general provisions; design descriptions; ITAAC; significant site parameters; and significant interface requirements. The proposed revisions to section II.D would provide further clarification by identifying specific sections and tables within the generic DCD that correspond to each of these categories of Tier 1 information. Since the proposed rule would implement different change control processes for these various categories of Tier 1 information, there would be a need to clearly identify what Tier 1 information in the generic DCD corresponds to each category. For definitions and general provisions (section II.D.1), significant site parameters (section II.D.4), and significant interface requirements (section II.D.5), the specific sections in the generic DCD would be identified. For ITAAC (section II.D.3), the specific tables in the generic DCD would be listed. The proposed rule would also specify that only the inspections, tests, and analyses column and the acceptance criteria column of these tables would be considered ITAAC information. For design descriptions (section II.D.2), the proposed rule would identify the specific sections in the generic DCD and would clarify that figures and non-ITAAC tables referenced in these sections would also be considered design description information. Non-ITAAC tables would be any tables not specifically listed as an ITAAC table in the definition.

C. Processes for Changes and Departures

(i) Tier 1 Design Description Information

The NRC is proposing to change its regulations regarding licensee-requested changes during construction for COL holders referencing a certified design. Several of these proposed rule changes would impact the 10 CFR 50.59-like criteria in the appendices of 10 CFR part 52. These include proposed changes to the 10 CFR 50.59-like criteria themselves as well as their application to design information. The NRC acknowledges that section XII, ''Discussion—Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods,'' of this document describes proposed changes to 10 CFR 50.59 that would allow consideration of risk insights from PRAs and provide increased flexibility for changes to methods of evaluation. As part of the development of the final rule, the NRC will consider the rule revisions to 10 CFR 50.59 and their applicability to the 10 CFR 50.59-like process in 10 CFR part 52.

The NRC proposes to amend section VIII.A, ''Tier 1 Information,'' of

appendices A, D, E, F, and G to 10 CFR part 52 regarding licensee-requested changes to Tier 1 design description information. Currently, exemptions from all Tier 1 information are governed by the requirements in 10 CFR 52.63(b)(1) and 52.98(f). The proposed rule would revise the change process for Tier 1 design descriptions and provide a conforming change in 10 CFR 52.63(b)(1) reflecting that some Tier 1 design description changes within the scope of the new change process would not require an exemption. Licensee-requested exemptions from definitions and general provisions, significant site parameters, and significant interface requirements would be unchanged and any departure from this Tier 1 information would continue to require an exemption. The NRC recognizes that some of the change requests for Tier 1 information based on construction experience from Vogtle Units 3 and 4 may not have been important to safety. Providing flexibility in determining which changes to Tier 1 design description information require NRC approval would reduce burden on licensees and minimize possible construction delays due to licensing reviews without impacting safety.

The NRC proposes to add section VIII.A.5 to appendices A, D, E, F, and G to 10 CFR part 52 to allow an applicant or licensee to depart from Tier 1 design description information without NRC approval if certain criteria are met. The criteria for determining whether a proposed departure from Tier 1 design description information requires an exemption would be listed in the proposed new section VIII.A.6 of appendices A, D, E, F, and G of 10 CFR part 52. These criteria are based upon the 10 CFR 50.59-like criteria currently listed in sections VIII.B.5.b and VIII.B.5.c in appendices A, D, E, F, and G of 10 CFR part 52 for determining whether changes to Tier 2 information require NRC approval. Since Tier 1 design description information is based on Tier 2 information, these criteria would also be appropriate to use for changes to Tier 1 design description information. The criteria in the proposed new section VIII.A.6 would be identical to those in section VIII.B.5.b. The criteria in the proposed new section VIII.A.6 would also include criteria similar to those in current section VIII.B.5.c but these criteria would be revised to consider all severe accident design features and not just ex-vessel severe accident design features, consistent with proposed changes to section VIII.B.5.c that would be made by this proposed rule. Additional discussion for this change is in section XXII.C.(iii), ''Severe Accidents,'' of this document. If any of the criteria in the proposed section VIII.A.6 were met, then the proposed departure from the Tier 1 design description would require an exemption request for NRC approval.

Section VIII.A.2 of appendices A, D, E, F, and G to 10 CFR part 52 states that generic changes to Tier 1 information are applicable to all applicants or licensees who reference the applicable appendix, except those for which the change has been rendered technically irrelevant by plant-specific actions under paragraphs VIII.A.3 or VIII.A.4. Because the NRC proposes to add paragraphs VIII.A.5 and VIII.A.6 as means for making plant-specific changes to Tier 1 design descriptions, the NRC also proposes a conforming change that would amend section VIII.A.2 of appendices A, D, E, F, and G to 10 CFR part 52 to add the new paragraphs VIII.A.5 and VIII.A.6 to the list of plant-specific actions that can render a generic change to Tier 1 information technically irrelevant.

Section VI.B of appendices A, D, E, F, and G to 10 CFR part 52 lists matters the Commission considers resolved in subsequent proceedings for issuance of a COL, amendment of a COL, or renewal of a COL, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing the applicable appendix. Section VI.B.4 of these appendices identifies one resolved matter as all exemptions under and in compliance with the change processes in paragraphs VIII.A.4 and VIII.B.4 of the applicable appendix. Section VI.B.6 of these appendices identifies another resolved matter as all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of the applicable appendix that do not require prior NRC approval. Because the NRC proposes to add paragraphs VIII.A.5 and VIII.A.6 as means for making plant-specific changes to Tier 1 design descriptions, the NRC also proposes a conforming change that would amend section VI.B.4 of appendices A, D, E, F, and G to 10 CFR part 52 to add exemptions under and in compliance with section VIII.A.6 to the list of resolved matters. Another conforming change would amend section VI.B.6 of appendices A, D, E, F, and G to 10 CFR part 52 to add departures from Tier 1 under and in compliance with section VIII.A.5 that do not require NRC approval to the list of resolved matters. In addition, the NRC proposes to make a correction in section VI.B.6 of appendices A and F to 10 CFR part 52 by changing the reference, ''paragraph VIII.B.5.f,'' to ''paragraph VIII.B.5.g,'' of the applicable appendix.

Analogous changes are proposed for 10 CFR part 53. Specifically, the NRC proposes to revise 10 CFR 53.1525(b) to allow a holder of a license that references a design certification issued under 10 CFR part 53 to make changes to certification information that has not been incorporated into the license without requesting an exemption if certain criteria are met. Additional changes are proposed for 10 CFR 53.1535, ''Amendments and exemptions during construction,'' and 10 CFR 53.1550 to reflect the proposed change to 10 CFR 53.1525(b). Paragraph (a) of 10 CFR 53.1535 would be revised to add provisions that holders of a CP or LWA may also request an exemption, if an exemption is required. Paragraph (b) of 10 CFR 53.1535 would be revised to require any COL holders for which the 10 CFR 53.1452(g) finding has not yet been made to submit an exemption request within 45 days from the date the licensee begins the construction to implement a change requiring NRC approval. This requirement currently applies to requested license amendments, and the NRC is proposing to also apply it to exemptions to reflect the proposed change to 10 CFR 53.1525(b) under which certain departures from certification information would require an exemption but not an amendment. The proposed changes to 10 CFR 53.1550 would clarify that the evaluation of changes to the facility applies to certification information as well as FSARs. Finally, the NRC proposes to delete the current requirement in 10 CFR 53.1525(b) that a request for an exemption be included with a LAR since departures under proposed 10 CFR 53.1525(b) that require NRC approval would be subject to exemption requests and not require a license amendment unless the departure would change the license itself. A conforming change is proposed to 10 CFR 53.1530, ''Revising information within a Final Safety Analysis Report associated with a manufacturing license,'' to eliminate the requirement that a holder of an ML referencing a design certification request an exemption from the design certification rule as part of an amendment application. The proposed 10 CFR 53.1530 would state that, in these cases, the provisions of 10 CFR 53.1525 would apply.

(ii) Tier 1 ITAAC and Certification Information

The NRC proposes to amend section VIII.A of appendices A, D, E, F, and G to 10 CFR part 52 regarding licensee-

requested changes to Tier 1 ITAAC information. Under the current change control requirements, any change to generic ITAAC in a COL application referencing a certified design requires the COL holder to submit both an exemption request and a LAR to the NRC for approval. An exemption request is required to modify generic ITAAC because, like other Tier 1 information, ITAAC are certified information. Changes to either generic or plant-specific ITAAC also require a license amendment because section 185b. of the AEA requires the Commission to include the ITAAC within the COL.

The proposed rule would add a new section VIII.A.7 to appendices A, D, E, F, and G to 10 CFR part 52. Proposed section VIII.A.7 in each appendix would require licensees who reference that appendix to request a license amendment under 10 CFR 50.90 for any change to Tier 1 ITAAC information. However, unlike current requirements, licensees requesting a departure from Tier 1 ITAAC information would no longer be required to submit an exemption request in addition to the LAR due to the proposed requirements in section VIII.A.7 of appendices A, D, E, F, and G to 10 CFR part 52. Removing the requirement to submit an exemption request would reduce the unnecessary burden on licensees by eliminating the need to submit both an exemption request and a LAR for the same change. The NRC would still be required to review and approve any ITAAC changes to ensure that the requirements of 10 CFR 52.97(b)—namely, that the COL contains the ITAAC that are necessary and sufficient to provide reasonable assurance that the facility has been constructed and will be operated in conformity with the license, the provisions of the AEA, and the Commission's regulations—continue to be met. Experience from construction of Vogtle Units 3 and 4 demonstrated that there is no enhanced assurance of safety by evaluating these same ITAAC changes against the exemption criteria specified in 10 CFR 52.7 (which reference 10 CFR 50.12), 10 CFR 52.63(b), and section VIII.A.4 of the applicable appendix to 10 CFR part 52. The need for the exemption request for ITAAC information was simply due to the designation of ITAAC as Tier 1 (*e.g.,* certified) information.

Section VIII.A.2 of appendices A, D, E, F, and G to 10 CFR part 52 states that generic changes to Tier 1 information are applicable to all applicants or licensees who reference the applicable appendix, except those for which the change has been rendered technically irrelevant by plant-specific actions under paragraphs VIII.A.3 or VIII.A.4. In a conforming change, the NRC proposes to amend section VIII.A.2 of appendices A, D, E, F, and G to 10 CFR part 52 to add the new paragraph VIII.A.7 to the list of plant-specific actions that can render a generic change to Tier 1 information technically irrelevant.

Analogous changes are proposed for 10 CFR part 53. Specifically, the NRC proposes to amend 10 CFR 53.1525(a) to allow a holder of an OL or COL that references a design certification issued under 10 CFR part 53 to request a license amendment, in lieu of an exemption, if proposing changes to certification information that has been incorporated into the license. A conforming change is also proposed to 10 CFR 53.1550(a)(1) to clarify that changes could be made without a license amendment if the change to certification information incorporated into the license is not required.

The requirements for licensee-requested changes to Tier 1 information in the appendices of 10 CFR part 52 are not identical to those for certified information in 10 CFR part 53 because the Tier 1 definition in the appendices of 10 CFR part 52 states that Tier 1 information includes definitions and general provisions; design descriptions; ITAAC; significant site parameters; and significant interface requirements, whereas 10 CFR part 53 does not specify certification information. The 10 CFR part 52 change control process for Tier 1 ITAAC is similar to that for 10 CFR part 53 certified information that has been incorporated into the license. The 10 CFR part 52 change control process for Tier 1 design descriptions is similar to that for 10 CFR part 53 certified information that has not been incorporated into the license. The NRC proposes to amend section VIII.A.4 of the appendices of 10 CFR part 52 to state that licensee-requested departures from definitions and general provisions, significant site parameters, and significant interface requirements would continue to require an exemption from Tier 1 information. 10 CFR part 53 does not and would not have a similar requirement because it does not define this type of information. Despite this difference, the proposed requirements in 10 CFR parts 52 and 53 would establish appropriate thresholds for licensee-requested changes. During a review of a design certification under 10 CFR part 53, if the NRC determined that certain certification information always warranted prior NRC approval, this information could be designated as information required to be incorporated into a license referencing the certified design.

(iii) Severe Accidents

The NRC proposes to amend the criteria described in section VIII.B.5.c of appendices A, D, E, F, and G to 10 CFR part 52 used to determine if a proposed departure from Tier 2 information affecting the resolution of an ex-vessel severe accident design feature identified in the plant-specific DCD requires a license amendment.

The proposed rule would address the gap described in SECY–12–0081 and section XXI.C. of this document by revising section VIII.B.5.c of appendices A, D, E, F, and G to 10 CFR part 52 by removing the phrase ''ex-vessel'' from the description of severe accidents considered. This change would allow the revised criteria to consider all severe accident design features identified in the DCD, not just ex-vessel severe accident design features.

As discussed in section XXII.C.(i) of this document, another change proposed in this rulemaking would be to add a new section VIII.A.5 to appendices A, D, E, F, and G to 10 CFR part 52. Proposed section VIII.A.5 would allow an applicant or licensee to depart from Tier 1 design description information without NRC approval if certain criteria are met. The criteria for determining whether a proposed departure from Tier 1 design description information requires an exemption would be listed in the proposed section VIII.A.6. These criteria were based upon the 10 CFR 50.59-like criteria currently listed in sections VIII.B.5.b and VIII.B.5.c of appendices A, D, E, F, and G of 10 CFR part 52 for determining whether changes to Tier 2 information require NRC approval. The criteria in the proposed section VIII.A.6 would also include criteria similar to those in current section VIII.B.5.c but these criteria would be revised to consider all severe accident design features and not just ex-vessel severe accident design features.

(iv) Process for Changes and Departures During Commercial Operation

The NRC proposes to amend section VIII.A in appendices A, D, E, F, and G to 10 CFR part 52 regarding the treatment of Tier 1 information during commercial operation. A proposed section VIII.A.8 would be added to each appendix stating that after the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information would be subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information. Per 10 CFR 52.103(h), after

the Commission has made the 10 CFR 52.103(g) finding, ITAAC do not constitute regulatory requirements except for any specific ITAAC for which the Commission has granted a hearing under 10 CFR 52.103(a). Also, all ITAAC expire upon final Commission action in the proceeding under 10 CFR 52.103(a). Therefore, after the 10 CFR 52.103(g) finding and any proceedings held under 10 CFR 52.103(a), the only remaining Tier 1 requirements are the definitions and general provisions, design descriptions, significant site parameters, and significant interface requirements. As discussed in section XXII.C.(i) of this document, proposed section VIII.A.5 would allow an applicant or licensee, even during construction, to depart from Tier 1 design description information without NRC approval if certain criteria are met. Thus, the criteria for determining whether a proposed departure from Tier 1 design description information would require an exemption would be the 10 CFR 50.59-like criteria that apply to departures from Tier 2 information. With the NRC's additional proposal to treat licensee-initiated departures from Tier 1 the same as licensee-initiated departures from Tier 2 after first achieving full power, an exemption would be needed for a plant-specific departure from Tier 1 design description information during construction and start-up testing up to full power if the 10 CFR 50.59-like criteria are met, but a license amendment would be needed for such departures after full power operation is first achieved. The criteria for determining whether the change would need NRC approval would remain the same.

Since plant-specific departures from Tier 2 information are governed by the 10 CFR 50.59-like criteria, the proposed section VIII.A.8 would allow licensees, after first achieving full power, to use the 10 CFR 50.59-like process to determine if changes to definitions and general provisions, design descriptions, significant site parameters, and significant interface requirements would require prior NRC approval. Tier 1 definitions and general provisions, design descriptions, significant site parameters, and significant interface requirements would still remain requirements for the lifetime of the facility, but the proposed rule would provide additional flexibility to 10 CFR part 52 licensees by allowing them to use the 10 CFR 50.59-like process to determine if changes to this information would require prior NRC approval.

(v) Tier 2* Information

The NRC proposes to amend sections II.F and VIII.B of appendices A and E to 10 CFR part 52 to revert all Tier 2* information to Tier 2 status after the plant first achieves full power. Proposed amendments to section II.F of appendices A and E to 10 CFR part 52 would clarify that the Tier 2* designation expires for all Tier 2* matters, not just for those listed in section VIII.B.6.c. In addition, the proposed rule would modify section VIII.B.6.b of appendices A and E to 10 CFR part 52 to add the Tier 2* matters listed in section VIII.B.6.c and correspondingly remove those items from section VIII.B.6.c. Finally, section VIII.B.6.c of appendices A and E to 10 CFR part 52 would be revised to state that after the plant first achieves full power, all Tier 2* matters would revert to Tier 2 status and would thereafter be subject to the departure provisions in section VIII.B.5. These proposed changes would reduce the regulatory burden during operation for COL holders who reference appendix A or E to 10 CFR part 52 by allowing them to use the 10 CFR 50.59-like criteria to determine if a departure from Tier 2* information would require a LAR. This would also provide COL licensees under 10 CFR part 52 the same flexibility afforded to OL licensees under 10 CFR part 50 during plant operation.

The NRC also proposes to amend sections II.F and VIII.B of appendix D to 10 CFR part 52 regarding Tier 2* information. These changes would allow the use of the 10 CFR 50.59-like criteria in sections VIII.B.5.b and B.5.c to determine if licensees who reference appendix D to 10 CFR part 52 may depart from Tier 2* information without prior NRC approval. The proposed rule would revise sections VIII.B.5.a, VIII.B.5.b, and VIII.B.5.c to apply to both Tier 2* information as well as Tier 2 information. Section VIII.B.6 would be deleted in its entirety, along with cross-references to section VIII.B.6 elsewhere in appendix D to 10 CFR part 52. With these proposed changes, the Tier 2* information for the AP1000 design would effectively be treated as Tier 2 information during construction as well as operation. The bases for these proposed rule changes are as follows. First, SNC's experience with the Tier 2* departure evaluation process for Vogtle 3 and 4 during the first six years of construction demonstrated that the Tier 2* change process for the AP1000 design imposed an administrative burden on both the licensee and the NRC because LARs were needed to change Tier 2* information that had minimal safety significance. This was also documented in SECY–17–0075 and the ''10 CFR part 52 Construction Lessons Learned Report,'' issued after the completion of construction of Vogtle units 3 and 4. Second, the 10 CFR 59.59-like process is an acceptable approach to determine which changes are safety significant and require prior NRC approval. The 10 CFR 50.59 process is used successfully by the operating fleet of plants licensed under 10 CFR part 50. In addition, as part of this proposed rule, the NRC is proposing to apply the 10 CFR 59.59-like process to the Tier 1 design description information for existing certified designs.

Section VI.B of appendix D to 10 CFR part 52 lists matters the Commission considers resolved in subsequent proceedings for issuance of a COL, amendment of a COL, or renewal of a COL, proceedings held under 10 CFR 52.103, and enforcement proceedings involving plants referencing appendix D. Section VI.B.6 of appendix D identifies one resolved matter as all departures from Tier 2 under and in compliance with the change processes in paragraph VIII.B.5 of appendix D that do not require prior NRC approval. Because the NRC proposes to amend section VIII.B of appendix D to 10 CFR part 52 to apply the change process in paragraph VIII.B.5 to Tier 2* information, the NRC also proposes a conforming change that would amend section VI.B.6 of appendix D to 10 CFR part 52 to add departures from Tier 2* under and in compliance with section VIII.B.5 that do not require NRC approval to the list of resolved matters.

At this time, the NRC is not proposing that Tier 2* information for the ABWR and ESBWR designs be treated as Tier 2 information during construction. The NRC acknowledges some inconsistency in the treatment of Tier 1 design description and Tier 2* information but wants to provide considerations for the construction and licensing experience from COLs referencing the AP1000. However, the NRC has posed a specific question in section XXXVI, ''Specific Questions,'' of this document asking if the flexibility afforded the AP1000 design should include the ABWR and ESBWR designs and for the basis of a response to that question.

Section VIII.B.2 of appendix A to 10 CFR part 52 states, in part, that generic changes to Tier 2* information are applicable to all applicants or licensees who reference that appendix, except those for which the change has been rendered technically irrelevant by certain plant-specific actions. The NRC proposes to amend section VIII.B.2 of appendix A to 10 CFR part 52 to add

paragraph VIII.B.6 to the list of plant-specific actions that can render a generic change to Tier 2* information technically irrelevant. This proposed addition would make appendix A to 10 CFR part 52 similar in this regard to other appendices in 10 CFR part 52 and avoid an unnecessary imposition of a generic change to a plant for which the underlying issue has already been addressed.

(vi) Section IX of Appendix D to 10 CFR Part 52

The NRC proposes to delete the requirements in section IX, ''Inspections, Tests, Analyses, and Acceptance Criteria (ITAAC),'' of appendix D to 10 CFR part 52 and reserve this section for future use. The ITAAC requirements currently listed in this section were incorporated into 10 CFR 52.99 and 52.103 in a 2007 rulemaking (72 FR 49352; August 28, 2007). Therefore, the language in this section is no longer needed, and removal of it is consistent with previous Commission direction. As stated in the rulemaking for the ESBWR design certification (79 FR 61944; October 15, 2014), ''The language of the ESBWR design certification rule differs from the rule language of other DCRs in two substantive areas. First, paragraph IX was reserved for future use because the substantive requirements in this paragraph (for other DCRs) has since been incorporated into 10 CFR part 52 in a 2007 rulemaking (72 FR 49352; August 28, 2007) and thus are no longer needed in the four existing DCR appendices. The NRC intends to remove these requirements from Section IX of the four existing DCR appendices in future amendment(s) separate from this rulemaking.''

This change would also make appendix D to 10 CFR part 52 similar in this regard to the other appendices in 10 CFR part 52.

(vii) Manufacturing Licenses

The NRC proposes to revise 10 CFR 52.171(b)(1) to allow the holder of an ML to use the regulations in 10 CFR 50.59 to determine whether changes to the facility or procedures as described in the FSAR would require prior Commission approval of an amendment to the ML. If prior Commission approval is required, then the change would need to be submitted in the form of a license amendment per 10 CFR 50.90, 50.91, and 50.92. The NRC also proposes a conforming change to 10 CFR 50.71(f) regarding FSAR updates for ML holders. Instead of requiring FSAR updates that reflect only design modifications approved by the Commission, the revised 10 CFR 50.71(f) would require that FSAR updates reflect safety analyses and evaluations that support approved amendments to the ML or support conclusions that changes did not require a license amendment. This revision would be consistent with the requirements in 10 CFR 53.1530 and would provide additional flexibility to licensees and reduce unnecessary regulatory burden in the regulations governing licensee-requested changes.

(viii) Applicants and Licensees That Reference Manufacturing Licenses

The NRC proposes to revise its regulations to allow licensees who reference an ML license to use the applicable change processes in 10 CFR part 50 to determine whether changes to the facility or procedures as described in the FSAR would require prior Commission approval. This would be accomplished with two proposed revisions to 10 CFR 52.98. The first proposed change would be to delete 10 CFR 52.98(d), which establishes requirements for changes or departures for COLs that reference an ML under subpart F of 10 CFR part 52. The second proposed change would be to revise 10 CFR 52.98(b). The current requirement in 10 CFR 52.98(b) is that only COLs that do not reference either a design certification or an ML may make changes to the facility using the applicable 10 CFR part 50 change processes. The NRC proposes to eliminate the restriction for COLs that reference a reactor manufactured under an ML by deleting the phrase ''or a reactor manufactured under a manufacturing license issued under subpart F of this part.'' The NRC also proposes to modify 10 CFR 52.171(b)(2) so that it would not apply to licensees referencing an ML. These proposed changes would allow a COL that references an ML to make changes to the facility using the applicable 10 CFR part 50 change processes.

The NRC proposes to add a new 10 CFR 50.59(f) that would allow the holder of an OL or COL that references a reactor manufactured under an ML to make changes in the facility or procedures as described in the FSAR without requesting a license amendment if the changes would be the same as changes approved by amendment to the ML and upon a determination that implementing the changes would be consistent with the basis for the Commission's approval of the amendment to the ML and would not involve any additional changes that would require an amendment to the OL or COL. The NRC proposes to add a similar provision as 10 CFR 53.1550(c) for holders of OLs or COLs that reference an ML. These proposed requirements would prevent OL and COL holders and the NRC from having to duplicate the amendment process for each manufactured reactor.

Sections 50.59(d)(1) and 53.1550(d) of 10 CFR would also be revised to require that the licensee maintain records of these changes.

The NRC proposes to amend 10 CFR 52.93(c), 52.171(b)(2), 53.1288(b), and 53.1437(c) to eliminate requirements that the Commission determine that departures from MLs by an applicant referencing the ML comply with the requirements for specific exemptions. Applicants that reference an ML would still request departures from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The NRC would review these proposed departures as part of its review of the application. Removing the requirement that approval of these departures also meets the requirements for exemptions would eliminate an unnecessary regulatory burden for applicants.

All of these proposed revisions would provide additional flexibility to licensees and applicants and reduce unnecessary regulatory burden in the regulations governing licensee-requested changes.

XXIII. Background—Revision of the Emergency Preparedness Regulations for Nuclear Power Reactors

A. Existing Emergency Preparedness Frameworks for Nuclear Power Reactors

Before December 18, 2023, appendix E, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' to 10 CFR part 50 identified the minimum requirements for emergency plans. Additionally, the regulations in 10 CFR 50.47, ''Emergency plans,'' provided emergency preparedness (EP) requirements for nuclear power reactors, including planning standards for onsite and offsite emergency response plans. Other relevant regulations included paragraphs (q), (s), and (t) of 10 CFR 50.54, ''Conditions of licenses.''

Efforts to develop a performance-based approach for EP have been ongoing for over two decades. In SECY–06–0200, ''Results of the Review of Emergency Preparedness Regulations and Guidance,'' dated September 20, 2006, the staff sought Commission approval to begin activities to develop a new voluntary performance-based EP regulatory regimen. On November 16, 2023, the NRC published a final rule creating 10 CFR 50.160, ''Emergency

preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities'' (88 FR 80050) (referred to herein as the ''2023 EP final rule''). Section 50.160 of 10 CFR provides a performance-based, technology-inclusive, risk-informed, and consequence-oriented EP framework as an alternative to 10 CFR 50.47 and appendix E to 10 CFR part 50. The alternative EP framework recognizes advances in reactor design and technology and credits the potential benefits of smaller sized reactors and non-light-water reactors (non-LWRs) associated with postulated accidents, including slower transient response times, and relatively small and slow release of fission products, as compared to large LWRs. The regulations in 10 CFR 50.160 are applicable to small modular reactors (SMRs) of rated power less than 1000 megawatts thermal (MWt), non-LWRs, and certain non-power production or utilization facilities. The NRC did not include large LWRs in the scope of 10 CFR 50.160 because an EP licensing framework already existed for those reactors, and licensees for those plants had not expressed a clear interest in changing that framework during development of the 2023 EP final rule. However, the work underpinning 10 CFR 50.160, originating from the motivations of SECY–06–0200, included considerations of large LWRs. Consistent with Commission direction in SRM–SECY–14–0038, ''Staff Requirements—SECY–14–0038—Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight,'' dated August 2, 2015, which directed the staff to ''be vigilant in continuing to assess the NRC's emergency preparedness program and should not rule out the possibility of moving to a performance-based framework in the future,'' the changes in this proposed rulemaking would expand the voluntary applicability of 10 CFR 50.160 to large LWRs. Part 53 of 10 CFR provided another opportunity to increase the use of performance-based regulation. The regulations in 10 CFR 53.855, ''Emergency preparedness,'' require each holder of an OL or COL under 10 CFR part 53 to have an emergency plan that complies with either the requirements in 10 CFR 50.160 or the requirements in appendix E to 10 CFR part 50 and the planning standards of 10 CFR 50.47(b).

B. Protective Actions and Emergency Planning Zones

EP is an operational safety program that provides reasonable assurance that adequate protective measures can and will be taken in the unlikely event of a radiological emergency. For radiological emergencies, protective actions should be carefully planned to balance protection with other important factors and ensure that actions result in more benefit than harm. The use of precautionary protective action strategies that rely on predetermined, prompt protective measures, including prompt evacuation, should be reserved for only the most severe incidents as protective actions are not without risk (see, for example, NUREG/CR–7285, ''Nonradiological Health Consequences from Evacuation and Relocation,'' issued September 2021). To balance these risks, the NRC applies a graded approach to EP in which the requirements and criteria are based on the relative radiological risks and hazards of the facility, among other considerations. The most detailed level of planning is associated with the implementation of predetermined, prompt protective actions and is reserved for only the most severe events. For less severe events, the level of planning can be scaled commensurately.

The emergency planning zone (EPZ) is a planning tool for implementing predetermined, prompt protective actions. It simplifies decision-making, particularly when such decisions may be time-constrained or require coordination across a large area involving multiple jurisdictions. Currently, protective actions within the EPZ are initiated promptly at the declaration of a General Emergency (*i.e.,* the highest emergency classification level that indicates that events are occurring or have occurred at the facility with the potential for an offsite release) as a precaution. However, a precautionary approach is not the only strategy that can be used for implementing protective measures. Risk-informed strategies, which make use of the best available information in a robust, transparent, and repeatable process to arrive at a decision can also be used to respond to radiological emergencies. Risk-informed protection strategies are particularly useful to reduce or avoid the risk of stochastic effects from radiation or when there is ample time to make a decision based on the actual conditions associated with the emergency event.

Under 10 CFR 50.33(g), 50.47(c)(2), and 53.1109(g), the plume exposure pathway EPZ for a nuclear power reactor consists of an area about 10 miles (16 km) in radius and the ingestion pathway EPZ for such facilities consists of an area about 50 miles (80 km) in radius. These regulations also provide that the size of plume exposure pathway and ingestion pathway EPZs for gas-cooled nuclear reactors and for reactors with an authorized power level less than 250 MWt may be determined on a ''case-by-case basis.''

For small modular reactors, non-LWRs, and other non-power production or utilization facilities, the size of the EPZ can be determined on a case-by-case basis under 10 CFR 50.33(g)(2). Specifically, 10 CFR 50.33(g)(2)(i) provides two criteria for determining whether an EPZ is needed, and if so, the size of the EPZ. The first criterion, located in 10 CFR 50.33(g)(2)(i)(A), is that the plume exposure pathway EPZ is the area within which public dose, as defined in 10 CFR 20.1003, ''Definitions,'' is projected to exceed 1 rem (10 millisieverts (mSv)) TEDE over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology. The second criterion, located in 10 CFR 50.33(g)(2)(i)(B), is that the plume exposure pathway EPZ is the area in which predetermined, prompt protective measures are necessary. These criteria were added in the 2023 EP final rule and were based, in part, on the methodology described in NUREG–0396, ''Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants,'' dated December 1978. Similar provisions for a case-by-case EPZ determination are contained in 10 CFR 53.1109(g)(2).

The EPZ is one element of the emergency planning basis, which is operational in nature. The EPZ is not a design feature of the reactor or a part of the ''design bases'' as defined in 10 CFR 50.2 (*i.e.,* the EPZ is not a plant structure, system, or component). The purpose of the EPZ analysis required by 10 CFR 50.33(g)(2) is to arrive at a robust and resilient protection strategy for managing radiological emergencies. The EPZs are scalable in size and commensurate with the planning needs for the facility. However, the EPZ size does not change the requirements for emergency planning; it only sets bounds on the planning for a predetermined, prompt response. The capabilities within the emergency plan can support expanding the response beyond the EPZ during an actual emergency, should that prove necessary.

When an EPZ extends beyond the site boundary, the NRC requires additional findings and determinations on the adequacy of offsite plans to implement a prompt response. In such cases, the

NRC considers Federal Emergency Management Agency (FEMA) findings and determinations on the adequacy of the offsite planning in its overall reasonable assurance determination. FEMA maintains a voluntary offsite radiological emergency preparedness (REP) program to administer EP for the areas surrounding commercial nuclear power plants. The EP rule changes in this proposed rule would not impact the ability of State, local, and Tribal governments to receive support from FEMA or any other Federal agency regardless of whether the NRC requires reasonable assurance of the offsite plans. For current facilities without offsite EPZs (*e.g.,* non-power reactors, decommissioning power reactors, independent spent fuel storage installations), the NRC does not require findings and determinations of the adequacy of the offsite plans as the risks from radiation exposure are manageable under comprehensive emergency management plans and local emergency response. Emergency plans for these types of facilities provide reasonable assurance that adequate protective measures can and will be taken in coordination with offsite response organizations.

XXIV. Discussion—Revision of the Emergency Preparedness Regulations for Nuclear Power Reactors

A. Emergency Plan Licensing Flexibility

(i) Flexible EP Licensing Paths

The proposed rule would provide all applicants and licensees under 10 CFR parts 50, 52, and 53, including power reactor applicants and licensees, with the option to use the performance-based requirements in 10 CFR 50.160. Specifically, the proposed rule would remove the provision in the current rule limiting the applicability of 10 CFR 50.160 to only small modular reactors, non-LWRs, and non-power production or utilization facilities. This proposed change would reduce the need for exemptions to use the performance-based EP regulations. For example, a reactor would not be limited in power to 1000 MWt to meet the definition of ''small modular reactor'' as defined in 10 CFR 50.2 and utilize 10 CFR 50.160. In addition, the proposed rule would revise paragraph I.5 of appendix E to 10 CFR part 50 to provide for a scalable approach for power reactors that choose to comply with the planning standards of 10 CFR 50.47(b). The proposed changes would ensure applicants are not restricted in licensing options for EP and would provide the appropriate regulatory flexibility to support the various licensing pathways.

The planning standards in 10 CFR 50.47(b) and the requirements in appendix E to 10 CFR part 50 were originally developed for the hazards and emergency planning needs of large LWRs. Additionally, the prescriptive planning elements of appendix E to 10 CFR part 50 can be applied to non-power production or utilization facilities on a case-by-case basis. Basic emergency planning functions are similar across NRC licensed facilities, as the operational aspects of EP are well established in regulation and in practice across all hazards. There is no technology-specific language used in the planning standards for required EP functions that limit application to a particular technology. Therefore, the proposed rule would revise the section heading of 10 CFR 50.160 from ''Emergency preparedness for small modular reactors, non-light-water reactors, and non-power production or utilization facilities,'' to ''Performance-based emergency preparedness standards,'' to be applicable to all reactor types. In addition, the proposed rule would amend 10 CFR 50.33(g), 50.34(b)(6), 50.54(q)(2), 50.54(q)(3), 52.79(a)(21), 53.1109(g), and 53.1565(d)(3) to remove the distinction among applicants and licensees of small modular reactors, non-LWRs, and non-power production or utilization facilities in complying with 10 CFR 50.160. The proposed rule would not change the definition of ''small modular reactor'' in 10 CFR 50.2 and 53.020 because the definition would no longer have specific relevance to EP regulations.

The proposed rule would amend paragraph I.5 of appendix E to 10 CFR part 50 to determine the degree to which compliance with the requirements in certain sections of appendix E is necessary on a case-by-case basis for power reactors with a site-boundary EPZ or no EPZ. The proposed revision would reduce the need for exemptions and would provide applicants with the flexibility to propose the planning elements appropriate to their facility. For licensing efficiency, the NRC and specific applicants could achieve agreement on applicable planning elements in pre-application interactions. Alternatively, generic guidelines could be developed and endorsed by the NRC to support the rapid deployment of similar reactor types that wish to apply appendix E to 10 CFR part 50 in lieu of 10 CFR 50.160.

The proposed rule would add new 10 CFR 50.47(h) to allow a licensee to submit a license amendment to comply with the requirements of 10 CFR 50.160 in lieu of 10 CFR 50.47 and appendix E to 10 CFR part 50. Similarly, the proposed rule would add new 10 CFR 50.160(c)(4) to allow a licensee to submit a license amendment to comply with the requirements of appendix E to 10 CFR part 50 and, for nuclear power reactor licensees, the requirements of 10 CFR 50.47 in lieu of 10 CFR 50.160. The proposed rule would also add new 10 CFR 53.855(d) to provide provisions for complying with alternative EP requirements.

(ii) Preoperational Exercises

The NRC is proposing to remove specific time requirements and add flexibility in the performance of preoperational exercises. Prior to initial loading of fuel, or power operations, successful completion of a preoperational exercise is required to ensure that the licensee staff is ready to implement the emergency plan and that the emergency plan, as written, is acceptable. The proposed rule would amend paragraphs IV.F.2.a.(i) through (iii) of appendix E to 10 CFR part 50 and 10 CFR 50.160(c)(1) and (c)(2) by removing the requirement to demonstrate compliance within 2 years before issuance of an OL or the scheduled date of initial loading of fuel. Regulatory flexibility in the performance of this exercise may be desirable for applicants and holders of a COL that are co-located on, or adjacent to, an existing site and that may be able to subsume this demonstration requirement within the emergency plan exercise program that already exists, up to and including offsite exercise requirements. The specificity of the requirement to conduct the initial exercise within 2 years of certain milestones creates the potential to repeat the demonstration if schedules change. The proposed rule would ensure that the initial exercise need only be performed one time. The proposed rule would also provide flexibility to applicants and holders of a COL in the performance of preoperational exercises if they have preexisting licensed power reactors at the same site with similar onsite and offsite emergency plan elements in place. In such cases, the applicant or holder of a COL and the licensee may credit the same exercise as both the preoperational exercise required under proposed paragraphs IV.F.2.a.(i) and IV.F.2.a.(iii) and the onsite exercise required under paragraph IV.F.2.b of appendix E to 10 CFR part 50.

(iii) Alert and Notification System

The proposed rule would provide clarity for when backup alert and notification system (ANS) methods are

required. Traditional ANS strategies typically consist of a single primary method based upon fixed sirens and a single backup method using route-alerting strategies, but alternative methods are available. For example, the Integrated Public Alert & Warning System (IPAWS) is FEMA's national system for local alerting that includes parallel methods of providing authenticated emergency and life-saving information to the public typically through mobile phones using Wireless Emergency Alerts, to radio and television via the Emergency Alert System, and on the National Oceanic and Atmospheric Administration's Weather Radio among others. IPAWS typically provides multiple, simultaneous, primary methods of alerting the public implemented in parallel, and as such, does not require a designated backup. Because of technologies like IPAWS, the proposed rule would amend paragraph IV.D.3 of appendix E to 10 CFR part 50 to provide flexibility in meeting the requirements based upon the ANS chosen by the applicable State as approved in the ANS Design Report.

(iv) Use of Modern Terminology

Certain terminology used in the current regulations is no longer common or does not align with advances in technology. The NRC proposes to revise 10 CFR 50.160(b)(1)(iv)(A)(*2*) to provide clarity and to simplify the language for the requirement to implement the emergency plan in response to a security event. The NRC also proposes to revise paragraph IV.D.2 of appendix E to 10 CFR part 50 to replace ''local broadcast services'' with ''media sources.''

B. Emergency Planning Zone Certainty

The proposed rule would provide greater certainty and a streamlined approach to EPZ determinations for all applicants and licensees. The NRC is proposing to amend the requirements in 10 CFR 50.33(g), 50.47(c)(2), and 53.1109(g) to simplify EPZ determinations for new reactors and to ensure the plume exposure pathway EPZ is no larger than needed to implement predetermined, prompt protective measures. Specifically, the proposed rule would (1) establish the bounds of an EPZ to generally be about 2 to 10 miles (3.2 km to 16 km) in radius; (2) provide certainty for a site-boundary EPZ for facilities with an authorized power level less than 300 MWt; and (3) allow for case-by-case determinations for all facilities. The proposed rule would make conforming changes to 10 CFR 50.160(b)(3) in referring to the requirements in proposed 10 CFR 50.33(g)(1) and 53.1109(g)(1) to determine and describe the boundary and physical characteristics of the EPZ in the emergency plan.

The recommended 10-mile (16-km) plume exposure pathway EPZ is a generic planning distance for pressurized water reactor (PWR) and boiling water reactor (BWR) technologies based on the analyses in NUREG–0396. In the decades since, many studies have provided additional risk insights and analyses that demonstrate the conservatism in the NUREG–0396 analyses. These analyses include insights from the NRC's State-of-the-Art Reactor Consequence Analyses (SOARCA) regarding the magnitude and timing of severe accidents; insights from the NRC's Level 3 Probabilistic Risk Assessment (PRA) Project regarding the margin to quantitative health objectives, multi-unit events, and integrated plant risks; and specific studies to inform NRC's EP program including: (1) NUREG/CR–7160, ''Emergency Preparedness Significance Quantification Process: Proof of Concept,'' dated June 2013; (2) Task 1.5–1.6 Report to User Need Request NSIR–2017–002, ''Analyses Informing Emergency Planning Zone Size Determinations: Identification of Parameter Sensitivities,'' dated December 2019; (3) SAND2022–3706, ''Scoping Analysis of MACCS Modeling Improvements for the Study of Protective Action Recommendations, dated March 2022; and (4) SAND2025–08913, ''Dose Exceedance Distance Sensitivity Based on Parametric Uncertainty,'' dated July 2025. Combined, these analyses support the use of an EPZ that is generally no less than 2 miles (3.2 km) and no more than 10 miles (16 km) for implementing predetermined, prompt protective measures. Certain analyses were also based, in part, on conservative source terms for designs with an authorized power level less than 300 MWt, which suggest that there is a very low risk of exceeding acute doses offsite requiring a predetermined, prompt response. Additionally, numerous research reports from national laboratories, peer-reviewed published articles, and studies on small modular reactors, microreactors, and advanced reactor designs consistently demonstrate these designs would not require extensive plume exposure pathway EPZs. Combined, these analyses support the proposed changes to 10 CFR 50.33(g), 50.47(c)(2), and 53.1109(g) to reduce the conservatism in the current 10-mile (16-km) EPZ size and provide certainty for a smaller EPZ or a site-boundary EPZ without requiring extensive analyses on the part of the applicant or licensee.

The proposed rule would also simplify the case-by-case EPZ determination under 10 CFR 50.33(g)(1) and (g)(2) and 53.1109(g)(1) and (g)(2). The EPZ determination should be a simple evaluation of the consequences of a spectrum of accidents to inform protective action strategies. Tools like PRA are useful to help inform EPZ determinations and the risk insights can be used to produce a robust and resilient emergency plan to deal with the residual risk of the facility and to account for uncertainty and unknowns in the design and operation of the facility. While a risk-informed design can provide valuable information to develop a risk-informed EP program, including sizing the EPZ, the EP program is not part of the design and the EPZ determination is not an analysis to reiterate the safety case of the design, demonstrate compliance with the Licensing Modernization Project (LMP) process, or enforce design changes on an applicant or licensee to ensure that no accident will ever exceed 1 rem (10 mSv) at the EPZ boundary. Accordingly, the EPZ criteria for the case-by-case analysis are not design criteria or dose limits. The 1 rem (10 mSv) TEDE value in 10 CFR 50.33(g)(2)(i)(A) is a threshold dose quantity below which it may be demonstrated that no EPZ is needed to manage the radiological risks and hazards of the facility. The EPZ criteria does not require an applicant to demonstrate that doses cannot exceed 1 rem (10 mSv) TEDE over 96 hours beyond the EPZ boundary for all accidents. When doses can exceed 1 rem (10 mSv) TEDE, it is generally necessary to risk-inform the EPZ size by considering additional factors as specified in 10 CFR 50.33(g)(2)(i)(A) and by considering the need for predetermined, prompt protective measures as specified in 10 CFR 50.33(g)(2)(i)(B). The EPZ criteria in 10 CFR 53.1109(g)(2) are applied in the same way. For analysis purposes, the dose criteria is applied to a reference individual, as is done with other dose criteria (*e.g.,* 10 CFR 50.34(a)(1)(ii)(D)(*1*) and (*2*)) and with the Environmental Protection Agency (EPA) protective action guides (PAGs) (see EPA, ''PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents,'' issued in 2017). Therefore, the proposed rule would amend 10 CFR 50.33(g)(2)(i)(A) and 53.1109(g)(2)(i)(A) to remove the reference to public dose as defined in 10 CFR 20.1003 and to

apply the dose to a reference individual. The EPZ dose criteria is not a limit, so the term ''public dose'' would be removed to avoid confusion.

When the radiological consequences can exceed 1 rem (10 mSv), dose criteria should not be strictly imposed at an EPZ boundary. There is significant inherent variability in any consequence analysis. For dose quantities less than 25 rem (250 mSv), this inherent variability can be on the order of kilometers. This creates a significant challenge for defining an EPZ boundary based on low dose, especially for EPZs less than 2 miles (3.2 km) in radius as the inherent variability in the consequence analysis could be as large or larger than the defined EPZ. In developing the 2023 EP final rule, the NRC extensively reviewed available studies and performed additional sensitivity analyses to understand the inherent variability of consequence analyses that inform the EPZ determination. The NRC is issuing, for public comment along with this proposed rule, DG–1430, ''Performance-Based Emergency Preparedness,'' which would be Revision 1 to the existing RG 1.242, with an updated methodology for a case-by-case EPZ determination. The revised guidance would provide applicants with clarification on the spectrum of accidents, including the consideration of security-related events and severe seismic events; additional guidance on risk-informing dose-distance evaluations to account for uncertainty and inherent variability in the calculation; and additional guidance for assessing the need for predetermined, prompt protective measures. These guidance updates, based on NRC analyses of parameter uncertainty and NRC staff experience with the review of EPZ methodologies, would provide simple methods to make better risk-informed EPZ determinations.

The proposed rule would reinforce the purpose of the EPZ as a planning tool and encourage the use of risk-informed protection strategies for situations that do not rely on EPZs. The proposed rule would amend 10 CFR 50.47(b)(10) by removing the word ''EPZ'' wherever it appears to ensure protection strategies are developed for the potential pathways of exposure and are not limited to a predefined zone. The proposed rule would also amend 10 CFR 50.33(g)(1), 50.47(c)(2), and 53.1109(g)(1) to state that emergency plans would need to describe such actions as are appropriate to avoid or reduce dose within and beyond the EPZ or site boundary. The EPZ concept is not limited to protective actions for the public, but applies to anyone within the EPZ, including emergency workers and onsite personnel. The proposed rule would ensure that the planning necessary to implement predetermined, prompt protective measures would be focused within the area most at-risk surrounding a nuclear power reactor, including areas within the site boundary. Consistent with the historical planning basis for the EPZ, this is an area where there is potential for acute doses or early health effects from the accidental release of radioactive material in addition to the risk of stochastic effects from radiation exposure. An EPZ may also be defined for purposes of managing the risk of stochastic effects, but the proposed rule would encourage the use of risk-informed protection strategies to make informed protective action decisions for the management of such risks, rather than rely on a predetermined, prompt response that could do more harm than benefit. The NRC proposes to clarify the requirements for use of evacuation time estimates (ETE) to inform protective action recommendations and protective action strategies to distinguish between the level of planning required for predetermined, prompt protective actions, as opposed to taking action as conditions warrant. Specifically, the proposed rule would amend the requirements in paragraphs IV.3 and IV.4 in appendix E to 10 CFR part 50 by adding the phrase, ''predetermined, prompt'' to clarify which protective action recommendations and strategies within the EPZ are informed by the ETE.

Consistent with the rationale for revision of the EPZ criteria, the proposed rule would amend 10 CFR 50.33(g)(1) and 53.1109(g)(1) by eliminating the requirement to submit response plans of State, local, and participating Tribal governmental entities. The proposed change to 10 CFR 50.33(g)(1) and 53.1109(g)(1) would require applicants to coordinate with offsite organizations with responsibilities for coping with emergencies, including State, local, and Tribal governmental agencies, as applicable. This coordination would ensure that response organizations are aware of potential radiological consequences of the facility and have been consulted on appropriate protective measures, including the extent of any EPZ. The proposed rule would require applicants to include information that describes the extent of interaction with these agencies. The NRC would not require FEMA findings and determinations on the extent of interaction between the applicant and offsite response organizations because this proposed change is not part of the FEMA review of offsite plans under FEMA's regulations in 44 CFR part 350, ''Review and Approval of State and Local Radiological Emergency Plans and Preparedness.''

The proposed rule changes to the plume exposure pathway EPZ would be consistent with Federal guidance and international standards. Section 2.2.4 of the EPA PAG Manual discusses the relation between PAGs and EPZs and states, ''The pre-designated areas for immediate protective action may be reserved for use only in the most severe incidents and in cases when the facility operator cannot provide a quick estimate of projected dose based on actual releases. For lesser incidents, or if the facility operator is able to provide prompt off-site dose projections, the area for immediate protective action may be specified at the time of the incident instead of using a pre-designated area.'' Similarly, the International Atomic Energy Agency (IAEA) Safety Standards in General Safety Requirements (GSR) No. 7, ''Preparedness and Response for a Nuclear or Radiological Emergency,'' specify use of a precautionary action zone (PAZ) for taking urgent protective actions before any significant release occurs on the basis of conditions at the facility in order to avoid or to minimize severe deterministic effects. The recommended size for the PAZ within IAEA standards is 1.9 to 3.1 miles (3 to 5 km) for reactors greater than 1000 MWt and 0.3 to 1.9 miles (0.5 to 3 km) for reactors 100 to 1000 MWt. The proposed change to 10 CFR 50.33(g), 50.47(c)(2), and 53.1109(g) would establish EPZs that remain aligned with EPA guidelines and international standards to meet the purpose of the EPZ as a planning tool for implementation of predetermined, prompt protective actions. Consistent with the PAG Manual, the zones for response could also be specified at the time of the emergency, rather than predesignated.

The proposed rule would add new 10 CFR 50.47(g), 50.160(c)(3), and 53.855(c) to allow a licensee to submit a license amendment to change its plume exposure pathway EPZ. The proposed rule would require the change to be agreed on by the applicable State, local, and Tribal governmental authorities before submission to the NRC. The FEMA REP Program Manual provides a process for offsite response organizations to follow for changes to the EPZ boundary in accordance with FEMA regulations in 44 CFR 350.14.

Consistent with the 2023 EP final rule, the proposed rule would remove

the requirement to define an ingestion pathway EPZ. The proposed rule would remove reference to the ingestion pathway EPZ in 10 CFR 50.33(g)(1) and 53.1109(g)(1), 50.47(b)(10), 50.47(c)(2), and paragraph IV.F.2.a.(i) and footnote 1 of appendix E to 10 CFR part 50. In lieu of a defined zone, the proposed rule would amend 10 CFR 50.33(g)(1), 50.47(c)(2), and 53.1109(g)(1) to require emergency plans to describe such actions as are appropriate to protect the ingestion pathway. The capabilities described in the emergency plan would need to address major exposure pathways associated with the ingestion of contaminated food and water. The duration of any exposure to contaminated food or water could range from weeks to months and represents a long-term response need. The current 50-mile ingestion pathway EPZ is based on the planning assumptions in NUREG–0396 and does not reflect technology advancements and modern response capabilities for interdicting to prevent ingestion of contaminated food and water, such as the use of Geographic Information System (GIS) tools and unmanned aerial vehicles for monitoring.

Currently, paragraph IV.E.8.b of appendix E to 10 CFR part 50 requires the licensee's emergency operation facility (EOF) to be located between 10 miles and 25 miles of the nuclear power reactor site(s), or a primary facility located less than 10 miles from the nuclear power reactor site(s) and a backup facility located between 10 miles and 25 miles of the nuclear power reactor site. The 10 miles is based on the current 10-mile EPZ requirement and does not account for scalable EPZs under current and proposed 10 CFR 50.33(g) and 53.1109(g). The proposed rule would amend paragraph IV.E.8.b of appendix E to 10 CFR part 50 to specify the location of the emergency operations facility in relation to the EPZ boundary. The proposed rule would not change the requirement for a licensee to request Commission approval to locate an EOF more than 25 miles from a nuclear power reactor site.

C. Eliminating Redundant Requirements

(i) Preliminary Emergency Plans

The NRC proposes to eliminate the requirements for applicants to submit preliminary plans for coping with emergencies because these submittals do not significantly enhance licensing efficiency. Many details of the emergency plan depend on conditions of the as-built facility and site-specific parameters, including agreements with offsite emergency response organizations. These details are often not available early in the licensing process. The NRC reviewed the content of CPs and ESPs and found that the level of information contained in the associated preliminary emergency plans or major features of emergency plans was very limited, often nothing more than a general structure and placeholder for more detailed information. The proposed rule would eliminate 10 CFR 50.34(a)(10) and 53.1309(a)(4) that require applicants to submit the preliminary plans for coping with emergencies as part of the preliminary safety analysis report for a CP application. The proposed change would reduce the burden on applicants to provide preliminary plans of limited benefit in licensing. The proposed rule would not change 10 CFR 52.17(b)(2)(i) because applicants may choose not to submit major features of the emergency plan in the ESP site safety analysis report if such details are not available. Instead, the NRC encourages applicants to engage the NRC in pre-application activities in preparation for submission of emergency plans as part of the FSAR or in preparation for submission of major features of the emergency plan as part of the ESP site safety analysis report. As a conforming change, the proposed rule would amend paragraphs I.1 and I.2 of appendix E to 10 CFR part 50 to remove the requirements to submit emergency plan information in the preliminary safety analysis report and would eliminate section II, ''The Preliminary Safety Analysis Report,'' of appendix E to 10 CFR part 50. Many of the elements in section II of appendix E to 10 CFR part 50 are redundant to other criteria or would be considered as part of the development of emergency plans in coordination with offsite response organizations under proposed 10 CFR 50.33(g) and 53.1109(g).

(ii) Independent Program Element Reviews

The proposed rule would amend 10 CFR 50.54(t) and 53.1565(d)(3)(vii) to eliminate the requirement for licensees to ensure that all program elements are reviewed by people who have no direct responsibility for implementation of the EP program. Since the implementation of this regulation, the NRC's oversight program has evolved such that this regulation is redundant to the NRC Reactor Oversight Program and adds no additional oversight benefit to the EP program. However, the proposed rule would retain the requirement in 10 CFR 50.54(t)(2) and 53.1565(d)(3)(vii)(B) for an annual review of the interface between licensee and offsite response organizations to ensure the adequacy of the interface with State and local governments.

(iii) Evacuation Time Estimate Updates

The NRC is proposing to eliminate requirements related to updates of the ETE that have limited utility in ensuring effective implementation of protective action recommendations. The proposed rule would eliminate the requirement to estimate EPZ permanent resident population changes during the years between decennial censuses and to update the ETE based on the criteria of paragraphs IV.5 and IV.6 of appendix E to 10 CFR part 50. This proposed change is based, in part, on an analysis of the limited number of licensees over the past decennial periods that met the criteria to perform the ETE update and an analysis of the impact of updated ETEs on protective action strategies, following the guidance in Supplement 3, ''Guidance for Protective Action Strategies,'' to NUREG–0654/FEMA–REP–1. Decennial ETE updates include sensitivity analyses that provide the expected change to the ETE as the permanent resident population changes. In addition, section 5.4.1, ''Extreme Conditions,'' of NUREG/CR–7002, ''Criteria for Development of Evacuation Time Estimate Studies,'' Revision 1, contains guidance for updating the ETE if conditions within the EPZ change significantly. The NRC has determined that the sensitivity analyses and the ETE guidance would ensure that ETEs remain adequate for use in protective action recommendations and in developing offsite protective action strategies in the years between decennial censuses. For similar reasons, a review of changes in the EPZ population under paragraph IV.7 of appendix E to 10 CFR part 50 would not be required for parts 52 and 53 licensees. As such, the proposed rule would eliminate paragraphs IV.5, IV.6, and IV.7 of appendix E to 10 CFR part 50.

(iv) Periodic Communication Tests With NRC

The proposed rule would eliminate the requirement to test each NRC Regional Office Operations Center under paragraph IV.E.9.d of appendix E to 10 CFR part 50. A monthly test between each licensee and the appropriate Regional Office Operations Center would not be required because the regional Operations Centers are not typically staffed by the NRC unless it is warranted by the escalation of an emergency event. Monthly testing of communication between the licensee's primary response location and the NRC

Headquarters Operations Center would be sufficient.

D. Risk-Informing the Emergency Plan Change Process

The NRC proposes to revise and risk-inform the emergency plan change process in 10 CFR 50.54(q) and 53.1565(d)(3) regarding which proposed changes would need to receive prior approval from the NRC. Licensees would be required to evaluate a reduction in effectiveness for only changes to the emergency plan involving risk-significant planning standards. Under the proposed rule, the licensee would analyze changes related to the other planning standards and applicable requirements in appendix E to 10 CFR part 50, or 10 CFR 50.160 only to ensure they continue to meet the regulatory requirements.

The proposed rule would add new 10 CFR 50.54(q)(1)(v) and 53.1565(d)(3)(i)(E) to define risk-significant planning standards as those providing the most essential functions of EP to ensure adequate protective measures are taken to protect the public in the event of a radiological emergency, including classification, notification, assessment, and protective actions. The proposed definition would also include the standards for providing adequate staffing and facilities as risk-significant for the purposes of evaluating changes to the emergency plan as these standards have a direct impact on the ability to effectively implement the risk-significant planning standards. The proposed definition would apply to the standards of 10 CFR 50.160 or 50.47 and applicable requirements in appendix E to 10 CFR part 50.

Consistent with the proposed changes to allow licensees the option to comply with either the requirements in appendix E to 10 CFR part 50 and, for nuclear power reactor licensees, the planning standards of 10 CFR 50.47(b), or the requirements in 10 CFR 50.160, the proposed rule would combine 10 CFR 50.54(q)(2)(i) and (ii) into a single paragraph (q)(2) and would revise (q)(3)(i) and (ii) for the evaluation of changes to the emergency plan. The proposed rule would similarly combine 10 CFR 53.1595(d)(3)(ii)(A) and (B) and revise 10 CFR 53.1595(d)(3)(iii).

XXV. Background—Optional Submittal of Operational Programs

For several years, stakeholders have expressed growing interest in the rapid, widespread deployment of reactors of a standard design (*e.g.,* July 31, 2024, letter from NEI to the NRC, ''Regulation of Rapid High-Volume Deployable Reactors in Remote Applications (RHDRA) and Other Advanced Reactors,'' followed by a July 14, 2025, supplement to that letter). At the same time, the NRC staff developed strategies to provide for the predictable and efficient licensing and regulation of microreactors that would use standard designs. The staff sought Commission approval for some of these proposals in SECY–24–0008, ''Micro-Reactor Licensing and Deployment Considerations: Fuel Loading and Operational Testing at a Factory,'' dated January 24, 2024, and SECY–25–0052, ''Nth-of-a-Kind Microreactor Licensing and Deployment Consideration,'' dated June 18, 2025. The latter paper recommended a change in Commission policy to allow the NRC to review, approve, and afford finality to, as appropriate, standard operational programs submitted to the NRC in connection with a design certification or ML application. These agency actions would support the rapid licensing and high-volume deployment of new microreactors and other low consequence reactors and the direction in E.O. 14300 to adopt shorter timeframes tailored to particular licensing pathways.

The Commission approved the staff's recommendations in SRM–SECY–0008, ''Staff Requirements—SECY–24–0008—Micro-Reactor Licensing and Deployment Considerations: Fuel Loading and Operational Testing at a Factory,'' dated June 17, 2025, and SRM–SECY–25–0052, ''Staff Requirements—SECY–25–0052—Nth-of-a-Kind Microreactor Licensing and Deployment Consideration,'' dated November 13, 2025. The NRC included many of these proposals, including the proposal to allow an ML applicant to include standard operational program information in its application, in the ''Licensing Requirements for Microreactors and Other Reactors With Comparable Risk Profiles'' proposed rule (91 FR 23628; May 1, 2026). The NRC is proposing conforming changes to 10 CFR parts 52 and 53 in this rulemaking to allow microreactor and other developers the option to submit essentially complete programmatic controls, operational programs, or operational requirements with an ML application under 10 CFR part 52 or 53.

XXVI. Discussion—Optional Submittal of Operational Programs

The NRC proposes to modify 10 CFR 52.158, ''Contents of application; additional technical information,'' to allow ML applicants the option to submit essentially complete operational program information with their applications and 10 CFR 52.171, ''Finality of manufacturing license; information requests,'' to provide finality to such program information that is reviewed and approved by the NRC as part of the ML review. As stated in proposed 10 CFR 52.158(c), this optional program information would be submitted ''to satisfy requirements for license applications that may reference a manufacturing license,'' and this program information submitted with the ML application would be assessed against the pertinent requirements for these other license applications.

The appropriate change control mechanism for changes to this information by an ML holder would be established through the issuance of the ML. Under current regulations, the change control requirements in 10 CFR 52.171(b)(1) for changes sought by the holder of an ML apply to design information, not operational program information. Elsewhere in this proposed rule, the NRC proposes to modify 10 CFR 52.171(b)(1), but as modified, the change control provision would apply to information in the FSAR submitted under 10 CFR 52.157 and not to non-FSAR information submitted under 10 CFR 52.158. Moreover, the change control process in proposed 10 CFR 52.171(b)(1) relies on the change control criteria in 10 CFR 50.59, whereas some operational programs are subject to other change control provisions (*e.g.,* 10 CFR 50.54(a), (p), and (q)). Therefore, the NRC would establish the appropriate change control process for the optionally submitted operational program information as part of issuing the ML.

An applicant or licensee who references or uses a nuclear power reactor manufactured under an ML who wishes to depart from or omit (in whole or part) the optional operational program information approved in the ML would not be subject to the process in 10 CFR 52.171(b)(2) because this optional operational program information would not constitute design characteristics, site parameters, terms and conditions, or approved design information subject to 10 CFR 52.171(b)(2). Departures from, or omissions of, the optional operational program information approved in the ML would be reviewed in accordance with the applicable operational program requirements for the license being applied for (*e.g.,* OL or COL).

This proposed change would enhance regulatory certainty and expedite review timelines for CP/OL and COL applicants wishing to reference operational programs approved with an ML but would still allow flexibility for these applicants to submit their own

programs. There would be no additional obligations imposed on license applicants as this would be optional information for a developer to provide and optional for a CP/OL or COL applicant to reference. Additionally, the hearing opportunity provided as part of the ML review process would allow for public engagement on the program information included in the ML application. For licensing efficiency, agreement on operational programs being considered to be essentially complete could be achieved between the NRC and applicants through pre-application interactions.

The NRC is proposing a similar change to 10 CFR part 53 to allow for the optional submittal with the ML application of operational program information not material to the design. The NRC is proposing to modify 10 CFR 53.1282, ''Contents of applications for manufacturing licenses; other application content,'' to allow for the submittal of such program information and 10 CFR 53.1288, ''Finality of manufacturing licenses,'' to provide finality to the information that would be reviewed and approved by the NRC.

XXVII. Background—Early Site Permit for Nuclear Power Plants

Section 5(i) of E.O. 14300 directs the NRC to ''[r]econsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.'' In response, the NRC is proposing to amend its regulations to remove the ESP fixed term requirement.

The NRC issued 10 CFR part 52 on April 18, 1989 (54 FR 15372), to provide procedures for the early resolution of safety and environmental issues in commercial power reactor licensing proceedings and to provide for the standardization of the design of nuclear power plants. To further those ends, the Commission issued 10 CFR part 52 to add alternative licensing processes for early site permits (ESP), standard design certifications, and COLs. These alternatives in 10 CFR part 52 were in addition to the two-step licensing process that already existed in 10 CFR part 50. The processes in 10 CFR part 52 allow for resolving safety and environmental issues early in licensing proceedings, which would result in regulatory stability, and were intended to enhance the safety and reliability of nuclear power plants through standardization. Part 53 of 10 CFR also provides for ESPs.

In particular, ESPs provide a process for applicants to resolve the majority of site-specific safety and environmental issues prior to applying for a CP or COL. Subsequent to promulgating 10 CFR part 52, the NRC has issued six ESPs,—the Exelon Generation Company, LLC ESP Site, ESP–001, March 15, 2007; System Energy Resources, Inc., Grand Gulf ESP Site, ESP–002, April 5, 2007; Dominion Nuclear North Anna, LLC, North Anna ESP Site, ESP–003, November 27, 2007; Southern Nuclear Operating Company Vogtle Electric Generating Plant ESP Site, ESP–004, August 26, 2009; PSEG Power, LLC and PSEG Nuclear, LLC PSEG Site Early Site Permit, ESP–005, May 5, 2016; and Tennessee Valley Authority, Clinch River Nuclear Site Early Site Permit, ESP–006, December 19, 2019.

XXVIII. Discussion—Early Site Permit for Nuclear Power Plants

Under the current regulations in 10 CFR 52.26, ''Duration of permit,'' the NRC may issue an ESP with a term no longer than 20 years. Upon the elapse of 20 years, the ESP expires, but an ESP holder has the option to renew it for an additional term under current 10 CFR 52.29, ''Application for amendment to update an early site permit.'' The term for an ESP is similarly limited in 10 CFR 53.1164, ''Duration of permit.''

This proposed rule would remove the requirement in 10 CFR 52.26 and 53.1164 for an ESP to include a fixed term. Because each ESP would be issued without a fixed term, renewal would no longer be needed. Nonetheless, the revised regulations in 10 CFR 52.29 would provide an option by which an ESP holder may choose to update its ESP, which could maintain the preclusive effect of the ESP if the ESP is referenced in a COL or CP application. The proposed rule would similarly revise 10 CFR 53.1173, ''Application for renewal.'' The requirements specific to renewal at 10 CFR 52.33, ''Duration of renewal,'' and 10 CFR 53.1179, ''Duration of renewal,'' would be removed and reserved.

As noted in the 1989 10 CFR part 52 final rule, the ESP provides for early resolution of site-related issues, making possible the ''banking'' of the site, to enable more efficient licensing of a future nuclear power plant. The current rule mandates renewal of the ESP at a set point in time, not to exceed 20 years after issuance, and therefore requires the holder of the ESP to undertake updating the ESP to retain the benefits of issue finality. However, there are a number of factors that may influence the time that elapses between NRC's issuance of an ESP and a determination by the ESP holder to reference the ESP in a CP or COL application. Indeed, two of the issued ESPs are nearing 20 years since issuance without having been referenced in a CP or COL application. Therefore, this maximum 20-year duration of an ESP and the associated renewal requirement may artificially constrain the ESP holder's development planning because the renewal-requirement lacks a direct linkage to either a change in the ESP identified by the holder or the holder's plans to reference the ESP in a CP or COL application.

By removing the fixed term duration and providing a process for the permit holder to update the ESP through an amendment, the proposed rule would provide permit holders with flexibility to retain the site as ''banked,'' rather than referencing the ESP in a CP or COL application in a shorter time frame, and determine when or if the ESP will be updated. Removing the fixed term, however, would necessitate a change to the finality provisions in 10 CFR 52.39, ''Finality of early site permit determinations,'' to provide clarity regarding the limited duration of finality for site-specific characteristics of the initial ESP application and to account for stale environmental evaluations. Accordingly, the proposed rule would establish a 20-year timeframe for information in the ESP to retain finality, which would account for the limited time for which site data remains valid and the potential for environmental evaluations to become stale. The proposed rule would similarly revise 10 CFR 53.1188, ''Finality of early site permit determinations.''

The proposed 20-year timeframe would provide a boundary for both preparing a CP or COL application that references an ESP and NRC review, to avoid the level of uncertainty that would exist with providing analyses without a fixed term. However, ESP holders would have the option to update the information in the ESP to refresh the site data and environmental evaluations and thereby extend the 20-year timeframe at their discretion. Thus, when developing an ESP application, applicants for future ESPs should consider the 20-year expected duration for potentially time sensitive information, such as seismic, meteorological, hydrologic, and geologic characteristics; the presence of nearby facilities such as industrial, military, or transportation; the population profile; and environmental data and evaluations.

Under this proposed rule, the ESP holder may choose to update the ESP by submitting an amendment to update the potentially time sensitive information, which would provide an additional 20 years of finality for the updated safety

and environmental information if the NRC grants the amendment. Alternatively, an ESP holder could forgo finality and address those issues directly in a CP or COL application that references the ESP. The request for amendment of the ESP could be made by the ESP holder at any time. Unlike the current regulatory framework, where information must be updated prior to expiration of the ESP at year 20 through renewal to maintain issue resolution, the proposed changes would enable the ESP holder to retain the ESP for as long as desired and identify needed updates only when and if the holder determines the update would be advantageous to support a future CP or COL application. The proposed rule would allow the ESP holder to submit an amendment to update the time-sensitive information and request an extension for an already extended permit, providing flexibility for the ESP holder to update the ESP at such time and as many times as needed. To support the removal of a fixed term, a provision would be added to enable the ESP holder to request termination of an ESP at any time, with consideration for the status of any required redress for authorized activities. The changes would enhance flexibility for the ESP holder and reduce the effort associated with ESP renewal at year 20. NRC resources, likewise, would not be expended for review of ESP renewal applications. To be sure, some portions of an ESP, such as design parameters specified in the permit, are not time-sensitive and would continue in effect unless the ESP holder seeks to amend them or an applicant for a CP or COL referencing the ESP proposes to change them.

This proposed rule would remove and reserve paragraph (c) of 10 CFR 2.109, ''Effect of timely renewal application,'' which provides for timely renewal of the ESP.

This proposed rule would revise 10 CFR 52.15, ''Filing of applications,'' to remove the reference to ''renewal'' and replace it with ''amendment,'' reflecting that the permit would be issued with no fixed term and would not expire.

This proposed rule would revise 10 CFR 52.18, ''Standards for review of applications,'' to clarify its applicability to the initial issuance of the ESP. This proposed rule would revise 10 CFR 52.25, ''Extent of activities permitted,'' to remove the reference to the duration of the permit, reflecting that an ESP would no longer have a fixed term. The requirement for an ESP to remain in effect for site redress by the ESP holder if any activities authorized by 10 CFR 52.24(c) are performed would be unchanged. The proposed rule would similarly revise 10 CFR 53.1161, ''Extent of activities permitted.''

This proposed rule would revise 10 CFR 52.26(a) to remove the current duration, identifying that the permit would be issued with no fixed duration. The proposed rule would similarly revise 10 CFR 53.1164. Removal of the expiration date from the ESP would enable the permit holder to retain the site as banked until such time as either the permit is subsumed into another application or a decision is made to terminate the ESP. Because some site-specific characteristics are potentially time dependent, 10 CFR 52.39 and 53.1188 would limit finality for safety issues to 20 years from issuance of the ESP or an amendment to update the information for those items. Finality for environmental issues would also be limited to 20 years from issuance of the ESP or an amendment. Because the ESP would be issued with no fixed term, this proposed rule would revise 10 CFR 52.35, ''Use of site for other purposes,'' to provide a provision for the permit holder to request termination and to ensure the ESP holder identifies site redress activities to the Commission as part of the termination request. The ESP would not be terminated until site redress activities have been performed in accordance with 10 CFR 52.25. Termination of the ESP would not preclude the same or another applicant from submitting another application for an ESP or another license for the same site at a future time. The proposed rule would similarly revise 10 CFR 53.1182, ''Use of site for other purposes.''

This proposed rule would rename 10 CFR 52.29 and 53.1173 to, ''Application for amendment to update an early site permit,'' and revise these sections to provide the requirements for submitting an amendment. Following NRC review and completion of the hearing process, issuance of the amended ESP would extend finality for future use of the ESP for reference in a CP or COL application. The specific information limited to a 20-year duration for finality would be specified in 10 CFR 52.39 and 53.1188.

This proposed rule would rename 10 CFR 52.31, ''Criteria for renewal,'' as ''Issuance of amendment to update an early site permit,'' and revise it to include specific provisions for the Commission's issuance of an amended ESP. An application for amendment would be reviewed against similar criteria to that previously identified for renewal, which reflect the AEA, the Commission's regulations, and orders applicable and in effect at the time the ESP was originally issued. New requirements to be imposed during the amendment would be limited to those necessary for adequate protection to public health and safety or common defense and security. Additionally, for the purpose of site characteristic data and environmental data and evaluations which may be time dependent, the proposed rule would limit finality for those issues to 20 years while providing flexibility for the ESP holder to update that information through an amendment at any time. Therefore, the NRC's review of those potentially time-dependent characteristics would encompass the 20-year timeframe that aligns with the finality that would be afforded to that information. The proposed rule would similarly revise 10 CFR 53.1176, ''Criteria for renewal,'' and rename it as, ''Issuance of amendment to update an early site permit.''

This proposed rule would revise 10 CFR 52.39 to remove reference to a renewed ESP and replace it with an amended ESP. The site characteristic data on which an ESP is based, however, is valid for only a limited duration. Accordingly, the finality provisions in 10 CFR 52.39 would be revised to reflect that an ESP does not resolve siting issues in 10 CFR part 100, ''Reactor Site Criteria,'' specifically including site characteristics in the ESP, in a proceeding on a referencing application submitted more than 20 years after the date of issuance of the ESP or the date of an update to the ESP in which a matter has been resolved, whichever is later. This revised provision would not affect the finality of the source term included in the ESP. The duration limitation on finality of safety issues would be updated by revising 10 CFR 52.39(c)(1)(v) and finality of environmental issues would be updated by revising 10 CFR 52.39(c)(1)(vi). The proposed rule would similarly revise 10 CFR 53.1188.

The new provisions in 10 CFR 52.29 would provide for amendments to update ESPs in paragraph (e) of 10 CFR 52.39. The proposed rule would similarly revise 10 CFR 53.1188(e) to add 10 CFR 53.1173 as a requirement.

This proposed rule would amend 10 CFR 52.79 by redesignating paragraphs (b)(3) through (5) as paragraphs (b)(4) through (6) and revising paragraph (3) to add a requirement for a referencing COL application to confirm whether the potentially time-dependent site characteristics were updated in the ESP within the 20 years prior to filing the COL application and thus resolved under 10 CFR 52.39. If not, the COL applicant would need to evaluate and update that information in the FSAR. The information to be evaluated would be that information in the site safety analysis report required by paragraphs

10 CFR 52.17(a)(1)(vi) through (ix), which includes seismic, meteorological, hydrologic, and geologic characteristics; the presence of nearby facilities such as industrial, military, or transportation; and the population profile. The safety assessment based on these characteristics would also require evaluation and update, except that the referencing COL application would not need to update the postulated source term stated in the ESP if it fell within the source term derived from the design. If the postulated source term stated in the ESP did not fall within the source term derived from the design, then the referencing application would need to propose a variance from the ESP in accordance with 10 CFR 52.39 and 10 CFR 52.93. The proposed rule would similarly revise 10 CFR 53.1416.

This provision parallels the requirement in 10 CFR 52.39 and 53.1188 that specifies the 20-year limitation for finality on this type of potentially time-dependent information and recognizes that the holder of an ESP may choose not to update the ESP to retain finality once the ESP is 20 years past issuance. Together, the proposed revised provisions of 10 CFR 52.39 and 52.79, as well as 10 CFR 53.1188 and 53.1416, would provide flexibility for an ESP holder to determine when and what information to update while retaining the ESP for reference until such time as the holder chooses to terminate, and for a referencing COL applicant to have clarity regarding which aspects of the ESP would need to be evaluated and updated in the FSAR submitted as part of the application.

XXIX. Background—Manufacturing License Term Extension

Section 5(i) of E.O. 14300 directs the NRC to ''[r]econsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.'' In response, the NRC is proposing to amend its regulations to extend the term for initial issuance and the renewal of an ML to enhance the NRC's regulatory effectiveness and efficiency in implementing its licensing and approval processes. This change would align the term of MLs with the current term of design certifications.

On August 28, 2007, the NRC revised the provisions applicable to the licensing and approval processes for nuclear power plants with the final rule, ''Licenses, Certifications, and Approvals for Nuclear Power Plants'' (72 FR 49352). In that final rule, a new subpart F, ''Manufacturing Licenses,'' of 10 CFR part 52 replaced former appendix M of 10 CFR parts 50 and 52 that previously governed MLs. Under subpart F, an ML would be issued upon the submission of an acceptable final reactor design, equivalent to that required for a design certification under 10 CFR part 52, and certain information on the manufacturing process. The term for an ML was set to be for not less than 5, nor more than 15 years from the date of issuance, and was established to be consistent with the maximum term for a standard design certification in 2007. The Commission's stated intent was ''to encourage the use of a manufacturing license for the manufacture of more than one nuclear power reactor.'' However, no ML has been issued under subpart F of 10 CFR part 52.

In the July 2, 2025, direct final rule, ''Revising the Duration of Design Certifications'' (90 FR 28869), the NRC replaced the 15-year duration for design certifications with a 40-year duration period, both for certifications currently in effect and generically for future certifications, including renewals. As explained in that direct final rule, extending the term of design certifications reduces unnecessary regulatory burden on applicants and saves NRC resources without any reduction in safety or security.

XXX. Discussion—Manufacturing License Term Extension

The proposed amendments to the regulations in 10 CFR 52.173, ''Duration of manufacturing license,'' and 52.181, ''Duration of renewal,'' would change the duration of an ML to a maximum of 40 years and the duration of the renewed ML to a maximum of 40 years. The minimum terms of initial and renewed MLs would remain at 5 years. Amending the regulations to extend the term of an ML would make the duration of the ML consistent with the current durations of design certifications. The current landscape for nuclear power reactors designs, which encompasses potential microreactors and small modular reactors in addition to traditional large LWRs, may significantly benefit from the regulatory stability afforded by a longer ML term. This proposed change would allow ML holders to significantly decrease the burden associated with license renewal as the frequency of renewals would decrease. No other impact on licensees or other stakeholders is expected.

The NRC proposes to align the maximum term for an ML with the maximum term for a design certification because of the similarities between the scope of the two approvals. Most of the required information for an ML pertains to the same final design information required for a design certification. While part of an ML application pertains to organizational and QA information on manufacturing activities, this information is similar in kind to the organizational and QA information required for reactor COLs, which are also subject to a 40-year license term. Finally, consistent with the explanation provided by the NRC when it extended the term of a design certification to 40 years, the proposed extension to the term of MLs would not lead to any reduction in safety or security. If a safety or security issue is discovered during the term of an ML, the issue finality provisions in 10 CFR 52.171 allow the NRC to impose requirements to address the issue, as well as allow the holder of an ML or the applicant or licensee who references or uses a nuclear power reactor manufactured under an ML to seek a change to address the issue.

XXXI. Background—Nuclear Power Plant License Renewal

Section 5(i) of E.O. 14300 directs the NRC to ''[r]econsider the regulations governing the time period for which a renewed license remains effective, and extend that period as appropriate based on available technological and safety data.'' Also, as set forth in section 2 of the E.O., it is the policy of the United States to facilitate appropriate operational extensions of the current nuclear fleet. In response, the NRC is proposing to make several amendments to its nuclear power reactor license renewal regulations.

The NRC first issued the license renewal rule (10 CFR part 54) on December 13, 1991 (56 FR 64943) and later revised it on May 8, 1995 (60 FR 22461). The rule establishes the procedures, criteria, and standards governing the renewal of nuclear power plant OLs. It also references the environmental protection requirements in 10 CFR part 51 for the evaluation of the environmental effects of the extended plant operation.

Since publishing the 1995 rule, the NRC has issued renewed licenses for nearly all currently operating plants, extending their operation from 40 to 60 years. The NRC has also issued second, subsequent renewed licenses for several plants, allowing them to operate for up to 80 years. Based on the experience gained through these renewals, the NRC has identified several opportunities to revise the regulations to make the process more flexible, efficient, and better able to support operational extensions.

XXXII. Discussion—Nuclear Power Plant License Renewal

This rulemaking proposes revising requirements in the following areas:

A. Extension of the Renewal Time Period

When the NRC issued the 1991 license renewal rule, it noted that the 40-year limit on licenses in section 103 of the AEA was not based on safety or security reasons; rather, it ''was adopted for antitrust and financial reasons'' (56 FR 64960; December 13, 1991). Section 103 of the AEA also provides that OLs may be renewed. However, the NRC noted that, because existing plants were licensed for 40-year periods, some aging-related issues expected to arise beyond 40 years of operation may not have been fully considered. (Id. at 64946, 64954). Therefore, while the NRC determined that there was no reason to assess all aspects of a plant's licensing basis during license renewal, the NRC should ensure that aging will be effectively managed during the period of extended operation. Moreover, this aging management does not ensure that a plant will operate until the end of its period of extended operation; rather it ensures that aging-related degradation will be identified and addressed before it becomes a safety issue.

The current regulation in 10 CFR 54.31(b) limits a renewed license to no more than 20 years beyond the existing license expiration. The NRC explained that the intent of the 20-year limit was to provide ''a useful opportunity to validate and reassess, if necessary, the current understanding of age-related degradation effects.'' (Id. at 64964). At that time, the NRC also noted that it might revisit the limit once additional experience is acquired and the NRC gains confidence in licensee programs that manage age-related degradation.

The NRC has examined its experience with aging management and in light of that experience is proposing to revise 10 CFR 54.31(b) to extend the maximum renewal term to 40 years, consistent with the maximum license period in section 103 of the AEA. Most U.S. reactors are already operating beyond 40 years under renewed licenses and are following their approved aging management programs. The NRC's oversight has confirmed that licensees are effectively detecting and resolving aging issues in a timely manner. The NRC has not identified any fundamental gaps in the understanding of aging that licensees have not been able to adequately address through the current renewal process or other existing regulatory processes.

The NRC has long recognized that issuing a renewed license for a full 40-year term is legally consistent with the terms of the AEA. When the NRC issued the 1991 rule, it considered two approaches to renewing licenses: (1) a ''tack-on'' license, which would take effect at the end of the current OL term, and (2) a ''supersession'' license, which would be immediately effective upon renewal and would add a number of years, at the time up to 20, to the existing license. The NRC chose to use the supersession approach. At that time, the NRC also noted that future efforts to extend the 20-year limit closer to the 40-year maximum would require a reappraisal of the use of supersession licensing. The supersession license approach that the Commission currently uses never results in a license greater than 40 years because the renewal term is 20 years and licensees currently may not apply for renewal until there are 20 years or less remaining on the license. In contrast, a renewed license that includes any number of years remaining on the existing license plus a 40-year extension would necessarily extend the term of the renewed license past the limit in section 103 of the AEA. Therefore, the NRC concludes that granting a 40-year extension would require the use of a tack-on license. Moreover, as the NRC noted when it initially promulgated its license renewal rules, a tack-on license may be more compatible with the terms of the AEA that state that licenses ''may be renewed upon the expiration'' of the license term. (Id. at 64964).

Maintaining a tack-on license may require additional administrative steps, particularly if it is issued well before the beginning of the period of extended operation. Therefore, these amendments to 10 CFR part 54 would also include a requirement that the licensee take steps to ensure the renewed license remains up to date, consistent with the current licensing basis as defined in 10 CFR 54.3, prior to the period of extended operation. Also, currently, certain activities are implemented prior to the period of extended operation in accordance with the conditions of the renewed license that is immediately in effect upon issuance, such as implementing new aging management programs and enhancing existing programs. The NRC's oversight program verifies that these activities are completed, including taking advantage of the plant's refueling outage prior to the period of extended operation to observe licensee activities that take place at reduced power levels. The NRC is considering alternative means of conditioning these activities, given that a tack-on license would not be in effect until the start of the period of extended operation, and the NRC is seeking the public's input on this topic.

With the change to a longer renewal term, applicants may need to address potential gaps in the current safety and environmental review guidance until the guidance is updated. For example, the current revision of NUREG–2191, ''Generic Aging Lessons Learned for Subsequent License Renewal (GALL–SLR) Report,'' was based on evaluations of up to one term of subsequent license renewal under the current regulation, or 80 total years of plant operation. Likewise, NRC regulations at subpart A of appendix B to 10 CFR part 51 codify the conclusions of NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants,'' (LR GEIS) for one initial term of renewal and one term of subsequent renewal. However, the NRC staff noted in SECY–22–0109, ''Proposed Rule: Renewing Nuclear Power Plant Operating Licenses—Environmental Review,'' dated December 6, 2022, that, when it provided the draft LR GEIS to the Commission, the underlying analysis of environmental issues in that document ''could apply to any license renewal term,'' even one beyond the first subsequent license renewal term.

However, with the proposed change to allow license extensions of 40 years, plants currently operating in their initial renewal period (40 to 60 years) could apply for a 40-year subsequent renewal that would bring the plant to a total of 100 years of operation. Similarly, licensees that will be operating in their approved subsequent renewal period (60 to 80 years under existing regulations) could apply for a third 40-year renewal that would bring the plant to a total of 120 years of operation. As a result, applicants seeking to operate beyond 80 years would need to consider whether to supplement the guidance to address any aging and environmental effects specific to the longer operating life. No such gap analysis would be needed for applicants for an initial renewal, extending operation from 40 to 80 years, as the current subsequent renewal guidance readily applies to 80 total years of plant operation. For environmental effects, because the analysis in the LR GEIS is term neutral, licensees could consider using the LR GEIS as a starting point for that environmental analysis (although for environmental impacts past year 80, that analysis is not codified in 10 CFR part 51). The NRC has prepared draft

interim staff guidance, LR–ISG–2026–01, ''Updated Review Criteria for License Renewal,'' on this topic as part of this rulemaking. The NRC is also seeking the public's input on this topic.

B. Alternative Risk-Informed and Performance-Based Criteria

The current license renewal rule is often described as a deterministic rule because it prescribes the specific structures and components whose function must be demonstrated to be maintained. Under 10 CFR 54.21(a)(1), in-scope structures and components are included in the aging management review if they perform their function without moving parts or without a change in configuration or properties (*i.e.,* they are ''passive'') and if they are long-lived. In addition, 10 CFR 54.21(a)(3) requires applicants to demonstrate that the effects of aging will be adequately managed so that intended function(s) will be maintained for ''each structure and component identified in'' 10 CFR 54.21(a)(1). These regulations do not explicitly allow applicants to use risk insights to weigh the importance of the need to evaluate aging for license renewal.

When the NRC issued the 1995 license renewal rule, it considered allowing risk-informed methods, specifically PRA. The NRC decided against it due to concerns about the quality of risk data and models at that time. However, in SRM–SECY–98–144, ''Staff Requirements—SECY–98–144—White Paper on Risk Informed and Performance-Based Regulation,'' dated March 1, 1999, the Commission defined its expectations for risk-informed and performance-based regulation. Since then, the agency has encouraged the use of such approaches to improve regulatory decision-making, enhance safety, and reduce unnecessary regulatory burden. There has since been widescale adoption of risk initiatives such as 10 CFR 50.69 and risk-informed technical specification completion times and surveillance frequencies that require PRAs to have a high level of acceptability. Since 1995, PRA standards have matured, data collection has improved, and NRC reviews of these activities have strengthened.

As a result, the NRC is proposing to add 10 CFR 54.21(a)(4) to allow applicants to voluntarily propose risk-informed and performance-based alternatives to the current prescriptive requirements of the aging management review. Applicants could use these alternative criteria to decide which structures and components need an aging management review and how to show that aging effects will be managed. Similarly, the NRC is also proposing to revise 10 CFR 54.29, ''Standards for issuance of a renewed license,'' to clarify that the NRC's safety finding could rely on risk insights in assessing the adequacy of an applicant's actions, or lack thereof, to maintain the functionality of structures and components.

The purpose of the license renewal rule is to ensure the preservation of intended functions during long-term operations for which the understanding of aging is more limited. The NRC focused the aging management requirements on passive structures and components because they generally lack performance and condition indicators that can be easily monitored. Although operating experience shows that passive components are typically more reliable than active ones, and PRA often assigns them a low contribution to plant risk, this does not guarantee their future performance over extended operating periods. New degradation mechanisms may emerge, existing mechanisms may progress faster than expected, or safety margins may be reduced. In addition, common cause aging issues that impact overall system function may emerge.

For these reasons, alternative risk-informed or performance-based criteria could not inappropriately weaken the capability of aging management programs to preserve intended functions over long-term operations. These criteria could not be used to eliminate aging management review requirements solely because past operating experience suggests passive structures and components are reliable. The criteria would need to be applied carefully to preserve the intent of 10 CFR part 54. The NRC has prepared draft interim staff guidance, LR–ISG–2026–01, ''Updated Review Criteria for License Renewal,'' on this topic as part of this rulemaking.

C. Eliminate the Limitation on Early Application Submittal

The current regulation in 10 CFR 54.17(c) states that a licensee cannot apply for renewal more than 20 years before its current license expires. When the NRC issued the 1995 license renewal rule, it stated that the purpose of this limitation was to ensure that plants had sufficient operating experience to reveal any aging concerns before applying for renewal. At the same time, this 20-year limit was also intended to give utilities enough time to plan for alternatives, like replacing a plant, if the license was not renewed.

The NRC is proposing to remove the 20-year limit. Instead, the proposed regulations in 10 CFR 54.17(c) would permit licensees to apply for a renewed license anytime within their current operating period. For example, licensees could apply for initial renewal anytime within their initial 40-year license, and they could apply for subsequent renewal anytime within the period of extended operation. Removing the 20-year limit would give licensees more flexibility, such as coordinating their renewal applications with other licensing actions at the same plant or across their fleet to make the process more efficient. This change would not change the timely renewal provisions in 10 CFR 2.109.

The NRC has already granted exemptions from this regulation to several plants, based on the availability of operating experience from similar facilities (*i.e.,* similar materials and service environments) to inform the renewal decision. At this time, most U.S. plants have been operating past 40 years, and many for more than 50 years. As a result, there is a large amount of industry-wide operating experience to inform the NRC's renewal reviews, even if a specific plant has been operating for a short time. Also, the regulatory process will continue to provide the NRC with the means to verify that plants are effectively addressing emergent aging issues after a license is renewed. As described in NUREG–2191, Appendix B, ''Operating Experience for Aging Management Programs,'' holders of renewed licenses should have processes to capture and review operating experience to assess the need to enhance their aging management programs, as appropriate.

The NRC understands that newer reactor designs might use unique materials in new service environments, so they may not immediately have a complete base of operating experience. If licensees with newer designs request a renewed license early in plant life, the NRC's review guidance (*e.g.,* GALL Report) might not fully apply in some areas. In those cases, applicants would be expected to explain how they will address any unique issues and uncertainties in their demonstration of adequate aging management.

D. Eliminate the Required Application Content on Exemptions

The current regulation in 10 CFR 54.21(c)(2) requires that the application for a renewed license include a list of plant-specific exemptions granted under 10 CFR 50.12 that are based on time-limited aging analyses (TLAAs), along with a justification for continuing those exemptions during the extended operating period. When the NRC issued the 1995 rule, it explained that this

requirement was important because it was necessary to make an independent assessment that all exemptions based on TLAAs had been evaluated as part of the license renewal process.

However, the NRC's experience in reviewing applications has found that this requirement leads to duplication of submitted information and adds unnecessary burden for applicants in their preparations to support the NRC's application review. The regulation in 10 CFR 54.21(c)(1) already requires applicants to identify and evaluate all TLAAs, whether or not they involve an exemption. Repeating the same information to meet the separate 10 CFR 54.21(c)(2) requirement does not aid the NRC's review. As a result, the NRC is proposing to remove 10 CFR 54.21(c)(2) to streamline the process and reduce the burden on applicants.

E. Eliminate the Required Application Content on Technical Specifications

The current regulation in 10 CFR 54.22, ''Contents of application—technical specifications,'' requires that applicants include and justify any technical specification changes needed to manage the effects of aging. However, based on its experience in reviewing renewal applications, the NRC has found that this requirement is not necessary. As the renewal process is meant to maintain a plant's current licensing basis (not change it), technical specification changes are very rarely needed. Also, even without this explicit application content requirement, the review process is capable of ensuring that any needed technical specification changes are identified. As a result, the NRC is proposing to remove 10 CFR 54.22. In addition, this regulation would no longer be cited in 10 CFR 54.9, ''Information collection requirements: OMB approval,'' and 10 CFR 54.43, ''Criminal penalties.''

F. Reduce Ongoing, Post-Renewal Updates to the Final Safety Analysis Report

The license renewal rule requires applicants to include a supplement to the plant's final safety analysis report (FSAR). This supplement must provide a summary description of the programs and activities credited for managing the effects of aging and the evaluation of TLAAs. In addition, after the NRC issues a renewed license, the regulation in 10 CFR 54.37(b) requires a licensee to keep the FSAR updated. These required updates are to ''include systems, structures, and components newly identified'' and ''describe how the effects of aging will be managed.'' The NRC Regulatory Issue Summary (RIS) 2007–16, Revision 1, ''Implementation of the Requirements of 10 CFR 54.37(b) for Holders of Renewed Licenses,'' dated April 28, 2010, explained the definition of ''newly identified'' systems, structures, and components (SSCs) as those that are either related to a change to the plant's licensing basis or were already installed during the original license renewal review but were not included in that review.

When the NRC issued the 1995 license renewal rule, some commenters pointed out that 10 CFR 54.37(b) requires more detail in the ongoing FSAR updates than the summary description provided in the original renewal application. At that time, the NRC justified the discrepancy on the grounds that, after a renewed license is issued, the ongoing FSAR updates serve dual purposes. They function as both the renewal application (in that they describe how the licensee evaluated the effects of aging for newly identified SSCs) and the FSAR supplement (establishing appropriate regulatory controls on aging management programs).

However, based on its oversight experience, the NRC believes the current level of detail in the required FSAR update is not necessary, provided that licensees keep details of their evaluation of newly identified SSCs available for NRC inspection. As a result, the NRC is proposing to revise 10 CFR 54.37(b) to only require a summary description of aging management activities, consistent with what is required in the renewal application. Under this change, a newly identified SSC would trigger an FSAR update only if it affects the summary description of aging management programs or TLAAs. However, regardless of whether an FSAR update is needed, the licensee would be required to keep the full evaluation of newly identified SSCs available in a form that could be audited and retrieved.

Finally, the other currently proposed revisions to 10 CFR part 54 (described in sections XXXII.A. and C. of this document) would change how licensees would need to address some physical plant additions or modifications made prior to the start of the period of extended operation. To date, newly installed SSCs have not been considered to be subject to 10 CFR 54.37(b), based on the idea that they would not be in service for more than 40 years during the extended license period. In its responses to comments on draft RIS–2007–16, Revision 1, ''Implementation of the Requirements of 10 CFR 54.37(b) for Holders of Renewed Licenses'' dated May 27, 2009, the NRC explained that plant operating programs and NRC regulatory activities are adequate to address aging during the first 40 years of service, and aging management is only necessary when that service life is exceeded. However, with the other proposed changes to 10 CFR part 54—extending the renewal term from 20 to 40 years with a tack-on license and removing the 20-year limit on early applications—SSCs newly installed after the NRC completes its license renewal review, but prior to start of the period of extended operation, could significantly exceed 40 years of service during the period of extended operation. Because of that, any of these SSCs that are installed before the start of the period of extended operation would be subject to the provisions of 10 CFR 54.37(b).

XXXIII. Background—Enhancing Flexibility of Reactor Site Criteria

The NRC acknowledges the importance of site characterization in the determination of site suitability to demonstrate reasonable assurance of adequate protection of public health and safety, particularly as it relates to external hazards with broad impacts and the potential to cause failure of all preventative and mitigative controls with one initiating event. Site investigations performed to determine the site-specific external hazards and to adequately characterize the geology, seismology, meteorology, and hydrology of a proposed power reactor site can be time consuming and expensive. The NRC further recognizes that the emergence of new reactor technologies, including non-stationary reactors, and alternate fuels may justify greater flexibility within the siting requirements, and site investigations performed to meet those requirements.

In the current regulatory framework, 10 CFR part 100, ''Reactor Site Criteria,'' consists of two subparts: subpart A, ''Evaluation Factors for Stationary Power Reactor Site Applications Before January 10, 1997 and for Testing Reactors,'' and subpart B, ''Evaluation Factors for Stationary Power Reactor Site Applications on or After January 10, 1997.'' The requirements in subpart B to 10 CFR part 100 are more prescriptive than the requirements of subpart A to 10 CFR part 100 and impose an increased burden to obtain the required information. For example, subpart A of 10 CFR part 100 requires an applicant to consider the seismology, meteorology, geology, and hydrology of a site, but the requirements in subpart B of 10 CFR part 100 demand greater specificity, such as maximum probability wind speed, data on site

foundation materials, earthquake recurrence rates, and groundwater velocity. Within the current framework, all power reactor applicants, even those for new reactor designs with smaller physical footprints, potentially lower radiological risk, and enhanced safety features, would perform the same site characterization and hazard analysis under the requirements in subpart B to 10 CFR part 100.

Subpart B to 10 CFR part 100 and the supporting guidance on acceptable site characterization methods impose a higher burden because they were developed primarily with large LWR sites in mind and were informed by the scale and potential radiological consequences of these facilities. Conversely, subpart A to 10 CFR part 100, including appendix A, contains less prescriptive requirements applicable to older LWR sites not reflective of updated method of external hazards analysis or testing reactors with a lower potential radiological consequence. Applying this regulatory framework and associated site characterization guidance as it currently exists to new reactor designs may not reflect a risk-informed, performance-based approach to site characterization that fully considers the site, design, and hazard-specific conditions at a prospective site.

Therefore, the NRC is proposing changes to these criteria to introduce a more risk-informed, performance-based approach to siting. The proposed changes to the regulations would clearly define a graded approach to site characterization for nuclear power reactor applicants, including non-stationary reactors, by introducing a tiered approach in the regulatory framework that would allow a lower consequence power reactor applicant to demonstrate site suitability through an appropriately scaled site investigation rather than the potentially more burdensome requirements in the current subpart B to 10 CFR part 100. Further, the draft guidance documents issued for public comment along with this proposed rule would provide a risk-informed approach that could be leveraged by reactor applicants under any licensing pathway to optimize their site characterization to achieve an acceptable level of risk for external hazards. This proposed approach is consistent with other recent rulemaking actions, such as the 10 CFR part 53 rulemaking, and would provide similar requirements for applicants across licensing frameworks.

The NRC has a long-standing preference to site reactors in areas of low population density but recognizes that safety, environmental, economic, or other factors may justify siting nuclear plants in areas with greater population densities. Therefore, the NRC proposes to revise its regulations in subparts A and B of 10 CFR part 100 to allow reactors to be sited in areas with greater population densities when justified by an assessment that compares the societal risks and societal benefits of siting reactors in those areas. This proposed change is consistent with the recent 10 CFR part 53 rulemaking and would provide similar requirements for applicants across licensing frameworks.

XXXIV. Discussion—Enhancing Flexibility of Reactor Site Criteria

The proposed changes to 10 CFR part 100 would allow power reactor applicants under 10 CFR part 50 or 52 to have greater flexibility to determine the appropriate level of site characterization. Specifically, these proposed changes would utilize existing flexibility in the regulatory framework for licensing testing and power reactors, including non-stationary reactors, by allowing certain lower consequence power reactor applicants to use the same siting criteria used for testing reactors under subpart A to 10 CFR part 100. Additionally, these proposed changes would remove outdated information on a deterministic approach to seismic hazards analysis in appendix A to 10 CFR part 100 that no longer applies to new reactor applications. The proposed changes to 10 CFR 100.10, ''Factors to be considered when evaluating sites,'' would streamline the regulation and be accompanied by guidance on how to meet the regulatory requirements for subpart A to 10 CFR part 100. The proposed title change to subpart B to 10 CFR part 100 would retain the more prescriptive regulatory requirements that would remain applicable to higher consequence power reactor applicants. These more prescriptive regulatory requirements would continue to ensure appropriate siting criteria for this class of applications. The existing titles of subparts A and B to 10 CFR part 100 are currently reflected in 10 CFR 50.34(a) and (b). Accordingly, conforming changes to those sections would be needed to align the proposed changes in 10 CFR part 100 with the requirements for content of applications described in 10 CFR 50.34(a) and (b). These conforming changes include updating 10 CFR 50.34(a) and (b) to remove references to applications on or after January 10, 1997, and stationary power reactors.

Specific proposed changes to 10 CFR part 100 implementing this approach are described below. The title of subpart A to 10 CFR part 100 would be changed to ''Subpart A—Evaluation Factors for Tier 1 Power and Testing Reactors.'' Appendix A to 10 CFR part 100 would be deleted in its entirety as it provides a description of an approach to determine the safe shutdown earthquake that is outdated and is not consistent with the current practice for performing a probabilistic seismic hazards analysis at nuclear power plant sites. The information necessary to perform an acceptable probabilistic seismic hazards analysis would be included in guidance. The proposed revisions to 10 CFR 100.3, ''Definitions,'' would be conforming changes to define the new terms introduced in proposed revisions to 10 CFR part 100: ''Tier 1 reactor'' and ''Tier 2 reactor.'' These terms would be defined based on an unmitigated consequence. The proposed revision to 10 CFR 100.8, ''Information collection requirements: OMB approval,'' would be a conforming change to remove the mention of appendix A, which would be deleted. The proposed revisions to 10 CFR 100.10 would remove the references to appendix A to 10 CFR part 100 and delete explanatory text. That explanatory text would instead be contained in the draft guidance documents issued for public comment along with this proposed rule. With the deletion of appendix A to 10 CFR part 100, a new reference to appendix S to 10 CFR part 50 would be added to 10 CFR 100.10(b) to provide earthquake engineering criteria for applicants pursuing siting under subpart A to 10 CFR part 100. Additional changes to 10 CFR 100.11, ''Determination of exclusion area, low population zone, and population center distance,'' related to the exclusion area, low population zone, and population center distance are being proposed to align with the dose reference values in subpart B to 10 CFR part 100, which references 10 CFR 50.34(a)(1). Other proposed changes to the text describing the consequence analysis in 10 CFR 100.11 would align with proposed revisions to the text in 10 CFR 50.34(a)(1)(ii)(D) to be more technology-inclusive and meaningful for designs with functional containments. The proposed rule would also revise footnote 1 to 10 CFR 100.11, which provides additional information on the fission product release, to be more technology inclusive and allow for the evaluation of designs with mechanistic source terms and functional containments. In addition, the proposed rule would remove outdated information from footnote 2 to 10 CFR

100.11, which discusses the use of 25 rem (0.25 Sv) TEDE as a reference value.

These proposed changes to subpart A to 10 CFR part 100 would enable power reactor applicants that meet the Tier 1 entry criterion for subpart A to 10 CFR part 100 to develop the appropriate level of site characterization information to support the permit or license application. The proposed entry criterion for a Tier 1 reactor would be to demonstrate an unmitigated consequence of less than 25 rem (0.25 Sv) TEDE at the site exclusion area boundary. The draft guidance documents issued for public comment along with these proposed rule changes would provide guidance on how to determine the unmitigated consequence, select the site parameters to include when defining a site parameter envelope and apply graded approaches for seismic and other external hazard characterization for any power reactor applicant. The draft guidance documents also would describe appropriate uses of existing site characterization information and alternative site investigation techniques, which would increase regulatory clarity and review efficiency.

Proposed entry criteria for subpart A to 10 CFR part 100 and guidance on graded approaches for external hazards with the potential to impact all safety controls with a single initiating event (*e.g.,* seismic) would be based on an unmitigated consequence analysis. The unmitigated consequence analysis would be necessary to account for the common-cause failure aspect of external hazards and to determine the appropriate target performance criteria for acceptable risk. Information on appropriate methods for performing unmitigated consequence analyses will be provided in the draft guidance documents being issued for public comment along with this proposed rule.

Additionally, an appendix within the draft guidance would provide considerations for optimizing seismic design bases using the unmitigated consequence analysis. The NRC recognizes that the seismic design basis for a nuclear facility often has a significant impact on cost and schedule. This appendix would enable applicants to optimize the seismic design basis, reducing the burden of seismic design while still ensuring safety.

With the proposed introduction of the concept of a Tier 1 reactor in subpart A to 10 CFR part 100, the title to subpart B to 10 CFR part 100 would be changed to ''Subpart B—Evaluation Factors for Tier 2 Power Reactor Site Applications.'' The NRC proposes to make additional changes to 10 CFR 100.20, ''Factors to be considered when evaluating sites,'' and 100.23, ''Geologic and seismic siting criteria,'' to reflect the new ''Tier 2'' terminology. Tier 2 reactors would be power reactors that have not been demonstrated to meet the Tier 1 entry criterion. This would include power reactors with an unmitigated consequence of greater than 25 rem (0.25 Sv) TEDE at the site exclusion area boundary or where the unmitigated consequence is undetermined. No other changes are proposed to subpart B as part of this rulemaking, and the framework would be maintained to accommodate higher consequence reactor applications.

The NRC proposes to maintain its long-standing preference for siting reactors in areas of low population density, while providing flexibility to allow siting reactors in areas of greater population density when warranted. The NRC recognizes that safety, environmental, economic, or other factors may justify siting nuclear plants in areas with higher population densities or within a densely populated center containing more than about 25,000 residents. Therefore, the NRC is proposing to revise 10 CFR 100.10, 100.11(a)(3), 100.21(b), and 100.21(h) to allow applicants to justify siting reactors at such sites by performing assessments of additional societal risks associated with siting a reactor in areas of higher population density (*e.g.,* potential increases in population dose or economic consequences from reactor accidents) and comparing those risks to the societal benefits of a specific proposed site (*e.g.,* ability to use existing infrastructure for a retired fossil fuel power plant). Implementing guidance for these assessments will be developed.

The proposed changes to 10 CFR part 100 and the explanations provided in the draft guidance documents issued for public comment along with this rulemaking could result in timelier and more efficient site investigations, more appropriate seismic design bases, and more streamlined reviews for new power reactor applications.

XXXV. Background—Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors

A. Accident Tolerant Fuels

Accident tolerant fuels (ATFs) are advanced nuclear fuel technologies that have the potential to enhance safety at U.S. nuclear power plants by offering better performance during normal operation, transient conditions, and accident scenarios. Section 107, ''Commission Report on Accident Tolerant Fuel,'' of the Nuclear Energy Innovation and Modernization Act defines ATF as a new technology that makes an existing commercial nuclear reactor more resistant to a nuclear incident (as defined in section 11 of the AEA (42 U.S.C. 2014)) and lowers the cost of electricity over the licensed lifetime of an existing commercial nuclear reactor.

While this proposed rule would not make any fuel-design-specific conclusions, it would facilitate the adoption of increased enrichment and higher burnup to enable entities, licensed to use conventional or ATF designs, to use LWR fuel containing uranium enriched to greater than 5.0 weight percent uranium-235 (U-235), in most cases, without the use of exemptions.

B. Rulemaking Development

(i) Early Considerations of Increased Enrichment

From interactions with stakeholders, the NRC is aware that licensees and applicants plan to request to deploy ATF concepts and operate fuel to extract more energy from each fuel rod (*i.e.,* operate fuel at higher burnups). Specifically, the NRC expects requests to raise fuel burnup limits to higher than the 62 gigawatt-days per metric ton of uranium (GWd/MTU) rod-average burnup limit set by the NRC in most safety analysis methodologies. To achieve higher burnup limits, licensees and applicants would need to request increases in fuel enrichment from the current standard of 5.0 weight percent U–235 up to approximately 10.0 weight percent U-235. Additionally, in February 2019, nuclear power industry representatives identified potential advantages of increased enrichment fuel for LWRs in the NEI white paper, ''The Economic Benefits and Challenges with Utilizing Increased Enrichment and Fuel Burnup for Light-Water Reactors.''

In September 2021, the NRC issued version 1.2 of the ''Project Plan to Prepare the U.S. Nuclear Regulatory Commission for Efficient and Effective Licensing of Accident Tolerant Fuels,'' which describes the pursuit of higher burnup and increased enrichment as key components of nuclear power industry ATF efforts. Currently, the industry plans to deploy batch loads of fuels enriched to levels greater than the current standard of 5.0 weight percent U-235 by the mid-to-late 2020s. Paragraph (b)(7) of 10 CFR 50.68, ''Criticality accident requirements,'' requires that U-235 enrichment levels in power reactor fuel be no more than 5.0

percent by weight, unless the NRC approves exemptions from this limit. The development of the current regulatory framework did not foresee use of enrichments greater than 5.0 weight percent U-235. The NRC established the current weight percent limits as reasonable bounding assumptions for its safety analysis methodologies. As part of this rulemaking, the NRC evaluated the framework and considered whether the current weight percent limits can be adjusted while maintaining reasonable assurance of adequate protection of public health and safety. In addition, the NRC considered whether rulemaking would support a more efficient review of licensing actions.

In response to industry interest in LWR fuels enriched to between 5.0 to 10.0 weight percent U-235, the NRC staff submitted to the Commission a rulemaking plan in SECY–21–0109, ''Rulemaking Plan on Use of Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors,'' dated December 20, 2021. The staff requested Commission approval to initiate rulemaking to amend NRC requirements to facilitate the use of LWR fuel containing uranium enriched to greater than 5.0 weight percent U-235. In SECY–21–0109, the staff recommended rulemaking to reduce the number of exemption requests and facilitate increased regulatory efficiency and consistency. The staff explained that rulemaking on this topic would allow the staff to thoroughly review the potential regulatory implications of fuels enriched to greater than 5.0 weight percent U-235 and identify and assess the potential costs and benefits of changing regulatory requirements that impact the use of these fuels. Rulemaking also would provide options for a generic resolution of these issues and invite stakeholder participation in decisions affecting this regulatory area, rather than deciding issues on a case-by-case basis as in the current regulatory framework.

In SRM–SECY–21–0109, ''Staff Requirements—SECY–21–0109—Rulemaking Plan on Use of Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors,'' dated March 16, 2022, the Commission approved the staff's plan to initiate rulemaking to amend requirements for the use of LWR fuel containing uranium enriched to greater than 5.0 weight percent U-235. The Commission stated that the provisions of the rule should apply only to high-assay, low-enriched uranium (HALEU) fuel, both for nonproliferation and safeguards reasons, and that the staff's analysis should focus on the range of enrichment most likely to be contemplated in future applications.

In addition, the Commission directed that (1) fuel fragmentation, relocation, and dispersal (FFRD) issues relevant to fuels of higher enrichment and burnup levels should be appropriately addressed and analyzed in the regulatory basis for this rulemaking; and (2) staff should take a risk-informed approach when developing this rule and the associated regulatory basis and guidance.

(ii) Other Considerations

On April 11, 2024, the Commission returned the 10 CFR 50.46c draft final rule to the staff in SRM–SECY–16–0033, ''Staff Requirements—SECY–16–0033—Draft Final Rule—Performance-Based Emergency Core Cooling System Requirements and Related Fuel Cladding Acceptance Criteria.'' As a result, this rulemaking proposes to leverage the previously proposed performance-based approach to emergency core cooling system (ECCS) requirements, including the expanded applicability to advanced fuels, and incorporate the embrittlement research findings from the 10 CFR 50.46c draft final rule into the new voluntary 10 CFR 50.46a proposed rule. This is discussed in sections XXXV.C.(v)(c), ''10 CFR 50.46c Rulemaking and Cladding Embrittlement Research Findings,'' and XXXVI.F.(v), ''Alternative ECCS Analysis Requirements and Acceptance Criteria,'' of this document.

C. Background and History of Affected Regulations

This section provides the regulatory history and the background of each of the affected regulatory areas and its relationship to fuel enrichment.

(i) 10 CFR 70.24 and 10 CFR 50.68 Criticality Accident Requirements

One regulation initially evaluated by the NRC for its relationship to fuel enrichment is 10 CFR 70.24, ''Criticality accident requirements.'' This regulation was established as part of the rulemaking for 10 CFR part 70, ''Domestic Licensing of Special Nuclear Material,'' in 1974 (39 FR 39020; November 5, 1974). Section 70.24 ensures that licensees handling special nuclear material (SNM) have the appropriate monitoring systems in place for detecting a criticality accident and establish an emergency plan.

During the 1980s and 1990s, nuclear power reactor licensees sought exemptions from several requirements in 10 CFR 70.24, including those related to active criticality monitoring alarm capabilities, criticality emergency drills, and plans for evacuations, decontamination, medical treatment for radiation exposure, and reentry protocols, which must also be demonstrated through the regular criticality safety drills. As discussed in SECY–97–155, ''Staff's Action Regarding Exemptions from 10 CFR 70.24 for Commercial Nuclear Power Plants,'' dated July 21, 1997, in response to these numerous exemption requests, the staff evaluated the likelihood of an inadvertent criticality accident during fuel handling operations at nuclear power plants and concluded that such events would be unlikely for power reactor facilities because existing administrative and design controls were based on no more than 5.0 weight percent U-235 fuel enrichment. As a result, in 1998 the NRC issued 10 CFR 50.68 to offer these licensees an alternative to 10 CFR 70.24, provided that they meet certain criteria (63 FR 63127; November 12, 1998).

Under 10 CFR 50.68, licensees may decide not to comply with the requirements of 10 CFR 70.24 and, instead, must comply with the requirements in 10 CFR 50.68(b), if they can demonstrate appropriate subcriticality margins that are expressed in terms of k-effective (keff), the estimated ratio of neutron production to neutron absorption and leakage, for new and fresh fuel storage facilities. Section 50.68(b) specifies the following keff limits:

- *10 CFR 50.68(b)(2):* keff ≤ 0.95 at 95 percent probability and 95 percent confidence level for fresh fuel wet storage racks in unborated water.
- *10 CFR 50.68(b)(3):* keff ≤ 0.98 at 95 percent probability and 95 percent confidence level for fresh fuel storage in low-density hydrogenous fluid (fog). This keff limit is only applicable to the current fleet of operating LWRs if they use a dry new fuel storage vault that is susceptible to moderation by natural weather or fire suppression fogging conditions. If new fuel is stored submerged in the fuel pool (*i.e.,* 10 CFR 50.68(b)(2) wet storage conditions), then 10 CFR 50.68(b)(3) does not apply.
- *10 CFR 50.68(b)(4):* keff ≤ 0.95 at 95 percent probability and 95 percent confidence level for spent fuel wet storage racks in unborated water.
- *10 CFR 50.68(b)(4):* keff ≤ 0.95 at 95 percent probability and 95 percent confidence level for spent fuel wet storage racks in borated water; furthermore, keff must remain < 1.0 at 95 percent probability and 95 percent confidence level without soluble boron credit taken.

In addition to the keff requirements, 10 CFR 50.68(b)(6) requires radiation monitoring only during fuel handling and movement. Finally, 10 CFR 50.68(b)(7) limits current applications to 5.0 weight percent U–235 for fresh fuels. The NRC added 10 CFR 50.68(c) in 2006 (71 FR 66648; November 16, 2006) to delineate independent spent fuel storage installation dry storage cask loading applicability.

Most operating reactors currently adhere to 10 CFR 50.68(b) requirements in lieu of the criticality monitoring requirements in 10 CFR 70.24. When fuel transition changes are made, if enrichments are being increased, the licensee must perform a safety analysis of spent fuel pool criticality as part of the fuel transition because increasing enrichments may cause a decrease in margin to the applicable keff safety limits of 10 CFR 50.68(b)(4). There is also a plant-specific criticality safety limit for the new and spent fuel storage areas listed in Standard Technical Specification Design Feature 4.3, ''Fuel Storage,'' in NUREG–1430, ''Standard Technical Specifications—Babcock and Wilcox Plants''; NUREG–1431, ''Standard Technical Specifications—Westinghouse Plants''; NUREG–1432, ''Standard Technical Specifications—Combustion Engineering Plants''; NUREG–1433, ''Standard Technical Specifications—General Electric Plants (BWR/4)''; NUREG–1434, ''Standard Technical Specifications—General Electric Plants BWR/6''; and NUREG–2194, ''Standard Technical Specifications—Westinghouse Advanced Passive 1000 (AP1000) Plants.'' The guidance in these NUREGs assists the NRC's review of any proposed fuel changes that could affect 10 CFR 50.68 compliance.

Nonetheless, given that 10 CFR 50.68(b)(7) limits current applications to 5.0 weight percent U-235, if reactor licensees transition to using fuel enriched above 5.0 weight percent U-235, then 10 CFR 50.68 would not be available as an alternative to 10 CFR 70.24. Absent rulemaking, the NRC expects that reactor licensees seeking to transition to fuel enriched above 5.0 weight percent U-235 would likely request exemptions from 10 CFR 50.68.

Unlike 10 CFR 50.68, 10 CFR 70.24 does not have an enrichment limit, so a licensee or applicant could comply with 10 CFR 70.24 and implement enrichments beyond 5.0 weight percent U-235. Licensees or applicants complying with 10 CFR 70.24 that seek exemption from that section's active criticality monitoring and emergency planning requirements could not justify the exemptions with the subcriticality margin approach methodology used in 10 CFR 50.68. Furthermore, under 10 CFR 70.24(d)(2), any exemption from 10 CFR 70.24 held by a licensee becomes ineffective once that licensee elects to comply with 10 CFR 50.68. Industry stakeholders have also acknowledged the greater regulatory flexibility of the 10 CFR 50.68 subcriticality margin approach, and licensees have expressed interest in applying the 10 CFR 50.68 methodology to higher enrichments in lieu of meeting the 10 CFR 70.24 criticality safety approach. Proposed amendments to address this issue are discussed in section XXXVI.A., ''Criticality Accident Requirements in 10 CFR 50.68,'' of this document.

(ii) Environmental Requirements in 10 CFR 51.51 and 51.52

In 10 CFR 51.51, table S–3, ''Table of Uranium Fuel Cycle Environmental Data,'' references the original environmental assessments in WASH–1248, ''Environmental Survey of the Uranium Fuel Cycle,'' issued April 1974, and NUREG–0116, ''Environmental Survey of the Reprocessing and Waste Management Portions of the LWR Fuel Cycle: A Task Force Report,'' Supplement 1 to WASH–1248, issued October 1976.

In 10 CFR 51.52, summary table S–4, ''Environmental Impact of Transportation of Fuel and Waste to and From One Light-Water-Cooled Nuclear Power Reactor,'' references the environmental assessments in WASH–1238, ''Environmental Survey of Transportation of Radioactive Materials to and from Nuclear Power Plants,'' issued December 1972, and Supplement 1 to NUREG–75/038, ''Environmental Survey of Transportation of Radioactive Materials to and from Nuclear Power Plants,'' issued April 1975.

The aforementioned environmental surveys were based on enrichments up to 4.0 weight percent U-235. Subsequent analysis by the NRC, incorporated into section 4.12.1.1 of NUREG–1437, ''Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Final Report,'' Revision 1, issued June 2013, confirmed that table S–3 of 10 CFR 51.51 and table S–4 of 10 CFR 51.52 are also bounding for enrichments up to 5.0 weight percent U-235. The NRC does not have an approved assessment of environmental impacts related to the uranium fuel cycle in current 10 CFR 51.51, or to transportation of enriched fresh, nonirradiated fuel to a reactor in current 10 CFR 51.52, for enrichments greater than 5.0 weight percent U-235.

Under 10 CFR 51.51 and related to 10 CFR 51.50, ''Environmental report—construction permit, early site permit, or combined license stage,'' the environmental data of table S–3 apply for enrichments up to 5.0 weight percent U-235 and apply to the environmental report for the CP stage, ESP stage, or COL stage of an LWR. Also, as required in 10 CFR 51.50, an applicant for a CP, ESP, or COL must submit an environmental report that contains information specified in 10 CFR 51.45, ''Environmental report,'' 10 CFR 51.51, and 10 CFR 51.52.

Under 10 CFR 51.52, an environmental report prepared for the CP stage, ESP stage, or COL stage of an LWR must contain a statement concerning the environmental impacts of transportation of fuel and radioactive waste to and from the LWR. If the conditions in 10 CFR 51.52(a) as extended to 5.0 weight percent U-235 are met, then table S–4 gives these environmental impacts and can be so stated in the applicant's environmental report. If an LWR applicant for a CP, ESP, or COL cannot meet the conditions for using table S–4 (for example, the plant has enrichments greater than 5.0 weight percent U-235), then the environmental report must contain a full description and detailed analysis of the environmental effects of transportation of fuel and radioactive waste to and from the reactor, including values for the environmental impact under normal conditions of transport and for the environmental risk from accidents in transport.

For licensing actions other than CP, ESP, and COL applications, which may not require submission of an environmental report (*e.g.,* license amendment requests), the uranium fuel cycle and the transportation of the fuel and waste could be considered necessary to support the operation of the plant. In such situations, the NRC would assess the environmental effects of the licensing action with respect to the uranium fuel cycle or transportation of fuel and waste or both.

Sections XXXVI.B., ''Uranium Fuel Cycle Environmental Data—Table S–3 in 10 CFR 51.51,'' and XXXVI.C., ''Environmental Effects of Transportation of Fuel and Waste—Table S–4 in 10 CFR 51.52,'' of this document include discussions of proposed amendments to support the use of fuel with enrichments greater than 5.0 weight percent U-235 for the uranium fuel cycle in 10 CFR 51.51 and transportation and waste requirements in 10 CFR 51.52. In a separate rulemaking, the NRC is considering changing the types of environmental impacts considered in tables S–3 and S–4.

(iii) Fissile Packaging Requirements

In an effort to fully utilize ATF capabilities, licensees and applicants are expected to seek approval for the transport of fissile material with enrichments that range between 5.0 and 10.0 weight percent U-235. The fuel cycle for commercial LWR fuel includes enrichment of uranium hexafluoride (UF_6) and shipment of the enriched UF_6 to a fuel fabricator for deconversion to uranium dioxide (UO_2). The enriched UF_6 is transported in NRC-approved packages that incorporate 30-inch cylinders.

The regulation in paragraph (b) of 10 CFR 71.55, ''General requirements for fissile material packages,'' requires that a transportation package be designed and constructed, and its contents limited, so that it would be subcritical if water were to leak into the containment system. This criticality analysis with moderation ensures criticality safety in transport in the unanticipated event that water leaks into the containment vessel and provides moderating materials for the fissile contents.

In the 2004 amendments to 10 CFR part 71 (69 FR 3698; January 26, 2004), the NRC implemented an exception to 10 CFR 71.55(b) in 10 CFR 71.55(g), which codified a longstanding NRC and worldwide practice for evaluating the leakage of water into UF_6 packages. This exception for UF_6 transportation packages can be used if all of the following conditions are met:

- The UF_6 cylinder remains leak tight following the tests specified for hypothetical accident conditions.
- The valve body of the cylinder does not impact any other part of the package, other than where it is attached to the cylinder.
- There is adequate quality control in the manufacture, maintenance, and repair of packagings.
- Each package is tested to demonstrate closure before each shipment.
- The uranium is enriched to not more than 5.0 weight percent U-235.

This exception is a performance-based assessment of the structural and containment integrity of the UF_6 cylinder, which is independent of the enrichment level of the contents.

Similarly, 10 CFR 71.55(c) also provides for an exception to the requirements in 10 CFR 71.55(b) if the applicant specifies that the package incorporates special design features that ensure that no single packaging error would permit leakage and that appropriate measures are taken before each shipment to ensure that the containment system does not leak. This exception does not limit the enrichment of the package contents.

In the 2004 amendments to 10 CFR part 71, the NRC explained the basis for the specific exception in 10 CFR 71.55(g) and its enrichment limit of 5.0 weight percent U-235 as follows: (1) it would maintain consistency with worldwide practice, (2) operation experience and history demonstrate safe shipment of fuel enriched to less than or equal to 5.0 weight percent U-235, and (3) it is necessary to transport an essential commodity (UF_6 feed material).

Currently, the regulations in 10 CFR part 71 are sufficiently performance-based and, except for 10 CFR 71.55(g), do not directly reference or limit the enrichment level of the radioactive contents. The regulatory issue with 10 CFR 71.55(g) is that it specifies an enrichment limit (5.0 weight percent U-235) for UF_6 that does not bound the range of enrichment that applicants may choose to ship in their UF_6 transportation packages in the future.

Section XXXVI.D., ''Fissile Material Packaging Requirements in 10 CFR 71.55,'' of this document includes a discussion of proposed amendments to the fissile packaging requirements in 10 CFR 71.55 to support the use of fuel with enrichments greater than 5.0 weight percent U-235.

(iv) Appendix A to 10 CFR Part 50 (General Design Criterion 19) and 10 CFR 50.67(b)(2)(iii)

The general design criteria (GDC) in appendix A to 10 CFR part 50, ''General Design Criteria for Nuclear Power Plants,'' Criterion 19, ''Control room'' (GDC 19), provide minimum design, fabrication, construction, testing, and performance requirements for structures, systems, and components (SSCs) that provide reasonable assurance that the facility can be operated without undue risk to public health and safety. Additionally, 10 CFR 50.67, ''Accident source term,'' allows applicable licensees to voluntarily revise the accident source term used in design basis radiological consequences analyses if certain requirements in 10 CFR 50.67(b)(2) are met.

Both GDC 19 and 10 CFR 50.67(b)(2)(iii) provide a specific dose-based criterion of 5 rem (0.05 Sv) TEDE for demonstrating the acceptability of the control room design. They represent a distinct layer of defense-in-depth that assumes a major accident that results in substantial meltdown of the reactor core with subsequent release of appreciable quantities of fission products. In application, GDC 19 and 10 CFR 50.67(b)(2)(iii) are performance based and require that a licensee or applicant provide a control room habitability design using traditional deterministic radiological consequence analyses methods to judge the acceptability of the design.

An acceptable level of control room habitability for design basis events (DBEs) is necessary to provide reasonable assurance that the control room would continue to be staffed and operated effectively to mitigate the effects of the postulated accident and protect public health and safety. GDC 19 and 10 CFR 50.67(b)(2)(iii) are *design* criteria and should not be construed as operational *limits.* While the design criteria are computed in terms of dose, they are figures of merit used to characterize the minimum requirements for design, fabrication, construction, testing, and performance for SSCs. The design criteria do not represent actual occupational exposures received during normal and emergency conditions, which are primarily controlled by 10 CFR part 20, ''Standards for Protection Against Radiation.''

The preamble for the 1971 final rule (36 FR 3255; February 20, 1971) that first published the GDC addressed the criteria only in the aggregate; the individual criteria were not discussed. However, there is a record of a change made to the proposed GDC 11 (32 FR 10213; July 11, 1967), which became the final GDC 19. The proposed GDC 11 referred to the occupational exposure limits of 10 CFR part 20 rather than specifying a numeric dose criterion. Industry comments on that proposal generally recommended deletion of the reference to 10 CFR part 20 (see SECY–R–143, ''Amendment to 10 CFR 50—General Design Criteria for Nuclear Power Plants,'' dated January 28, 1971). The Commission resolved these comments by deleting the reference to 10 CFR part 20 occupational exposure limits and providing the current ''5 rem whole-body, or its equivalent to any part of the body, for the duration of the accident'' in its place.

Section 50.67 of 10 CFR was established shortly after a revision to 10 CFR part 20 was issued in 1991, providing the voluntary regulatory mechanism for licensees to replace the original design criteria of whole body and thyroid with the new TEDE criteria. The preamble for the 10 CFR 50.67 final rule included the Commission's rationale for establishing 5 rem (0.05 Sv) TEDE as the GDC 19 numeric design criterion for licensees using an alternative source term. That rationale was composed of the following:

- The criteria in GDC 19 were based on a primary occupational exposure limit.
- The use of 5 rem (0.05 Sv) TEDE as the control room criterion did not imply that this value would be an acceptable exposure during emergency conditions, or that other radiation protection standards of 10 CFR part 20, including individual organ dose limits, might not apply. This criterion was provided only to assess the acceptability of design provisions for protecting control room operators under postulated design-basis accident (DBA) conditions. The DBA conditions assumed in these analyses, although credible, generally did not represent actual accident sequences but were specified as conservative surrogates to create bounding conditions for assessing the acceptability of engineered safety features.
- The regulations at 10 CFR 20.1206, ''Planned special exposures,'' permitted a planned special dose of five times the annual dose limits. Also, the pertinent U.S. Environmental Protection Agency (EPA) guidance at that time, ''Manual of Protective Action Guides and Protective Actions for Nuclear Incidents,'' EPA–400/R–92–001, issued May 1992, set a limit of five times the annual dose limits for workers performing emergency services such as lifesaving or protection of large populations. The Commission did not suggest that control room dose during an accident can be treated as a planned special exposure or that the EPA emergency worker dose limits are an alternative to GDC 19. However, the Commission stated that these provisions offer a useful perspective that supports the conclusion that the organ doses implied by the 5 rem (0.05 Sv) criterion can be considered to be acceptable due to the relatively low probability of the events that could result in doses of this magnitude.

Development of the current control room design criterion did not foresee how licensees are currently operating their facilities and managing their fuel or considering fuel enrichments up to but less than 20.0 weight percent U-235. The history of fuel utilization for the current large LWR fleet has seen a gradual progression toward higher fuel burnups and increased enrichments. The original control room design criteria were developed during the late 1960s when burnup rates and enrichments were relatively low. During that time, there was enough margin in the facilities' design bases to accommodate the control room design criteria, even for power uprates of up to 120 percent of the originally licensed steady-state thermal power level. Today, vendors, licensees, and other members of the nuclear power industry have indicated to the NRC that they are looking for further power uprates using fuel enrichments up to 10.0 weight percent U-235 with fuel burnup limits higher than the 62 GWd/MTU rod-average burnup.

Depending on how the reactor core is designed with increased U-235 enrichment fuel elements and operation at higher burnup levels to reach longer cycle time, the results of a licensee's DBA radiological consequence analysis results would increase. The impact of this increase would decrease the retained margin maintained by the licensee to provide operational flexibility. An unjustifiably low design criteria can unnecessarily burden licensees for seeking increased enrichments with extensive analyses to preserve margin for operational flexibility purposes. These additional analyses may not result in safety benefits and can increase actual operational exposure to workers due to increased maintenance activities.

Under the current definition of ''safety-related structures, systems and components'' in 10 CFR 50.2, ''Definitions,'' any SSCs credited with providing mitigation functions during a DBE (or accident) must be designated as ''safety-related.'' The traditional radiological consequence analyses performed to demonstrate compliance with the control room design criterion assess the performance of safety-related SSCs because they are relied upon to remain functional during and following DBAs to ensure the capability to prevent or mitigate the consequences of accidents that could result in potential exposure. The analyses are not intended to be actual event sequences but, rather, are intended to be surrogates to enable deterministic evaluation of the response of the plant-engineered safety features. These accident analyses are intentionally conservative in order to address uncertainties in accident progression, fission product transport, and atmospheric dispersion. With few exceptions, these analyses do not credit non-safety-related SSCs or operator actions that would otherwise lower the radiological consequence results. This analysis approach can ensure conservative results, but the results can also have large uncertainties. Due to the modeling approach and inherent uncertainty, overly conservative results can lead licensees to perform extensive re-analyses to preserve margin for operational flexibility purposes that do not necessarily enhance safety.

The radiological consequence analyses also confirm several aspects of the facility's design- and licensing-basis when safety-related SSCs are credited as input parameters. These input parameters are often specific values and limits found in the facility's updated FSAR and technical specifications, pursuant to 10 CFR 50.36, ''Technical specifications.'' Deviations from the Technical Specification identified during maintenance or testing (*e.g.,* higher leakage rates or lower filter efficiencies) indicate a non-conformance issue with the facility's licensing basis. In such cases, additional maintenance must be performed to correct the discrepancy to bring the facility back into compliance with established licensing requirements. The degree of maintenance necessary to ensure the facility is in compliance can significantly influence the amount of radiation exposure incurred by workers. The numerical value of the control room design criteria, through the radiological consequence analyses that utilize specific values and limits found in the facility's technical specifications, factors into the licensee's decisions when performing maintenance activities and thus directly impacts the amount of workers' exposure to ionizing radiation. A very low design criteria value can result in an excessive amount of maintenance, leading to potentially avoidable occupational exposure and unnecessary operational disturbances. Conversely, a very high value may allow for unacceptable degradation, potentially compromising overall safety and performance over time. Adequate protection of public health and safety and occupational radiological safety can still be achieved at a higher and safe control room design criteria performance level while balancing both dose-savings to workers and providing some regulatory relief to maintain operational flexibilities. As discussed in section XXXVI.E., ''Control Room Requirements in 10 CFR 50.67 and GDC 19,'' of this document, the NRC proposes to address these issues so licensees would not need to perform potentially extensive re-analyses or excessive maintenance activities, or possibly request exemptions, to demonstrate compliance without a commensurate increase in safety.

The NRC's Radiation Protection and Emergency Response Framework

The NRC's comprehensive radiation protection and emergency response framework, which covers both normal operations and accident conditions, is another important aspect of the control room design criteria rulemaking efforts. This framework helps to protect occupational workers from ionizing radiation as well as prepare the licensee

to respond to abnormal and emergency conditions to protect the public health and safety.

At the time that GDC 19 was established in 1971, 10 CFR part 20 limited occupational radiation exposure to 3 rem (0.03 Sv) whole body dose per calendar quarter, provided the total lifetime dose was verified not to exceed 5 rem (0.05 Sv) times the individual's age in years minus 18. Thus, a worker could receive a radiation exposure of up to 12 rem (0.12 Sv) in a given year.

The current annual limit on occupational radiation dose exposure in 10 CFR 20.1201, ''Occupational dose limits for adults,'' is 5 rem (0.05 Sv) TEDE. Under 10 CFR 20.1201, an adult worker could receive occupational radiation exposure of up to 10 rem (0.10 Sv) TEDE over a 12-month period straddling two calendar years. The current 10 CFR 20.1206 also permits an adult worker to receive doses in addition to, and accounted for separately from, the doses received under the limits specified in 10 CFR 20.1201 of five times the annual dose limits during the individual's lifetime, not to accumulate faster than 5 rem (0.05 Sv) TEDE in any one year. As such, an adult worker could receive radiation exposure of up to 10 rem (0.10 Sv) TEDE within a single calendar year period. In setting these standards in the 1991 amendment of 10 CFR part 20 (56 FR 23360; May 21, 1991), the Commission concluded that an infrequent exposure of workers up to twice the occupational dose limit was adequately protective of radiation workers.

The NRC's emergency planning regulations in appendix E to 10 CFR part 50, ''Emergency Planning and Preparedness for Production and Utilization Facilities,'' and planning standards for nuclear power reactors in 10 CFR 50.47, ''Emergency plans,'' require each nuclear power reactor licensee to have an emergency plan that gives the NRC reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency. The regulation at 10 CFR 50.47(b)(11) requires licensees to establish the means for controlling radiological exposures in an emergency and states that the means for controlling radiological exposures must include exposure guidelines consistent with EPA Emergency Worker and Lifesaving Activity Protection Action Guides (PAG). The EPA exposure guidelines found in the current version of its ''PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents,'' recommend that doses received under emergency conditions should be maintained as low as reasonably achievable and, to the extent practicable, limited to 5 rem (0.05 Sv). The guideline for actions to protect valuable property is 10 rem (0.10 Sv) where a lower dose is not practicable, the guideline for actions to save a life or to protect large populations is 25 rem (0.25 Sv) where a lower dose is not practicable, and exposures greater than 25 rem (0.25 Sv) may be appropriate for lifesaving or protecting large populations if the workers are volunteers who are fully aware of the risks involved.

The events that could result in control room radiation exposures comparable to the 10 CFR part 20 normal occupational exposure limit of 5 rem (0.05 Sv) TEDE would result in the activation of the facility's emergency response plan and the emergency response organization. These emergency actions include establishing higher exposure limits for control room operators if necessary to provide public health and safety, as permitted by paragraph (x) of 10 CFR 50.54, ''Conditions of licenses,'' and paragraph (b) of 10 CFR 20.1001. The emergency coordinator can also authorize issuing potassium-iodide tablets for thyroid protection or use of emergency respiratory protection equipment.

The Commission's framework for emergency planning and response encompasses a combination of regulatory requirements and industry commitments tailored to address a spectrum of potential events, from design-basis scenarios to extremely low-probability severe accident events. This comprehensive approach ensures preparedness to effectively protect public health and safety by enabling robust planning and response capabilities.

Scientific Recommendations for Radiation Protection for Worker and Regulations Under Accident and Emergency Conditions

The NRC reviewed several source materials to understand the current recommendations from national and international organizations responsible for making recommendations for radiation protection standards. The purpose of this review was to determine whether reexamining the scientific and technical basis for the numerical value of the control room design criteria would be warranted. Section XXXVI.E., ''Control Room Requirements in 10 CFR 50.67 and GDC 19,'' of this document describes how the NRC used this review to inform the development of this proposed rule.

ICRP Publication 109, ''Application of the Commission's Recommendations for the Protection of People in Emergency Exposure Situations,'' issued in 2009, specifies a reference range of 2 to 10 rem (0.02 to 0.10 Sv) acute, or per year, for emergency exposure situations. The reference level represents the level of residual dose or risk above which it is generally judged to be inappropriate to plan to allow exposures to occur. The ICRP considers that a dose rising towards 10 rem (0.10 Sv) will almost always justify protective measures and that protection against all exposures, above or below the reference level, should be optimized.

The IAEA 2024 guidance, ''Portable Digital Assistant for First Responders to a Radiological Emergency: Emergency worker turn-back dose guidance,'' specifies a range of 5 to 100 rem (0.05 to 1 Sv), depending on the severity of the actions needed.

The 2018 NCRP Report No. 180, ''Management of Exposure to Ionizing Radiation: Radiation Protection Guidance for the United States,'' specifies the following: (1) during lifesaving activities or actions to prevent a catastrophic situation, which includes other urgent rescue activities, 50 radiation-absorbed dose (rad) (0.5 gray (Gy)) cumulative whole-body absorbed dose (50 rad) should be implemented at the command level, and (2) for other emergency activities, including extended activities following initial lifesaving, rescue, and damage control response, an effective dose to emergency workers should not exceed 10 rem (0.10 Sv).

Modern Health Physics and Radiation Epidemiology Knowledge

The NRC's comprehensive radiation protection and emergency response framework for protecting individuals during normal and emergency conditions is informed by scientific recommendations by national and international organizations. These recommendations are based on fundamental modern health physics and radiation epidemiology knowledge. The NRC's consideration of these organizations' recommendations has contributed to developing this proposal to amend the control room design criteria value from 5 rem (0.05 Sv) TEDE to 10 rem (0.10 Sv) TEDE with the additional provisions to justify a higher numerical value up to 25 rem (0.25 Sv) TEDE.

The range of proposed control room design criteria values is significantly below the threshold for observable deterministic health effects such as acute radiation syndrome and

hematopoietic syndrome, which occurs at a dose around 70 to 100 rad (0.7 to 1 Gy). This range is also far below the mean lethal dose of ionizing radiation without medical treatment, which is estimated to be approximately 300 to 500 rad. This demonstrates that the proposed design criteria range is well within safe limits relative to acute radiation effects that could impair workers from performing their safety function in response to an event. Additionally, the criteria range results in a small radiation risk for cancer mortality, which would be further mitigated by radiation protection and emergency planning actions during an actual event. This ensures a high level of protection is still provided, thereby minimizing long-term health impacts.

In RG 8.29, Revision 1, ''Instruction Concerning Risks from Occupational Radiation Exposure,'' the NRC adopted a risk value, for an occupational dose of 1 rem (0.01 Sv) TEDE, of 4 in 10,000 of developing a fatal cancer, or approximately 1 chance in 2,500 of fatal cancer per rem of TEDE received. The uncertainty associated with this risk estimate does not rule out the possibility of higher risk, or the possibility that the risk may even be zero at low occupational doses and dose rates. The radiation risk incurred by a worker depends on the amount of dose received. Under current health physics models, a worker who receives 5 rem (0.05 Sv) in a year incurs 10 times as much risk as another worker who receives only 0.5 rem (0.005 Sv).

Thus, in a group of 10,000 people, each exposed to 1 rem (0.01 Sv) of ionizing radiation, and using the risk factor of 4 effects per 10,000 rem (100 Sv) of dose, 4 of the 10,000 people might die from delayed cancer because of that 1 rem (0.01 Sv) dose in addition to the 2,000 normal cancer fatalities expected to occur in that group from all other causes. From an individual perspective, a 1 rem (0.01 Sv) dose may increase an individual worker's chances of dying from cancer from 20 percent to 20.04 percent. If one's lifetime occupational dose is 10 rem (0.1 Sv), the estimate would increase to 20.4 percent. A lifetime dose of 100 rem (1.0 Sv) may increase chances of dying from cancer from 20 to 24 percent. This small increase in cancer risk could be inferred over the lifetime, however it is unlikely that an increased incidence of cancer due to irradiation would be discernible. This is because the normal variability in baseline rates of cancer incidence is much larger than the inferred radiation-associated cancer rates. As a point of reference, according to NUREG–0713, Volume 43, ''Occupational Radiation Exposure at Commercial Nuclear Power Reactors and other Facilities,'' published in 2021, the average measurable dose for radiation workers reported to the NRC was 0.16 rem (0.0016 Sv) for 2021.

(v) Fuel Dispersal

(a) 10 CFR 50.46 and Fuel Dispersal

In 1974, the Atomic Energy Commission (AEC) established ECCS acceptance criteria during postulated loss-of-coolant accidents (LOCAs) in 10 CFR 50.46, ''Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors'' (39 FR 1001; January 4, 1974). The core cooling acceptance criteria in 10 CFR 50.46 were based on the available research, operating experience, and fuel operating conditions applicable to that era. Potential impacts of FFRD phenomena were not understood at that time and were not referenced in 10 CFR 50.46 or the accompanying analysis methods described in appendix K to 10 CFR part 50, ''ECCS Evaluation Models.'' The lack of reference to such phenomena in these regulations may be attributed to the fact that, in the early 1970s, fuel discharge burnups were well below the threshold local burnup (*i.e.,* 55 GWd/MTU) at which FFRD phenomena are now recognized to be a risk. Now that increased enrichment and higher fuel discharge burnups are being contemplated, the NRC is examining the original intent of the rulemaking as well as the current state of knowledge and operational experience to date to develop a performance-based regulatory framework that addresses fuel dispersal in a manner that maintains reasonable assurance of adequate protection of public health and safety.

The acceptance criteria in the original 10 CFR 50.46(b) included limits on peak cladding temperature (PCT) and maximum local oxidation (MLO) in 10 CFR 50.46(b)(1) and (b)(2), respectively, as well as the requirement in 10 CFR 50.46(b)(4) that the core should remain amenable to cooling. As stated in the AEC's 1973 opinion announcing its decision on the 10 CFR 50.46 final rule, the limits on PCT and MLO were intended ''to ensure the zircaloy cladding would remain sufficiently intact to retain the UO_2 fuel pellets in their separate fuel rods and therefore remain in an easily coolable array.'' In other words, these criteria were intended to prevent the fuel from leaving the confines of the cladding.

Regarding the coolability criterion, the AEC envisioned two scenarios that were deemed unacceptable: (1) the ballooning of the cladding to the extent that the coolant passages are blocked and (2) allowing the fuel pellets to fall together into a heap that would be difficult to cool. The 1973 AEC opinion stated that the coolability criterion should be superfluous because of the PCT and MLO criteria, but that the AEC maintained it as a basic objective in view of its fundamental and historical importance. In other words, the objective of the core coolability criterion should not be viewed as different from that of the PCT and MLO criteria. While brittle failure is precluded under the PCT and MLO criteria of 10 CFR 50.46, the AEC understood and accepted that ductile failure (*i.e.,* ballooning and burst) would occur, but it would be limited such that it would not block the coolant flow, as stated in the first unacceptable scenario considered in the formulation of the coolability criterion. Fuel dispersal is typically associated with the ductile failure of cladding encapsulating finely fragmented fuel at local burnups in excess of 55 GWd/MTU. Based on the historical record, the AEC expected the fuel would remain confined by the cladding following ductile failure, as fine fuel fragmentation and dispersal was not a known phenomenon at the time and further would not have been operative at the fuel discharge burnups attained in the early 1970s.

After the AEC's approval of 10 CFR 50.46 in 1973, fuel discharge burnups at operating reactors continued to increase. Fuel fragmentation and relocation were first discovered in the early 1980s, when experiments conducted at several test facilities showed that irradiated fuel could fragment into small pieces during a LOCA and may relocate axially, settling into the ballooned regions. In 1984, the NRC decided to consider the implications of the phenomena in the generic issue (GI) program, specifically as GI–92, ''Fuel Crumbling During LOCA,'' as described in NUREG–0933, ''Resolution of Generic Safety Issues,'' issued September 2021. The NRC found that the known conservatisms in appendix K to 10 CFR part 50 would more than offset the heat generation in the balloon region because of the fragmentation and relocation of fuel in calculations performed under appendix K to 10 CFR part 50.

In the early 1990s, the conclusion of GI–92 was that fuel fragmentation and relocation should be placed no higher than the low priority category of the GI program. This meant that there was insufficient justification for starting a major re-review of existing ECCS performance analyses conducted in adherence to appendix K to 10 CFR part

50. However, there were ongoing efforts to develop and license more realistic (and thus less conservative) ECCS performance models. Therefore, the NRC expected that the ECCS evaluation methodologies would appropriately address fuel fragmentation and relocation in their calculations. As a result, the NRC decided that a separate GI was not necessary, and the issue was later dropped from the GI program in 1995.

Until 2006, there was no expectation from any prior research that fragmentation and relocation into the balloon region could result in the loss of fuel particles through the rupture opening. In 2006, several research tests challenged this assumption. Integral LOCA tests conducted at the U.S. Department of Energy's (DOE's) Argonne National Laboratory on rods up to local burnups of 64 GWd/MTU observed a small amount of fuel loss (about the quantity of one fuel pellet). Since the amount of material was small, this discovery was not thought to be of safety significance. In April 2006, a LOCA test was run in the Halden Reactor Project in Norway on a fuel rod segment with a very high local burnup of 91.5 GWd/MTU. Results from this test showed gross loss of fuel material from above the rupture opening. In this very-high-burnup fuel specimen, more than 40 percent of the fuel material was in a nearly powdered form, as described in NUREG–2121, ''Fuel Fragmentation, Relocation, and Dispersal During the Loss-of-Coolant Accident,'' issued March 2012.

In 2008, the NRC's Office of Nuclear Regulatory Research (RES) issued Research Information Letter (RIL)–0801, ''Technical Basis for Revision of Embrittlement Criteria in 10 CFR 50.46,'' dated May 30, 2008, which discussed research findings in the area of high-burnup fuel performance during postulated LOCAs. The RIL–0801 noted that additional research on fuel dispersal was being conducted but concluded that ''the current NRC burnup limit of 62 GWd/MTU (average for the peak rod) is probably low enough to prevent significant fuel loss during a LOCA.'' The RIL–0801 recommended rulemaking be pursued to revise the criteria in 10 CFR 50.46(b) to account for high burnup phenomena that may cause the current criteria to be non-conservative.

In 2012, the NRC published NUREG–2121 to capture the state of knowledge and history of FFRD as of that time. NUREG–2121 concluded that additional experimental research was needed to quantify the extent and downstream effects of fuel dispersal. Additionally in SECY–15–0148, ''Evaluation of Fuel Fragmentation, Relocation and Dispersal Under Loss-of-Coolant Accident (LOCA) Conditions Relative to the Draft Final Rule on Emergency Core Cooling System Performance During a LOCA (50.46c),'' dated November 30, 2015, the staff concluded that there was ''no imminent safety concern'' for operating reactors with respect to FFRD and that the 10 CFR 50.46c rulemaking should not be delayed to address FFRD. The SECY paper also stated that additional research was ongoing, and that future regulatory action could be initiated, if needed, to address FFRD after more research was conducted.

In December 2021, RES published RIL 2021–13, ''Interpretation of Research on Fuel Fragmentation, Relocation, and Dispersal at High Burnup,'' to inform the NRC's Office of Nuclear Reactor Regulation about RES's interpretation of the FFRD research to date. In RIL 2021–13, the staff defines conservative empirical boundaries for FFRD-related phenomena, such as the amount of fuel that is expected to be dispersed during a LOCA. Additionally, RIL 2021–13 identifies data gaps associated with FFRD-related phenomena. While the models in RIL 2021–13 can be used to estimate the potential mass of fuel that could be dispersed to the coolant, that RIL does not attempt to address the consequences of fuel dispersal into the coolant. To fully characterize such consequences, the NRC needs to better understand the behavior of dispersed fuel particles in the coolant and their impact on core coolability and safety under LOCA conditions that may involve significant core geometry changes due to rod ballooning, significant and varying single- and two-phase core flows, and dynamic LOCA loads. The NRC is involved in several collaborative domestic and international research programs, such as the Studsvik Cladding Integrity Project, which are, in part, addressing some of the data gaps presented in RIL 2021–13. Additionally, the NRC sponsored a phenomena identification and ranking table (PIRT) exercise concerning the consequences of fuel dispersal. The findings of the expert PIRT panel are documented in NUREG/CR–7307, ''Phenomena Identification and Ranking Tables on High Burnup Fuel Fragmentation, Relocation, Dispersal, and Its Consequences for Design-Basis Accidents in Pressurized- and Boiling-Water Reactors,'' and have informed DG–1434, ''Addressing the Consequences of Fuel Dispersal in Light-Water Reactor Loss-of-Coolant Accidents,'' which is being issued for comment with this proposed rule. The PIRT will also help inform future research efforts and NRC review of applications that may evaluate FFRD.

In 2022, in SRM–SECY–21–0109, as part of its approval of the staff's plan to begin this increased enrichment rulemaking, the Commission directed that FFRD should be appropriately addressed and analyzed in the rulemaking's regulatory basis. The NRC considered several alternatives in the regulatory basis, along with other options received in the public comments on the regulatory basis, in developing the following path forward to addressing FFRD.

(b) 10 CFR 50.46a Rulemaking

In 2010, the staff sent to the Commission for approval via SECY–10–0161, ''Final Rule: Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements (10 CFR 50.46a) (RIN 3150–AH29),'' a draft final rule that would have created alternative ECCS requirements in 10 CFR 50.46a. The rule would have divided the current spectrum of LOCA break sizes into two regions. The division between the two regions would have been delineated by the transition break size (TBS). The first region included small breaks, up to and including the TBS. The second region included breaks larger than the TBS, up to and including the double-ended guillotine break (DEGB) of the largest reactor coolant system (RCS) pipe. The likelihood of these larger breaks is much lower than the smaller breaks in the first region, which was used to support a different regulatory treatment for the larger breaks.

In this rulemaking, the NRC proposes to build on the 10 CFR 50.46a rulemaking as a means of analytically resolving FFRD issues. The analytical margins gained from the treatment of large-break LOCAs as beyond-design-basis are expected to eliminate or greatly reduce the calculated quantity of fuel dispersal, as described in section XXXVI.F.(ii), ''Original Determination of the Transition Break Size,'' of this document. While the NRC has attempted to update this proposed rule with information available since SECY–10–0161 was issued, the NRC expects stakeholders will provide significant additional information in their comments on this proposed rule that could support the NRC further risk-informing these aspects of the rule.

(c) 10 CFR 50.46c Rulemaking and Cladding Embrittlement Research Findings

In 2016, the staff sent to the Commission for approval via SECY–16–

0033 a draft final rule to create 10 CFR 50.46c. The draft final rule would have established performance-based regulatory requirements for determining the acceptability of an ECCS for a nuclear power reactor. Similar to existing regulations in 10 CFR 50.46, the draft ECCS performance requirements in 10 CFR 50.46c were largely based upon acceptance criteria for fuel rod cladding performance. The final rule would have expanded the applicability of the 10 CFR 50.46 acceptance criteria from only uranium oxide pellets within cylindrical zircaloy or ZIRLO™ [1] cladding to any LWR fuel, regardless of fuel design or cladding material. The draft final rule also incorporated improved performance-based requirements to address research findings on fuel cladding integrity and degradation mechanisms that were described in RIL–0801.

The Commission returned the 10 CFR 50.46c draft final rule to the staff in SRM–SECY–16–0033, ''Staff Requirements—SECY–16–0033—Draft Final Rule—Performance-Based Emergency Core Cooling System Requirements and Related Fuel Cladding Acceptance Criteria,'' on April 11, 2024. In this SRM, the Commission stated that the staff should reconsider the topics presented in the 10 CFR 50.46c draft final rule and provided the following directions:

1. The staff should apply an appropriate risk-informed regulatory approach to address the research findings on cladding embrittlement effects under LOCA conditions described in SECY–16–0033.

2. The staff should evaluate Item 1 with other associated technical issues being addressed, such as FFRD and risk-informed treatment of LOCAs, including the 10 CFR 50.46a draft final rule.

3. The staff should evaluate whether specific ECCS criteria such as cladding temperature should be codified or instead addressed in regulatory guidance.

This rulemaking proposes to leverage the previously proposed performance-based approach to ECCS requirements, including the expanded applicability to advanced fuels, and incorporate the embrittlement research findings from the 10 CFR 50.46c draft final rule into the new voluntary 10 CFR 50.46a proposed rule and associated guidance. The following discussion describes the embrittlement research findings that the 10 CFR 50.46c draft final rule planned to address and that this rulemaking proposes to address.

[1] ZIRLO is a registered trademark of Westinghouse Electric Company LLC.

All licensees who adopt the new voluntary 10 CFR 50.46a proposed rule would address the embrittlement research findings through their updated analyses and associated acceptance criteria. The NRC would continue to conduct annual safety assessments for licensees that do not choose to adopt the new requirements to confirm reasonable assurance of adequate protection. After the completion of this rulemaking, the NRC would continue to consider whether any new regulatory requirements are needed for these licensees that do not adopt proposed 10 CFR 50.46a because the research findings show that the current criteria may not always ensure that the fuel cladding remains ductile after the reactor is reflooded, referred to as post-quench ductility (PQD). The NRC expects that its assessment of further actions would consider (1) the resource needs for and results of the ECCS annual safety assessments, (2) the industry's plans for adoption of 10 CFR 50.46a, and (3) whether there is a safety basis for additional requirements beyond the promulgation of this voluntary alternative proposed rule. If the majority of the industry adopts 10 CFR 50.46a, then little to no future regulatory action may be needed to resolve these matters.

1. Overview of Cladding Embrittlement Research Findings

Since 1997, the NRC has undertaken a fuel cladding research program to investigate the behavior of high-exposure fuel cladding under accident conditions. This research program included an extensive LOCA research and testing program at Argonne National Laboratory, as well as jointly funded programs at the Kurchatov Institute (supported by the French Institute for Radiological Protection and Nuclear Safety and the NRC) and the Halden Reactor Project (a jointly funded program under the auspices of the Organization for Economic Cooperative Development—Nuclear Energy Agency, sponsored by national organizations in 18 countries). The effects of both alloy composition and fuel burnup on cladding embrittlement (*e.g.,* loss of ductility) under accident conditions were studied in these research programs. The research programs identified new cladding embrittlement mechanisms that were not previously known and expanded the NRC's knowledge of previously identified mechanisms.

2. Major Research Findings Cladding Embrittlement

These research findings have been summarized in RIL–0801, and the detailed experimental results from the program at Argonne National Laboratory are contained in NUREG/CR–6967, ''Cladding Embrittlement during Postulated Loss-of-Coolant Accidents,'' dated July 31, 2008. Since the publication of NUREG/CR–6967 and RIL–0801, additional testing was conducted related to the embrittlement phenomenon, which has been documented in supplemental reports. Where the additional testing relates to conclusions and recommendations in RIL–0801, RIL–0801 has been supplemented to reference the additional reports and incorporate findings (''Update to Research Information on Cladding Embrittlement Criteria in 10 CFR 50.46,'' dated December 29, 2011).

i. Hydrogen-Enhanced Beta-Layer Embrittlement

In current 10 CFR 50.46, the preservation of cladding ductility, via compliance with regulatory criteria on PCT (10 CFR 50.46(b)(1)) and local cladding oxidation (10 CFR 50.46(b)(2)), provides a level of assurance that fuel cladding will not experience gross failure and that the fuel rods will remain within their coolable lattice arrays. The 1997–2016 LOCA research program, as summarized in NUREG/CR–7219, ''Cladding Behavior During Postulated Loss-of-Coolant Accidents,'' identified new cladding embrittlement mechanisms that demonstrated that the current combination of PCT (2200 degrees Fahrenheit (°F) (1204 degrees Celsius (°C)) and local cladding oxidation (17 percent equivalent cladding reacted (ECR)) criteria may not always ensure PQD. As explained in section 1.5 of NUREG/CR–7219, oxygen diffusion into the base metal under LOCA conditions promotes a reduction in the thickness (referred to as beta-layer thinning) and ductility (referred to as beta-layer embrittlement) of the metallurgical structure within the cladding that provides its macroscopic mechanical behavior. The presence of hydrogen within the cladding accelerates this embrittlement process. Hydrogen is produced from the corrosion of zirconium in water, some of which is absorbed by the cladding, which is frequently referred to as ''hydrogen pickup.''

The NRC's cladding embrittlement program did not investigate cladding degradation mechanisms or develop the technical basis for performance-based

requirements beyond the existing 2200 °F (1204 °C) PCT criterion. Examples of degradation mechanisms beyond cladding embrittlement (via oxygen diffusion) include excessive exothermic metal-water reaction, alloy-specific eutectics, and loss of fuel rod geometry due to plastic deformation. As a result, the existing 2200 °F (1204 °C) limit remains an upper limit on PCT for zirconium-based alloys. However, as reflected in this embrittlement criterion in DG–1263, ''Establishing Analytical Limits for Zirconium-Based Alloy Cladding,'' and based on the results of the fuel cladding research program, a lower PCT may be required to preserve ductility. Although the 2200 °F (1204 °C) limit in 10 CFR 50.46 remains unchanged in this rulemaking, the acceptance criteria in proposed 10 CFR 50.46a would establish a requirement to address cladding degradation phenomena, which would include cladding embrittlement. The 2200 °F (1204 °C) temperature is proposed as an acceptable limit in DG–1263 rather than codified in 10 CFR 50.46a.

ii. Oxygen Ingress From Cladding Inside Diameter

As explained in section 1.5.6 of NUREG/CR–7219, oxygen sources may be present on the inner surface of irradiated cladding due to gas-phase uranium trioxide transport prior to gap closure, fuel-cladding-bond formation (uranium dioxide in solid solution with zirconium dioxide), and the fuel bonded to this layer. Under LOCA conditions, this available oxygen may diffuse into the base metal of the cladding, which could cause the cladding to become more brittle.

iii. Breakaway Oxidation

As explained in section 1.5.5 of NUREG/CR–7219, zirconium dioxide can exist in several crystallographic forms, or allotropes. During normal operation, the zirconium dioxide layer that develops has a monoclinic crystallographic structure, which is neither fully dense nor fully protective. During LOCA conditions, the monoclinic oxide will transform to a tetragonal structure, and the oxide that newly forms under LOCA conditions is also tetragonal. The tetragonal oxide is dense, adherent, and protective against hydrogen pickup. However, there are conditions, both mechanical (*e.g.,* local regions of tensile stress) and chemical (*e.g.,* impurities at the metal surface), that promote a transformation of the zirconium dioxide from the tetragonal back to the monoclinic phase. The tetragonal-to-monoclinic transformation is an instability that initiates at local regions of the metal-oxide interface and grows rapidly throughout the oxide layer. Because this transformation results in an increase in oxidation rate, it is referred to as breakaway oxidation. Along with this increase in oxidation rate resulting from cracks in the monoclinic oxide, significant hydrogen pickup also occurs. Hydrogen that enters in this manner during a LOCA transient promotes rapid embrittlement of the cladding.

While all zirconium alloys will eventually experience breakaway oxidation when exposed to long enough durations of high-temperature steam oxidation, the fuel cladding research program demonstrated that alloying composition and manufacturing process (*e.g.,* surface roughness) influence the timing of this phenomenon.

iv. Applicability of Ductility-Based Analytical Limits to Burst Region

During a postulated LOCA, a portion of the fuel rod population may be predicted to experience fuel rod ballooning and cladding rupture as a result of rapid depressurization of the RCS in combination with elevated cladding temperature. The number of burst rods depends on several variables including initial conditions (*e.g.,* fuel rod design, rod internal pressure, rod power) and accident conditions (*e.g.,* LOCA break size, cladding temperature). A burst section of the fuel rod may experience degradation mechanisms beyond oxygen diffusion embrittlement encountered in the remaining portions of the fuel rod, including significant amounts of hydrogen uptake from steam entering the fuel rod through the rupture.

To investigate the mechanical behavior of ruptured fuel rods, the NRC conducted testing, designed to result in the ballooning and burst of as-fabricated and hydrogen-charged cladding specimens and high-burnup fuel rod segments exposed to high-temperature steam oxidation followed by rapid cooling by liquid water, or quench. The research results and conclusions are documented in the NUREG–2119, ''Mechanical Behavior of Ballooned and Ruptured Cladding.'' This testing confirms that continued exposure to a high-temperature steam environment weakens the already flawed region of the fuel rod surrounding the cladding rupture. Hence, limitations on PCT and integral time-at-temperature are necessary to preserve an acceptable amount of mechanical strength and fracture toughness to maintain a coolable fuel geometry. Integral time-at-temperature is related to the time spent at the elevated temperatures seen during the LOCA and typically expressed in terms of the ECR. In addition, the research demonstrated that the degradation in strength and fracture toughness with prolonged exposure to steam oxidation was increased with pre-existing cladding hydrogen content.

These research findings have been summarized in RIL–0801, and the detailed experimental results from the program at Argonne National Laboratory are contained in NUREG/CR–6967, ''Cladding Embrittlement during Postulated Loss-of-Coolant Accidents,'' dated July 31, 2008. Since the publication of NUREG/CR–6967 and RIL–0801, additional testing was conducted related to the embrittlement phenomenon, which has been documented in supplemental reports. Where the additional testing relates to conclusions and recommendations in RIL–0801, RIL–0801 has been supplemented to reference the additional reports and incorporate findings (''Update to Research Information on Cladding Embrittlement Criteria in 10 CFR 50.46,'' dated December 29, 2011).

These research findings presented the NRC with two options for revising the fuel performance requirements: (1) establish a separate performance requirement within the burst region (*i.e.,* analytical limits that preserve sufficient fracture toughness to ensure burst region survival), or (2) apply the hydrogen-based embrittlement analytical limits to the entire fuel rod.

In the absence of a credible analysis of loads, cladding stresses, and cladding strains for a core degraded by LOCA conditions, there are no absolute metrics to determine how much ductility or strength would be needed to provide assurance that fuel rod cladding would maintain its geometry during and following post-LOCA quench. It is also not clear what impact breakage of some fuel rods into two pieces, owing to potential loads following a hypothetical LOCA, would have on core coolability. Fragmentation of fuel rod cladding would be more detrimental to core coolability than severance of rods into two pieces. Even minimal ductility ensures that cladding will have high strength and toughness and, therefore, high resistance to fracturing. Brittle cladding, on the other hand, might fail at low strength and shatter. Therefore, the intent to maintain ductility is beneficial even with limited knowledge of LOCA loads. The research documented in NUREG–2119 showed that if wall thinning and double-sided oxidation are accounted for, then hydrogen-based embrittlement limits, such as the limit provided in Figure 2

of DG–1263, are sufficient to ensure reasonable behavior of the ballooned and ruptured region.

Therefore, the NRC elected to propose a revision to the fuel performance requirements by applying a single performance-based criterion to the entire fuel rod. This decision recognizes that portions of the cladding within the burst region may not maintain ductility. This position is reflected in DG–1263 and supported by the technical basis documented in NUREG–2119.

D. Regulatory Basis

The NRC published the regulatory basis to support a rulemaking for the ''Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors'' in the **Federal Register** on September 8, 2023 (88 FR 61986). In the regulatory basis, the NRC presented draft recommendations that focused on those requirements needed for LWR high-assay, low-enriched uranium fuel, specifically with approved conventional or ATF designs. The NRC requested public comment on these recommendations and asked specific questions associated with the identified regulatory topics. The NRC concluded that there was sufficient regulatory basis to proceed with rulemaking to address the regulatory issues associated with the use of fuel enriched to greater than 5.0 weight percent U–235. The NRC held a public meeting on October 25, 2023, to discuss the regulatory basis and issued a summary of the meeting on November 21, 2023.

The public comment period for the regulatory basis closed on January 22, 2024. The NRC received 15 public comment submissions on the regulatory basis, which are available for review at *www.regulations.gov* under Docket ID NRC–2020–0034. Table 1 of this document provides ADAMS references for these public comment submissions. Section XXXVI.F.(xiv), ''Discussion of Public Comments on the Fuel Dispersal Aspects of the Regulatory Basis,'' of this document includes the NRC's summaries of, and responses to, the comments that the NRC used to inform the development of this proposed rule and the draft regulatory analysis.

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Table 1—ADAMS References for Public Comment Submissions on the Regulatory Basis.

Commenter	Commenter Type	Accession Number
Michael Ravnitzky	Individual	ML23312A238
Union of Concerned Scientists	Advocacy organization	ML23331A263
PWR Owners Group	Nuclear industry trade association	ML24017A175
Urenco USA	Nuclear industry company	ML24022A127
World Nuclear Transport Institute	Nuclear industry trade association	ML24022A128
John Parillo	Individual	ML24022A241
Grant Wade	Individual	ML24022A242
BWR Owners' Group	Nuclear industry trade association	ML24023A601
Anonymous 1	Anonymous	ML24023A602
Anonymous 2	Anonymous	ML24023A603
Nuclear Energy Institute	Nuclear industry trade association	ML24023A604
Westinghouse Electric Company	Nuclear industry company	ML24023A655
Connie Kline	Individual	ML24024A051
Framatome	Nuclear industry company	ML24024A071
Kalene Walker	Individual	ML24025A012

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XXXVI. Discussion—Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors

This proposed rule would amend the current regulations related to the use of conventional and accident tolerant LWR fuel designs. From interactions with stakeholders, the NRC is aware that licensees and applicants plan to request higher fuel burnup limits (*i.e.,* above 62 GWd/MTU rod average) along with the deployment of ATF concepts. To achieve higher burnup limits, licensees and applicants would need to request increases in fuel enrichment above the current standard of 5.0 weight percent U–235.

One of the NRC's goals in this rulemaking is to establish effective and efficient licensing of applications using fuels enriched to greater than 5.0 weight percent U–235, including reducing the need for requests for exemptions from existing regulations, while continuing to provide reasonable assurance of adequate protection of public health and safety.

The NRC proposes revising requirements in six technical areas.

A. Criticality Accident Requirements in 10 CFR 50.68

The NRC proposes to amend 10 CFR 50.68(b)(7) to allow licensees or applicants that comply or propose to comply with that section's criticality safety requirements to enrich their fuel beyond the current limit of 5.0 weight percent U–235. Each licensee or applicant would have the option between the existing 5.0 weight percent U–235 enrichment limit or the value specified in their OL. The enrichment limit is most often specified as a technical specification design feature as defined in 10 CFR 50.36(c)(4) and is currently part of generic standard technical specifications for various reactor technologies, as described in section XXXV.C.(i), ''10 CFR 70.24 and 10 CFR 50.68 Criticality Accident Requirements,'' of this document.

The proposed change would not affect safety. Licensees and applicants electing higher enrichments would be required to ensure the same minimum margin to subcriticality that is required for licensees implementing 10 CFR 50.68 with fuel enriched up to 5.0 weight percent U–235. Maintaining these margins of safety would be accomplished by applying the same keff safety limits for higher enriched fuels as for fuel enriched up to 5.0 weight percent U–235. Licensees or applicants that would seek to implement the requirements of 10 CFR 50.68 while using fuel enriched above 5.0 weight percent U–235 would need to submit for NRC review and approval a fuel transition license amendment request. These requests would need to include calculations that show that the new and spent fuel storage applications demonstrate compliance with the keff safety limits specified in 10 CFR 50.68.

The proposed revision also would meet one of the purposes of this rulemaking: allow a licensee the option to implement fuel enriched to greater than 5.0 weight percent U–235 without requiring the licensee to seek specific exemptions from 10 CFR 50.68 requirements.

This change would not result in any significant radiological consequences that could impact plant workers or members of the public. While increased enrichment would add more radioactive material to the spent fuel pool, this increase would not change the anticipated dose rates for occupational dose to workers in and around the fuel storage areas or for members of the public beyond the site boundary because the material in the pool is completely shielded by water.

The keff safety limits specified in 10 CFR 50.68(b)(2), (3), and (4) would be maintained at their current levels with the same required probability and confidence levels. The feasibility study contracted by the NRC, ORNL/TM–2024/3350, ''Scoping Studies on the Impacts of Increased Enrichment on Nuclear Criticality Safety,'' May 2024, indicates that existing fuel technologies, like integral fuel burnable adsorber coatings and gadolinium burnable poisons, should be able to maintain compliance with 10 CFR 50.68 requirements for the entire range of low enriched uranium (*i.e.,* up to 19.75 weight percent U–235). However, if the increased enrichment were to adversely impact the subcriticality requirements, then additional modifications to the fuel storage facilities would be required to restore compliance.

The NRC received several comments on the regulatory basis that suggested that the NRC revise RG 1.240, ''Fresh and Spent Fuel Pool Criticality Analyses,'' in coordination with any changes to 10 CFR 50.68. In March 2021, the NRC issued RG 1.240, which endorses NEI 12–16, Revision 4, ''Guidance for Performing Criticality Analyses of Fuel Storage at Light-Water Reactor Power Plants,'' dated September 2019. The NRC reviewed this guidance during the development of the regulatory basis and determined that neither RG 1.240 nor NEI 12–16, Revision 4 is specifically dependent on enrichment levels, whether at the current levels or those considered in this proposed rule. During this review, the NRC also noted that RG 1.240, section C.1.o specifies that the document's recommendations are based on existing fuel applications currently in widespread industry use, and that new and novel configurations and concepts implemented in the future may require additional justification for continued use of the assumptions and recommendations. However, the NRC did not identify any cases where the regulatory guidance would not be applicable to the enrichment levels being considered in this proposed rule. Further, licensees may provide any necessary justification as part of license amendment requests. Therefore, the NRC concluded that the guidance does not need to be immediately updated as a part of this rulemaking effort. The NRC observes that future revisions of RG 1.240 desired by industry stakeholders should be pursued separately under the standard regulatory guide maintenance and revision process.

B. Uranium Fuel Cycle Environmental Data—Table S–3 in 10 CFR 51.51

The NRC proposes to provide a regulatory justification in 10 CFR 51.51(b) for the use of table S–3 for fuel enrichment up to 20.0 weight percent U–235. This rulemaking action is predicated on the information provided by current LWR licensees to use enriched nuclear fuel of up to 10.0 weight percent U–235 and by new reactor developers to use high-assay low enriched uranium with enrichment levels greater than 10.0 weight percent U–235 and less than 20.0 weight percent U–235. The regulatory justification would be included in a proposed amendment of 10 CFR 51.51(b), table S–3, note 1. Specifically, note 1 would be amended to add a discussion of NUREG–2249, ''Generic Environmental Impact Statement for Licensing of New Nuclear Reactors—Final Report,'' for the environmental effects of up to 20.0 weight percent U–235 on the uranium fuel cycle as still bounded by table S–3, and text explaining the rationale for the addition of this document. NUREG–2249 discusses the High-Assay Low-Enriched Uranium (HALEU) Availability Program under the DOE with the direction to secure a domestic supply of HALEU fuel following the Energy Act of 2020. As outlined in NUREG–2249 section 3.14.1.3, DOE has identified and contracted with partners for enrichment services for the production of HALEU as UF_6. Additionally, DOE has identified and contracted with partners for deconversion of HALEU stored as UF_6 to other chemical forms (*i.e.,* metal or oxide) for fuel fabrication purposes. The DOE HALEU Availability program is ongoing and has produced the first quantities of HALEU with further expansion of production capacities expected over the next several years. NUREG–2249 concludes that for the enrichment of uranium, table S–3 would bound the environmental impacts from a centrifuge enrichment facility to produce HALEU and the impact would be SMALL.

Note 1 would also be amended to add a reference to NUREG–2266, ''Environmental Evaluation of Accident Tolerant Fuels with Increased Enrichment and Higher Burnup Levels,'' for the environmental effects of up to 80,000 MWd/MTU maximum assembly averaged burnup as still bounded by table S–3, and text explaining the rationale for the addition of this document. This is because the analysis in WASH–1248 was based on 12-month refueling cycles and lower enrichment and burnup levels than are used for the

current fleet of LWRs. The higher burnup levels achieved since issuance of WASH–1248 result in greater utilization of the uranium fuel (*i.e.,* greater efficiency in extracting energy from the fuel). This also has resulted in extended time between refueling operations and the removal of fewer fuel assemblies on a per reactor-year basis for many of the operating nuclear power plants. Deployment and use of nuclear fuels with increased enrichment and higher burnup levels would result in further increases in fuel efficiency in extracting energy, resulting in further reductions in the number of spent nuclear fuel assemblies removed during refueling operations and further extending the time between refueling operations. Thus, the use of nuclear fuels with increased enrichment and higher burnup levels would reduce the annual nuclear fuel needs to support refueling to below the figures that were used in the analysis supporting Table S–3.

C. Environmental Effects of Transportation of Fuel and Waste—Table S–4 in 10 CFR 51.52

The NRC proposes to permit the use of table S–4 of 10 CFR 51.52 for fresh nuclear fuel shipments with increased enrichment up to 8.0 weight percent U–235 by applying the supporting transportation analysis from NUREG–2266. The maximum enrichment level in the supporting core analysis relied upon in NUREG–2266 went as high as 8.0 weight percent U–235. This proposed amendment would include a change to the enrichment and burnup conditions under 10 CFR 51.52(a), adding a new note 2 to table S–4 along with moving the current note 2 to note 3, and adding a new note 4 to table S–4 to replace the current note 3. The transportation analyses in NUREG–2266 would be referenced in table S–4, note 2, with text explaining the rationale for the addition of this document for addressing this enrichment level as well as a level of burnup of up to 80,000 MWd/MTU for UO_2 fuel. Any licensing action with enrichments above 8.0 weight percent U–235 would have to be addressed on a case-by-case basis, in accordance with 10 CFR 51.52(b), by providing a full description and detailed analysis of the environmental effects of the transportation of fuel and waste. The methodology in NUREG–2266, section 3, ''Transportation,'' could be applied for such a detailed analysis. Note 2 would also include the environmental effects of burnup levels of up to 133,000 MWd/MTU for TRISO fuel as still bounded by table S–4.

This rulemaking also proposes revisions and updates to 10 CFR 51.52(a), (b), and (c), which provide for the evaluation of the environmental impacts of transportation of fuel and waste to and from the reactor for LWRs. Reactors other than light-water-cooled nuclear power reactors (*i.e.,* non-LWRs) will utilize the same uranium fuel cycle as LWRs with the transportation of material between uranium fuel cycle stages plus transportation to and from the nuclear power plant. The transportation of fuel to and waste from non-LWRs, like transportation of fuel and waste for LWRs, is necessary to support the operation of the plant. Therefore, the environmental impacts of transportation, regardless of whether for an LWR or non-LWR, must be assessed by the NRC. Similarly, the NRC's regulations in 10 CFR 51.50(b)(3) and (c) already provide for the evaluation of the environmental impacts of the uranium fuel cycle for non-LWRs. To ensure there is regulatory clarity for the transportation of non-LWR fuel and waste in a similar manner as there is for the uranium fuel cycle for non-LWRs, and for the transportation of fuel and waste for LWRs and non-LWRs, the words ''other than light-water-cooled nuclear power reactors'' from 10 CFR 51.50(b)(3) and (c), would be added to the introductory paragraph of 10 CFR 51.52 and 10 CFR 51.52(b).

The NRC also proposes to update the information in paragraph (c), table S–4, to the current conditions for the transportation of radioactive material and the impacts important to such transportation. The transportation weight values would be adjusted for trucks to the current U.S. Department of Transportation regulations of 80,000 lb per truck (23 CFR part 658, ''Truck Size and Weight, Route Designations—Length, Width and Weight Limitations'') and for rail cars to 240 tons per cask per rail car based on DOE information on the developed Atlas spent fuel rail car (DOE Article, ''New Railcar Designed to Transport Spent Nuclear Fuel Cleared for Operation,'' June 4, 2024). The NRC also would remove the cumulative dose values from table S–4 because this information is redundant to the exposed individual doses also being provided in table S–4 and is a very small fraction of the average natural background annual radiation exposure of 310 millirem (0.0031 Sv) per person. For example, the 1,469,000 persons along the route for the updated table S–4 would receive on an annual basis approximately 1469 person-rem from natural radiation sources. Thus, the 3 or 4 person-rem in the current table S–4 would only add the insignificant amount of approximately 0.3 percent of additional cumulative radiation exposure from the transportation of fuel and waste for the 1,469,000 persons along the route for all annual shipments.

The $475 property damage per reactor year would be removed from table S–4 because this value dates back to 1972 in appendix C of WASH–1238, the risk of a transportation accident is very small as shown in NUREG–2266, and there has not been a radiological transportation accident in the United States that would have resulted in property damage greater than the amount of damages from a commercial hazardous material transportation accident. If necessary, to determine the property damage risk from transportation accidents, the same methodology in appendix C of WASH–1238 can be applied on a case-by-case basis by assessing the annual shipment miles multiplied by the probability of an accident per mile and multiplied by the average worth of property damage per accident with property damage in that year.

D. Fissile Material Packaging Requirements in 10 CFR 71.55

The NRC proposes to increase the allowable enrichment range in its fissile packaging requirements through a graded approach and include an additional design requirement for enrichment levels from 5.0 to 10.0 weight percent U–235 to enable the use of the exception in 10 CFR 71.55(g) and remove the requirement to consider water in-leakage. The existing 5.0 weight percent U–235 enrichment limitation is based on standard industry and worldwide practice rather than a calculated effect on criticality of moderator in-leakage for UF_6 enriched to this level. Because the basis for approval of the exception relies on the performance requirement for the cylinder during the specified tests in 10 CFR 71.73, ''Hypothetical accident conditions,'' the NRC has concluded that the addition of a design feature (*e.g.,* valve protection device) of the individual cylinders containing UF_6 with enrichments greater than 5.0 weight percent U–235 would be consistent with the current performance-based requirements contained in 10 CFR 71.55(g) as well as risk insights gained from operational experience. This design enhancement requirement would provide additional defense-in-depth against water in-leakage that considers the relative consequences of an inadvertent criticality as a function of increasing enrichment level.

The NRC considered including in the proposed rule enrichments between 10.0 weight percent U–235 up to but less than 20.0 weight percent U–235. Although the NRC could consider additional prescriptive and non-technology inclusive defense-in-depth design requirements to mitigate the increasing risk of a criticality event as a function of this range of enrichment levels, the NRC could not formulate a technical or regulatory justification for providing a redundant, prescriptive, and non-technology inclusive exception from 10 CFR 71.55(b), which was already functionally present in 10 CFR 71.55(c) for all fissile material transportation packages. The provisions in 10 CFR 71.55(c) could be used to achieve the same desired regulatory outcome, including enrichments for UF_6 packages up to but less than 20.0 weight percent U–235, while maintaining the principles of good regulation of efficiency, clarity, and reliability.

This proposed amendment to 10 CFR 71.55(g) differs from the regulatory basis recommendation to not pursue a change in the regulations. Part of the rationale for that recommendation was based on the staff's assumption that the rule change would be cost-neutral based on only rulemaking and licensing costs. However, that analysis did not consider indirect shipping costs to the industry, an exclusion that the nuclear industry, in comments on the regulatory basis, described as a departure from the principles of good regulation. The NRC received public comments on the regulatory basis that demonstrated that there was sufficient net positive effect for fuel enrichment facilities and fuel fabricators to consider a rulemaking approach that would be cost-beneficial and maintain adequate protection of the public health and safety.

During the development of the regulatory basis for this proposed rule, the nuclear industry and the NRC identified that a change to 10 CFR 71.55(g) could create a misalignment with U.S. Department of Transportation and IAEA standards. The American National Standards Institute (ANSI) was in the process of revising its N14.1 standard, ''Nuclear Materials–Uranium Hexafluoride–Packagings for Transport'' (ANSI N14.1), when the regulatory basis was developed. The standard ANSI N14.1 was subsequently finalized, and its incorporation into U.S. Department of Transportation regulations will likely remove any potential misalignment that was identified in the regulatory basis. Specifically, ANSI N14.1 maintains a reference to a 5.0 weight percent U–235 limit but now allows for additional flexibility to the regulatory authority to make the final safety determination independent of an enrichment limit. In addition, future routine harmonization activities for transportation regulations with the IAEA will also likely remove any misalignment.

E. Control Room Requirements in 10 CFR 50.67 and GDC 19

This proposed rule would increase the numerical value of the control room design criteria from 5 rem to 10 rem (0.05 to 0.10 Sv); the value may range up to 25 rem (0.25 Sv) TEDE with consideration of the plant-specific risk profile or risk information. Increasing this value would support increased fuel enrichments and the expected associated increases in power levels and fuel burnup by preserving operational flexibility by providing additional safety margin and avoiding occupational exposures. In addition, the NRC would make minor editorial changes to 10 CFR 50.67 to remove the term ''total effective dose equivalent'' after the abbreviation ''TEDE'' is provided for that term.

Comments on the regulatory basis document indicated potential misunderstanding and concern about potential outcomes resulting from the proposal to amend the control room design criteria. Although the control room design criteria are distinct from operational dose limits, the NRC recognizes the two concepts share some similarities. Specifically, both the operational occupational exposure limit in 10 CFR part 20 and the control room design criteria are numerically equivalent and use the same unit of ''rem TEDE.'' As part of this rulemaking effort, the NRC attempts to clearly explain that the proposed changes would only be to the control room design criterion and would not change normal operational and emergency exposure limits of 10 CFR part 20.

The NRC recognizes the challenges that licensees face to retain margin within their licensing bases for the purposes of operational flexibility and the small amount of margin to the control room design criteria itself. The key driver behind the proposal to amend the control room design criteria is to facilitate increased regulatory efficiency and consistency while continuing to provide adequate protection of public health and safety. An unjustifiably low design criteria could unnecessarily burden licensees for seeking increased enrichments by requiring extensive analyses to preserve margin for operational flexibility purposes. As discussed in section XXXV.C.(iv), ''Appendix A to 10 CFR part 50 (General Design Criterion 19) and 10 CFR 50.67(b)(2)(iii),'' of this document, these analyses do not necessarily result in safety benefits and can increase actual operational exposure to workers due to increased maintenance activities.

The proposed numerical value of the control room design criteria in 10 CFR 50.67 and GDC 19 would increase from 5 to 10 rem (0.05 to 0.10 Sv) with a consideration of the plant-specific risk profile or risk information. Nuclear power reactor licensees would benefit from a higher, and safe, performance level between 5 and 10 rem (0.05 and 0.10 Sv) TEDE when implementing advanced nuclear fuel technologies and operational flexibility. If additional operational flexibilities are needed beyond 10 rem (0.10 Sv) TEDE, facility-specific risk profile or risk information can be leveraged to justify a higher numerical value up to 25 rem (0.25 Sv) TEDE.

Under the current regulations in 10 CFR 20.1201 and 20.1206, an adult worker can receive radiation exposure of up to 10 rem (0.10 Sv) TEDE within a single calendar year or over a 12-month period straddling two calendar years under normal operations. The control room design criterion of 5 rem (0.05 Sv) TEDE, which is intended to assess the acceptability of a given control room design for a potential reactor accident of exceedingly low probability, is at least a factor of two lower than what is found to be acceptable under normal operations. Thus, the proposed rule increase in the control room design criterion to 10 rem (0.10 Sv) TEDE would be consistent with the Commission's current regulations for normal operations.

The proposed rule would enable a higher control room design criteria, ranging from 10 to 25 rem (0.10 to 0.25 Sv) TEDE, for licensees whose facility-specific risk profiles warrant them. This range is consistent with recommendations from national and international organizations responsible for radiation protection standards. These recommendations are based on fundamental modern health physics and radiation epidemiology knowledge. These organizations generally recommend emergency exposure doses up to 25 rem (0.25 Sv) TEDE or 50 rad (0.5 gray) whole body. Thus, the proposed control room design criterion of 10 rem (0.10 Sv) TEDE intended to assess the acceptability of a given control room design for a potential reactor accident of exceedingly low probability is generally bounded by recommended values to protect against radiation exposure during an accident. As described in section XXXV.C., ''Background and History of Affected

Regulations,'' of this document, updated scientific recommendations for radiation protection for workers under accident and emergency conditions help form the technical basis for the proposal to increase the control room design value from 5 rem (0.05 Sv) TEDE originally based on the occupational exposure limit in 10 CFR part 20.

The upper range of the proposed numerical values would be consistent with the Commission's use of the 25 rem (0.25 Sv) TEDE limit primarily in regulations for power reactor siting to protect the public during emergencies, as specified in 10 CFR 100.11, ''Determination of exclusion area, low population zone, and population center distance''; 10 CFR 50.34, ''Contents of applications; technical information''; 10 CFR 50.67; and 10 CFR part 52 for the exclusion area boundary and low population zone. As discussed in the preamble for the final rule updating the NRC's siting criteria (61 FR 65157; December 11, 1996), the Commission's use of 25 rem (0.25 Sv) TEDE does not imply that the Commission considers it to be an acceptable limit for an emergency dose to the public under accident conditions, but only that it represents a reference value to be used for evaluating plant features and site characteristics intended to mitigate the radiological consequences of accidents in order to provide assurance of low risk to the public under postulated accidents. The Commission, based upon extensive experience in applying this criterion and in recognition of the conservatism of the assumptions in its application (*i.e.,* a large fission product release within containment associated with major core damage; maximum allowable containment leak rate; a postulated single failure of any of the fission product cleanup systems, such as the containment sprays; adverse site meteorological dispersion characteristics; an individual presumed to be located at the boundary of the exclusion area at the centerline of the plume for two hours without protective actions), determined that the 25 rem (0.25 Sv) TEDE criterion clearly resulted in an adequate level of protection. As an illustration of the conservatism of this assessment, the Commission noted that the maximum whole-body dose received by an actual individual during the accident at Three Mile Island Nuclear Station in March 1979, which involved major core damage, was estimated to be about 0.1 rem (0.001 Sv).

A review of modern health physics and radiation epidemiology knowledge provides further technical background for proposing to amend the control room design criteria to a higher, and safe, performance level. An important distinction from this review (see section XXXV.C., ''Background and History of Affected Regulations,'' of this document) highlights that the control room design criterion radiation unit of ''rem TEDE'' does not technically correspond with the expected measured deterministic health effects from a reactor accident that would prevent operators from performing their safety function of protecting the public health and safety. These deterministic health effects are best expressed in the radiation unit of ''rad.'' The 10 CFR part 20 annual occupational exposure limit of 5 rem (0.05 Sv) TEDE, which is applicable under accident and emergency conditions, is set sufficiently low that no deterministic threshold dose would be reached.

To clarify the purpose of the control room design criteria contained in GDC 19 and repeated in 10 CFR 50.67, and to distinguish the control room design criteria from the radiation protection and EP frameworks, the NRC is proposing several editorial changes to both provisions. The phrase ''Adequate radiation protection'' in 10 CFR 50.67(b)(2)(iii) and GDC 19 would be replaced with ''The necessary design, fabrication, construction, testing, and performance criteria for structures, systems, and components important to safety.'' As explained in the introduction to appendix A to 10 CFR part 50, ''General Design Criteria for Nuclear Power Plants,'' SSCs important to safety are those SSCs that provide reasonable assurance that the facility can be operated without undue risk to the health and safety of the public. In the case of control room design, the original role of GDC 19 was to ensure that adequate SSCs were provided to permit occupancy of the control room during an accident. The adequacy of the control room SSCs was to be determined by the ability of workers to occupy the control room for the duration of an accident without exceeding the radiological design criteria specified in GDC 19. However, over time the phrase ''adequate radiation protection'' in GDC 19 has been conflated with the NRC's statutory standard of adequate protection. Adequate protection is achieved through a licensee's compliance with the NRC's comprehensive regulatory framework, of which the GDC is one part, and not just a particular design criterion. To increase consistency between these rules, the phrase ''Adequate radiation protection'' in 10 CFR 50.67(b)(2)(iii) and GDC 19 would be replaced with ''The necessary design, fabrication, construction, testing, and performance'' to be consistent with appendix A to 10 CFR part 50. Appendix A to 10 CFR part 50 requires that the principal design criteria establish the necessary design, fabrication, construction, testing, and performance requirements for SSCs important to safety.

To further clarify the purpose of 10 CFR 50.67 and GDC 19 as they relate to the radiation protection and emergency response frameworks, the phrase ''personnel receiving'' in 10 CFR 50.67 and GDC 19 would be replaced with ''calculated'' and the phrase ''access to and'' would be deleted because the traditional DBA radiological consequence analyses performed to demonstrate compliance with the criteria do not assess actual ''personnel receiving'' radiation exposures or plant personal traveling from the site boundary to the control room. The use of a dose-based control room design criterion does not imply that it would be an acceptable exposure during emergency conditions, or that the radiation protection standards and emergency response standards of 10 CFR part 20 and part 50 might not apply. Rather, these analyses assess the acceptability of design provisions for protecting control room operators under postulated DBA conditions. The DBA conditions assumed in these analyses, although credible, generally do not represent actual accident sequences. These DBA conditions are specified as conservative surrogates to create bounding conditions for assessing the acceptability of engineered safety features.

However, rare events (*e.g.,* events involving multiple failures) can exceed the design basis of the facility originally envisioned by the designers. During such events, the Commission's regulations for radiation protection and emergency response programs require licensees to take measures to minimize actual radiation exposures. The on-shift emergency coordinator has the authority and responsibility to immediately and unilaterally initiate any emergency actions. These emergency actions include establishing higher exposure limits if necessary to provide public health and safety. Furthermore, arrangements are made not only with respect to the detection and assessment of dose or intake of ionizing radiation, but also with respect to the mitigating interventions that may have to be applied to further protect workers. The traditional DBA radiological consequence analyses do not necessarily credit these mitigative interventions as they do not directly assess the performance of the control room

habitability envelop design itself. As a result, actual doses received during an event are expected to be significantly lower than the computed results in realistic accident scenarios.

The graded, risk-informed, and performance-based framework developed for DG–1425 (proposed revision 2 of RG 1.183), ''Alternative Radiological Source Terms for Evaluating Design-Basis Accidents at Nuclear Power Reactors,'' would enable a performance-based evaluation using traditional deterministic radiological consequence analysis methods within defined risk-informed boundaries as described in ''Method for Graded Risk-Informed Performance-Based Control Room Design Criteria Framework,'' dated September 2024. These boundaries would be defined by acceptable radiation exposure guidelines for radiation workers during accident and emergency conditions and acceptable contemporary nuclear facility risk profiles using modern PRA methods. Such a framework would provide flexibility when determining how to meet an established acceptance criterion in a way that encourages and rewards safety of the facility consistent with the Commission's policy in SRM–SECY–98–144, ''Staff Requirements—SECY–98–144—White Paper on Risk-Informed and Performance-Based Regulation,'' dated March 1, 1999. In practice, the method would produce a framework that uses, in part, the facility's safe design and operations to justify a higher control room design criterion with a lower plant-specific risk metric.

The DG–1425 framework leverages a licensee's existing PRA model. Acceptability of the PRA model used to demonstrate that the specified criterion is commensurate with the risk of the plant is determined for the following aspects: scope, level of detail, conformance with PRA technical elements (*i.e.,* technical robustness), and plant representation and PRA configuration control. The PRA model would be consistent with the philosophy in RG1.174 and the technical adequacy expectations for the model in RG 1.200. For instance, the use of overall core damage frequency (CDF) results from an NRC-approved license amendment request that incorporates the risk-informed completion time program into the facility's technical specifications (*i.e.,* Technical Specifications Task Force Traveler 505, ''Provide Risk-Informed Extended Completion Times—RITSTF Initiative 4b'') would be acceptable. The baseline PRA model would estimate the overall CDF for all significant sources of risk both internal and external to the plant (*e.g.,* internal, flood, fires, seismic, high winds, and others).

The CDF risk metric would be the most appropriate for the purposes of a graded, risk-informed, and performance-based control room design criteria framework. This is because CDF accounts for a broad range of accident scenarios and can generally encompass the risk relevant to the sequences considered for control room habitability when deriving the maximum hypothetical accident source term. There is also consistency between the CDF risk metric, which does not consider radiation protection protective actions, and the traditional DBA radiological consequence analysis performed to demonstrate compliance. Additionally, control room habitability design primarily concerns the ability of personnel to maintain reactor safety during and after accidents, which aligns closely with the overarching goals of preventing core damage and mitigating radiological releases, which are captured by the CDF risk metric.

In the regulatory basis for this proposed rule, the NRC sought comments on the alternatives proposed in that document's appendix A, ''Control Room Requirements.'' Additionally, the NRC asked two questions. The first question sought input as to whether the numerical selection of the control room design criteria would be better aligned with regulations designed to limit occupational exposures during emergency conditions or regulations designed to limit annual occupational radiation exposures during normal operations. The second question sought input as to whether a graded, risk-informed method to demonstrate compliance with a range of acceptable control room design criterion values instead of a single selected value, such as the current 5 rem (0.05 Sv) TEDE, provides the necessary flexibilities for current and future nuclear technologies.

Overall, public comments were supportive of the staff's recommendation to amend the control room design criteria. The comments in support of alternative 2 generally suggested a value of 25 rem (0.25 Sv) TEDE be applied in amended regulations. Commenters stated that using a value of 25 rem (0.25 Sv) TEDE would be more consistent with the various U.S. and international organizations' recommendations for emergency dose limitations up to 25 rem (0.25 Sv) TEDE. Nearly all comments included suggestions to develop a graded, risk-informed approach to the control room design criteria. Several comments relied on PRA technology and methods and contemporary understandings of facility risk to justify a higher numerical value for low-probability, high-consequence events.

Based, in part, on the comments received, the NRC is proposing to increase the numerical value of the control room design criteria from 5 to 10 rem (0.05 to 0.10 Sv) TEDE but range up to 25 rem (0.25 Sv) TEDE with a consideration of the plant-specific risk profile or risk information. In response to stakeholder interest, the NRC developed a graded, risk-informed, and performance-based control room design criteria framework for the supporting regulatory guidance.

F. Fuel Dispersal

(i) Overview

Based on the Commission's direction in SRM–SECY–21–0109, the public comments on the regulatory basis (see section XXXVI.F.(xiv), ''Discussion of Public Comments on the Fuel Dispersal Aspects of the Regulatory Basis,'' of this document) for details on the public comments received on the fuel dispersal portions of the regulatory basis), the anticipated impacts on this rulemaking's schedule from each of the alternatives described in the regulatory basis, the technical maturity of those alternatives, and the anticipated impact on safety of each of the alternatives, the NRC proposes to address fuel dispersal in this rulemaking. Specifically, the proposed rule would designate LOCAs above the TBS as beyond-design-basis, allowing for best-estimate analysis for such LOCAs, while instituting performance-based cladding embrittlement criteria, and clarifying and updating the NRC's definition of coolability for the LOCA event to encompass both fuel in the reactor core and any fuel dispersed into the RCS or containment.

The proposed flexibility in ECCS analyses for LOCAs above the TBS might enable entities using the proposed rule to demonstrate that no fuel dispersal occurs for LOCAs above the proposed TBS. These entities would be able to use the best-estimate (*i.e.,* based on conditions consistent with expected, nominal operating conditions without biases or uncertainties) modeling under proposed 10 CFR 50.46a(e)(3) for this category of LOCAs until more data or analyses are developed to address fuel dispersal in another way, such as a demonstration that the fuel remains coolable if there is fuel dispersal and the other downstream consequences of dispersal do not have any significant

deleterious impacts. The proposed rule would redesignate existing 10 CFR 50.46a (which contains acceptance criteria for RCS venting systems) as 10 CFR 50.46b and establish an alternative set of risk-informed requirements in a new proposed 10 CFR 50.46a with which entities could choose to comply in lieu of meeting the current emergency core cooling system requirements in 10 CFR 50.46. Using these alternative ECCS requirements would provide some entities with opportunities to change various aspects of their facility design and operation, although potential impacts of the changes pertaining to plant physical security or cybersecurity would be evaluated during license amendment reviews.

As used in proposed 10 CFR 50.46a and this discussion of proposed 10 CFR 50.46a, ''entities'' would include applicants for and holders of CPs, OLs, COLs, standard design approvals, and MLs, and applicants for standard design certification rules (including such applicants after NRC issuance of a final standard design certification rule).

The proposed rule would divide the current spectrum of LOCA break sizes into two regions. The division between the two regions would be delineated by the TBS. The first region would include small size breaks, up to and including the TBS. The second region would include breaks larger than the TBS, up to and including the DEGB of the largest RCS pipe. While both sets of breaks are unlikely to occur, the larger breaks are considered to have a much lower likelihood of occurring than the smaller breaks in the first region. Under the proposed rule, the ECCS design requirements for breaks smaller than the TBS would remain the same as the requirements for all breaks under the current 10 CFR 50.46 ECCS rule. By contrast, under the proposed rule, the ECCS design requirements for the pipe breaks larger than the TBS could be analyzed using less conservative assumptions based on their lower likelihood of occurrence. Although LOCAs for break sizes larger than the TBS would be classified as ''beyond-design-basis accidents'' for entities that implement the proposed 10 CFR 50.46a, these break sizes in license applications would still be subject to regulatory evaluation. The proposed rule would require that entities maintain the ability to mitigate all LOCAs, up to and including the DEGB of the largest RCS pipe. Mitigation analyses for LOCAs larger than the TBS would not need to assume the loss of offsite power or the occurrence of a coincident single failure event. Entities also would be allowed to credit the use of non-safety-grade systems.

Entities who perform LOCA analyses using the proposed risk-informed alternative requirements could find that their plant design or operation is no longer limited by certain parameters associated with previous DEGB analyses. Reducing the DEGB limitations would allow some entities to propose a wide scope of design or operational changes until another parameter in required accident analyses becomes limiting. Potential design changes could include fuel burnup increases and other management improvements; power uprates; and changes to the required number of accumulators, diesel start times, sequencing of equipment, valve stroke times, and containment spray system setpoints. Some of these design and operational changes could increase plant safety because an entity could modify its systems to better mitigate the more likely, but still very rare, smaller LOCAs. Other changes, such as increasing power, could increase the overall risk of inadvertent release of radioactive material, which may be acceptable if the overall plant risk increase is demonstrated to be acceptably small.

The risk-informed proposed 10 CFR 50.46a would include risk acceptance criteria for evaluating future design changes to ensure that any risk increases would be acceptably small. These acceptance criteria would be consistent with the guidelines for risk-informed license amendments in RG 1.174, ''An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis,'' and ensure both the acceptability of the changes from a risk perspective and the retention of sufficient defense-in-depth, safety margins, and performance monitoring. The requirements for the risk-informed evaluation process are discussed in detail in section XXXVI.F.(vi), ''Risk-Informed Changes to the Facility, Technical Specifications, or Procedures,'' of this document.

In addition to changes to current 10 CFR 50.46a, which would be redesignated as 10 CFR 50.46b, and establishing a new proposed 10 CFR 50.46a, the NRC would make conforming changes to existing 10 CFR 50.46, and 50.69; GDC 17, 35, 38, 41, 44, and 50 in appendix A to 10 CFR part 50; appendix K to 10 CFR part 50; 10 CFR 52.54; and appendix G to 10 CFR part 52.

(ii) Original Determination of the Transition Break Size

To help determine the TBS in support of the prior 10 CFR 50.46a rulemaking (see section XXXV.C.(v)(b), ''10 CFR 50.46a Rulemaking,'' of this document), the NRC developed pipe break frequencies as a function of break size using an expert elicitation process for degradation-related pipe breaks in typical BWR and PWR RCSs (NUREG–1829, ''Estimating Loss-of-Coolant Accident (LOCA) Frequencies through the Elicitation Process,'' March 2008). The elicitation process is used for quantifying phenomenological knowledge when data or modeling approaches are insufficient. The NUREG–1829 elicitation focused solely on determining event frequencies that initiate from failures of the unisolable reactor coolant pressure boundary (RCPB), or primary system side, related to material degradation. This effort did not consider the AP1000 and other similar passive-safety reactor designs.

A baseline TBS was established from the expert elicitation results for each reactor type (*i.e.,* PWR and BWR) that corresponded to a break frequency of once per 100,000 reactor years (1×10^{-5}, or 10^{-5} per reactor year). The NRC then considered uncertainty in the elicitation process, other potential mechanisms that could cause passive component failure that were not explicitly considered in the expert elicitation process, and the higher susceptibility to rupture/failure of specific locations in the RCS by adjusting the TBS upward to account for these factors. Other mechanisms that contribute to the overall LOCA frequency include LOCAs resulting from failures of non-passive components and LOCAs resulting from low probability direct and indirect events (*e.g.,* earthquakes of magnitude larger than the safe shutdown earthquake and dropped heavy loads). These LOCAs have a strong dependency on plant-specific factors.

LOCAs caused by failure of non-passive components, such as stuck-open valves and blown out seals or gaskets, have a greater frequency of occurrence than LOCAs resulting from the failure of passive components. LOCAs resulting from the failure of non-passive components would be small-break LOCAs, when considering the size of the opening that could result should components fail open or blow out (*e.g.,* safety valves, pump seals). LOCAs resulting from stuck-open valves are limited by the size of the auxiliary pipe. In some PWRs, there are large loop isolation valves in the reactor pressure vessel outlet and inlet piping. However,

a complete failure of the valve stem packing is not expected to result in a high rate of coolant loss due to the size of the resulting penetration in the system, because the valves are sealed in such a way that limits leaks when they are open (*i.e.,* they are back-seated in the open configuration). Based on these considerations, non-passive LOCAs are relatively small in size and are bounded by the selected TBS.

LOCAs could also be caused by dropping heavy loads that could cause a breach of the RCS piping or damage safety-related equipment. The majority of heavy loads are lifted during refueling when the reactor is shut down and the primary system is depressurized, further reducing the risk of a LOCA and a loss of core cooling. During power operation, personnel entry into the containment is typically infrequent and of short duration and the largest cranes are generally not accessible. There are also operational limitations designed to limit risk due to heavy load drops. Consequently, loads moved at power are substantially fewer than during refueling. In addition, the RCS is inherently protected by surrounding concrete walls, floors, missile shields, and biological shielding. For these reasons, the NRC did not consider the contribution of heavy load drops to overall LOCA frequency to be significant or affect the TBS.

Seismically induced LOCA break frequencies can vary greatly from plant to plant because of factors such as site seismicity, seismic design considerations, and plant-specific layout and spatial configurations. Seismic break frequencies are also affected by the amount of pipe degradation occurring prior to postulated seismic events. Seismic PRA insights were accumulated from the NRC Seismic Safety Margins Research Program and the Individual Plant Examination of External Events submittals available in the late 1990s. Based on these studies, piping and other passive RCPB components generally exhibit high seismic capacities and, therefore, are not significant risk contributors. However, these studies did not explicitly consider the effect of degraded component performance on the risk contributions. Therefore, the NRC conducted a study in the early 2000s to evaluate the seismic performance of undegraded and degraded passive system components (NUREG–1903, ''Seismic Considerations for the Transition Break Size,'' February 2008). This effort examined operating experience, seismic PRA insights, and models to evaluate the failure likelihood of undegraded and degraded piping. The operating experience review considered passive component failures that have occurred as a result of strong motion earthquakes in nuclear and fossil power plants as well as other industrial facilities. No catastrophic failures of large pipes resulting from earthquakes between 0.2g and 0.5g (where g is the gravitational acceleration or approximately 9.81 meters/second^2) peak ground acceleration have occurred in power plants. However, piping degradation could increase the LOCA frequency associated with seismically induced piping failures. The NUREG–1903 report evaluated seismic loadings on degraded piping and concluded that a large, pre-existing crack on the order of 30 percent through-wall and 145 degrees around the piping circumference would have to be present during a large, rare earthquake (*i.e.,* corresponding to the mean annual frequency of exceedance equivalent to 10^{-5} or 10^{-6} per year) in order for pipe failure to occur. The NRC concluded that the likelihood of flaws large enough to fail during such a seismic event was sufficiently low that the TBS need not be modified to address seismically induced direct piping failures.

Indirect RCPB failures are primary system ruptures that are a consequence of failures in primary and non-primary system components or structural support failures (such as reactor coolant pump supports and steam generator supports). Structural support failures could then cause displacements in components, causing stress on the piping and potential failure. The NRC performed studies on two plants to estimate the conditional pipe failure probability due to structural support failure given a large, rare earthquake (*i.e.,* 10^{-5} to 10^{-6} per year). These studies used seismic hazard curves from NUREG–1488, ''Revised Livermore Seismic Hazard Estimates for Sixty-Nine Nuclear Power Plant Sites East of the Rocky Mountains,'' April 1994. The results of these studies, as described in NUREG–1903, showed that indirectly induced piping failure attributable to major component support failure has a mean failure probability on the order of 10^{-6} per year, which was less than the TBS criterion. However, the NRC noted in NUREG–1903 that indirect failure analyses are highly plant-specific. Therefore, it is possible that example plants assessed in the NRC analyses were not necessarily limiting for all plants.

The NRC considered the importance of indirect failures on the selection of the TBS. For the cases considered in NUREG–1903, the likelihood of indirectly induced piping failures resulting from major component support failures was less than 10^{-5} per reactor year, the frequency criterion used to select the TBS. Also, the median seismic capacities for both the primary piping system and primary system components are typically higher than other safety-related components within the nuclear power plant. Because of these relative capacities, the NRC expected that a seismic event of sufficient magnitude to cause consequential failure within the primary system would also induce failure of components in multiple trains of mitigation systems, or even induce multiple RCS pipe breaks. Consequently, the risk contribution from seismically induced indirect failures was expected to depend more heavily on the relative fragilities of plant components and systems than the size of the TBS. Therefore, the NRC determined that adjustment to the TBS for seismically induced indirect LOCAs was not warranted.

The final consideration in selecting the TBS was actual piping system design (*e.g.,* piping sizes) and operating experience. For example, due to system configuration and operating environment, certain piping was considered to be more susceptible to degradation and failure than other piping in the same size range.

For PWRs, the NRC determined that 6- to 10-inch inside diameter (*i.e.,* inside dimension) was an appropriate range of pipe break sizes associated with the 95th percentile LOCA frequency estimates of 1×10^{-5}/yr from NUREG–1829. This range is only slightly smaller than the PWR surge lines, which are attached to the RCS main loop piping (*i.e.,* hot leg, cold leg, and crossover leg) and are typically 12- to 14-inch diameter Schedule 160 piping with inside diameters of 10.1 to 11.2 inches. The RCS main loop piping is in the range of 30 inches in diameter and has substantially thicker walls than the surge lines. The expert elicitation panel concluded that this main loop piping is much less likely to break than other RCS piping. The shutdown cooling lines and safety injection lines may also be 12- to 14-inch diameter Schedule 160 piping and are likewise connected to the RCS. In some cases (*e.g.,* Babcock and Wilcox plants), the core flood lines may be bigger than the surge and residual heat removal lines that are attached to the main loop piping. The difference in diameter and thickness of the reactor coolant piping and the piping connected to it forms a reasonable line of demarcation to define the TBS. Therefore, in SECY–10–0161, to capture the surge, shutdown cooling, core flood,

and safety injection lines in the range of piping considered to be equal to or less than the TBS, for PWRs, the NRC staff specified the TBS as the largest cross-sectional flow area of the RCPB piping excluding the main loop piping.

For BWRs, the NRC determined that 13- to 20-inch inside diameter was an appropriate range of pipe break sizes associated with the 95th percentile LOCA frequency estimates of 1×10^{-5}/yr from NUREG–1829. The information gathered from the elicitation for BWRs also showed that the estimated frequency of pipe breaks dropped markedly for break sizes beyond the range of approximately 18 to 20 inches. After evaluating BWR designs, the NRC determined that typical residual heat removal piping connected to the recirculation loop piping and feedwater piping is about 18 to 24 inches in diameter. These pipe sizes are consistent with break sizes beyond which the pipe break frequency was expected to decrease markedly below 10^{-5} per year. The NRC staff recognized that the sizes of attached pipes vary somewhat among plants. Thus, for BWRs, in SECY–10–0161, the staff specified the TBS as the larger cross-sectional flow area of either the feedwater or the residual heat removal piping inside primary containment.

Because the effects of TBS breaks on core cooling vary with the break location, the NRC evaluated whether the frequency of TBS breaks varies with location and whether TBS breaks could, therefore, vary in size with location. In PWRs, the pressurizer surge line is only connected to one hot leg and the pipes attached to the cold legs are generally smaller than the surge line. The cold legs (including the intermediate legs) also operate at slightly cooler temperatures such that thermally activated degradation mechanisms would be expected to progress more slowly in the cold leg than in the hot leg. The frequency of occurrence of a break of a given size is composed of both the frequency of a completely severed pipe of that size (*i.e.,* a complete circumferential break) plus the frequency of a partial break of that size in an equal or larger size pipe (*i.e.,* a partial circumferential or longitudinal break). Therefore, the NRC considered an option where the TBS for the hot and cold legs would be distinctly different by considering the frequency contributions of these two break components: (1) complete breaks of the pipes attached to the hot or cold legs at the limiting locations within each attached pipe, and (2) partial breaks of a constant size, as appropriate for either the hot or cold leg, at the limiting locations within the hot or cold legs. However, the elicitation was not envisioned to develop LOCA frequencies specific to piping systems. As a result, there was insufficient detail from the elicitation to draw conclusions about either the difference between hot and cold leg failure frequencies or the frequency of occurrence of smaller LOCAs within a large diameter pipe. Therefore, the NRC concluded that the TBS associated with partial breaks in the hot and cold legs should remain equivalent in size to the internal cross-sectional area of the largest piping system other than the main loop. Similarly, the elicitation results do not contain sufficient detail to quantify break frequency differences among the BWR recirculation, residual heat removal, and feedwater system piping. Thus, a smaller partial break TBS criterion also could not be established for BWR recirculation piping. Notably, mitigating the effects of such partial breaks up to and including a TBS break remains within the design basis for all RCPB piping with an inner diameter equivalent to or larger than the TBS.

During this time, the NRC also evaluated whether TBS breaks should be analyzed as single-ended or double-ended breaks. A postulated double-ended break assumes that the pipe rupture causes a complete separation and displacement of both ends of the pipe at the break such that coolant loss occurs from both sides of the displaced piping. A single-ended break results in an orifice through which the coolant would flow. To address this issue, the NRC reviewed the expert elicitation process and the guidance given to the experts in developing their frequency estimates. The NRC concluded that the expert elicitation LOCA frequency estimates correspond to a break area having an equivalent circular diameter at each break size. This correspondence is representative of a single-ended break. Additionally, the experts based their estimates on knowledge of postulated failure mechanisms in pressure boundary components and not on the flow rates emanating from the breaks. The flow rates are governed by the break location and system configuration, which determines whether reactor coolant will be discharged from both ends of the break.

The current design-basis analysis for LWRs requires analysis of a DEGB of the largest pipe in the RCS. Under the proposed rule, all breaks up to and including the TBS would be analyzed under existing requirements. A possible reason for specifying the TBS for PWRs as double-ended could be that a complete break of the pressurizer surge line would result in reactor coolant exiting both ends of the break. Although this occurs initially during a LOCA, core cooling requirements are dominated by the flow rate of coolant exiting from the hot leg side of the break, with much less contribution from the flow rate of coolant exiting from the pressurizer side. Therefore, specifying the TBS break as an area equivalent to a double-ended break of the surge line would be overly conservative. For BWRs, the effect of a double-ended break area is also considered to be overly conservative. The selected TBS for BWRs would be based on the larger of the residual heat removal or main feedwater lines. A single-ended break in these lines would bound double-ended breaks of the smaller lines in the reactor recirculation and feedwater system. Therefore, the NRC is proposing that the TBS be based on a single-ended break, which reasonably characterizes the expert elicitation results and represents the flow rates associated with postulated pipe breaks within the RCS. The NRC's proposed TBS definition is in proposed 10 CFR 50.46a(a)(9). As an option and to allow maximum flexibility, the proposed 10 CFR 50.46a(a)(9) definition would allow an entity to develop and justify an alternate TBS.

(iii) Determining the Ongoing Validity of the Transition Break Size

Because the work in the development of the TBS was conducted almost 20 years ago as part of the development of the earlier rulemaking to create alternative ECCS requirements in 10 CFR 50.46a, the NRC assessed if the TBS developed in the early 2000s is still valid today. This research identified possible scenarios not considered, or underestimated, in NUREG–1829 or NUREG–1903 that could result in primary pressure boundary breaches that are larger than the TBS in either PWR or BWR plants. These breaches could be directly due to operational transients (*e.g.,* anticipated transient without scram, water hammer, pressurized thermal shock) or indirectly due to other failures within the plant (*e.g.,* crane drop, secondary side failures). Age-related degradation of the RCPB components may be a contributing, or required, causal factor. Additionally, the breach could stem from failure of a single RCPB component or multiple common-cause RCPB component failures (*e.g.,* anticipated transient without scram event leading to the rupture of multiple degraded safety injection system lines on separate PWR loops). Improper maintenance and human factors may

also be a causal factor (*e.g.,* not properly torquing pressurizer manway bolts following inspection). The likelihood of such breaches was also considered up to the end of the subsequent license renewal period (*i.e.,* 80 years) or the maximum extent of the licensing period for plants that could adopt this proposed rule.

In its effort to determine the ongoing validity of the TBS, the NRC only considered reactors authorized to operate under 10 CFR part 50 on December 31, 2015 (*i.e.,* the NRC did not consider the AP1000 design or any other new LWR reactor design) because the NUREG–1829 study did not consider plant designs that were authorized to operate after December 31, 2015 or authorized to operate under 10 CFR part 52. LWRs licensed after that date may have different piping materials, configurations, and operational and service conditions, among other factors, that may impact the piping break frequencies and thus the TBS. A detailed description of the technical justification for the continued applicability of the NUREG–1829 results is found in the ''White Paper on Continued Applicability of NUREG–1829,'' dated November 13, 2024, while the technical justification for the continued applicability of NUREG–1903 is found in the ''White Paper on Continued Applicability of NUREG–1903,'' dated November 18, 2024.

To confirm the TBS's current validity, the NRC conducted a series of probabilistic fracture mechanics analyses using the xLPR code Version 2.3 to confirm the base cases analyzed in NUREG–1829. For these analyses, four of the original base case pipe systems were chosen for this validation: 12-inch recirculation line, 28-inch recirculation line, 30-inch hot leg, and a 10-inch surge line. The base case conditions, assumptions, and inputs from NUREG–1829 were generally adopted in these analyses. However, inputs were supplemented from Technical Letter Report TLR–RES/DE/REB–2021–09, ''Probabilistic Leak-Before-Break Evaluation of Westinghouse Four-Loop Pressurized-Water Reactor Primary Coolant Loop Piping using the Extremely Low Probability of Rupture Code,'' dated August 13, 2021, and Technical Letter Report TLR–RES/DE/REB–2021–14, ''Probabilistic Leak-Before-Break Evaluations of Pressurized-Water Reactor Piping Systems using the Extremely Low Probability of Rupture Code,'' dated September 28, 2021, for the PWR cases; and from NUREG–0313, ''Technical Report on Material Selection and Processing Guidelines for BWR Coolant Pressure Boundary Piping,'' dated January 1988, NUREG/CR–6674, ''Fatigue Analysis of Components for 60-Year Plant Life,'' dated June 2000, and NUREG/CR–4792, ''Probability of Failure in BWR Reactor Coolant Piping, Volume 1: Summary Report,'' dated December 1988, for the BWR cases as needed. Analyses were run to 80 years, and several sensitivity cases were conducted to investigate the impacts of mitigation and inspection on the probability of failure. The annual frequency of small-break, medium-break, and large-break LOCAs were calculated at 25, 40, 60, and 80 calendar years as well as the cumulative probability of a crack, leakage, and rupture at 80 years. A summary of the analyses and results can be found in section 5.3 of the ''White Paper on Continued Applicability of NUREG–1829.'' The analyses conducted show that annual frequencies calculated for the base case problems in the current effort were either bounded by, or representative of, those determined in NUREG–1829.

In addition to the probabilistic fracture mechanics analyses, the NRC conducted both an internal and external elicitation similar to the full elicitation conducted in the original development of NUREG–1829. The purpose of this elicitation was two-fold. The first objective was to determine scenarios that could result in primary pressure boundary breaches that are larger than the TBS in either PWR or BWR plants. The second objective was to determine the representativeness of NUREG–1829 to the current day. The internal elicitation included subject matter experts within the NRC with expertise in structural integrity analysis, materials performance, aged-related degradation, risk assessment, and thermal-hydraulic analysis. The external elicitation queried two of the original NUREG–1829 elicitation effort participants. The external elicitation confirmed that the current-day frequency of LOCAs, and specifically the frequency of LOCAs having a break size greater than the TBS, is conservatively represented by the NUREG–1829 estimates. Neither the internal nor external elicitations identified any generic issues or scenarios that either were not considered in the TBS development or have significantly changed since the TBS development that could undermine its technical basis.

However, both the internal and external elicitations did identify topics that should be addressed within the proposed rulemaking and associated guidance. Some of these topics included PRA requirements; impacts of plant changes; stress corrosion cracking in main loop and recirculation piping; indirect piping failures; direct and indirect seismic failure evaluations; maintaining mitigative capabilities; NUREG–1829 uncertainties; and attributes that could increase plant-specific LOCA frequencies. Many of these topics were already being addressed within this rulemaking effort, and the elicitations served to refine the proposed treatment of these topics, as well as identify some novel issues that were not initially considered. A more detailed summary of these elicitations is in the ''White Paper on Continued Applicability of NUREG–1829.''

The NRC reviewed operational experience since the original NUREG–1829 effort to use as a basis for determining both piping and non-piping failure frequencies. There have been only a few small (*i.e.,* smaller than 2-inch diameter piping) passive-system primary pressure boundary ruptures, and the operational experience indicates that degradation mechanisms such as cracking, wall thinning, or through-wall leakage are a precursor to a rupture. The precursor event frequency can be directly calculated from operational experience, while modeling is required to estimate the likelihood that these precursor events could lead to LOCAs of various sizes and, hence, estimate LOCA frequencies. The NUREG–1829 LOCA frequency estimates were based, in part, on operating experience accumulated up to approximately 2004. The NRC's more recent effort considered operating experience trends from 1970 to 2004, and then 2005 to the present day. This binning was used to compare precursor event frequencies and ultimately LOCA frequencies within the two time periods to assess trending since the completion of NUREG–1829.

Quantitative LOCA frequency estimates were calculated for each time period for PWR and BWR systems and for break sizes greater than and less than the TBS in this proposed rule. Initially, estimates were developed for each degradation mechanism that is applicable for a particular piping or non-piping primary pressure boundary system or component. The attribute-specific frequencies were then multiplied by the number of attributes (*e.g.,* number of welds) for each component and then the contributions from each applicable degradation mechanism were combined to develop component-specific piping and non-piping frequencies. The component-specific frequencies were then further combined to determine global piping and non-piping LOCA frequency estimates. Finally, the piping and non-

piping contributions are summed so that, ultimately, LOCA frequency estimates are determined as a function of rupture size. Uncertainties were initially addressed when determining degradation mechanism-specific estimates and appropriately combined so that the final estimates are expressed as distributions with associated mean values and 5th and 95th percentile LOCA frequency estimates. The findings predict that both the BWR and PWR large LOCA frequency estimates (*i.e.,* the largest NUREG–1829 LOCA size categories starting just below the TBS up to the highest category, which includes a DEGB of the largest pipe in the plant), based on operating experience from 2005 to the present day, are less than estimates based on operating experience from 1970–2004. Therefore, this work supports the expectation that the NUREG–1829 LOCA frequency estimates used to establish the TBS conservatively represent the current-day estimates, and that the TBS established for proposed 10 CFR 50.46a is appropriate. Additional details of this activity can be found in section 5.2 of the ''White Paper on Continued Applicability of NUREG–1829.''

In the ''White Paper on Continued Applicability of NUREG–1829,'' the NRC performed a qualitative analysis of the elicitation results, the operational experience, ongoing American Society of Mechanical Engineers (ASME) code activities, and recent research findings to determine if any of these findings impact the proposed TBS or may cause a break larger than the TBS. The NRC analyzed topics such as thermal embrittlement of cast austenitic stainless steel and stainless-steel welds; stress corrosion cracking in secondary PWR stainless lines; the effects of carbon macrosegregation, small surface breaking flaws, and quasi-laminar defects on reactor pressure vessel integrity; radiation embrittlement; and changes to passive-system inspection frequencies. The NRC evaluated each item's impact on both the direct and indirect failures and determined that these mechanisms would not impact the proposed TBS.

The NUREG–1903 report and the original analyses by the NRC considered the effects of direct (flawed and unflawed) and indirect piping failures on the selection of the TBS. For the direct unflawed piping failure, the NRC originally used the screening approach where the probability of exceedance of stresses corresponding to a 1 percent probability of failure was obtained for the 26 PWRs for the most highly stressed hot leg, cold leg, or crossover (suction) legs. The NRC concluded that failure probabilities of unflawed piping are significantly low compared to the frequency of 10^{-5} per year used as a basis to establish the TBS. For this original assessment, the NRC used the mean Lawrence Livermore National Laboratory seismic hazard curves corresponding to each selected site. Since then, all currently operating U.S. nuclear power reactor licensees have re-evaluated and submitted their Seismic Hazard and Screening Reports (SHSRs) in response to the March 12, 2012, letter issued by the NRC under 10 CFR 50.54(f), ''Request for Information Pursuant to Title 10 of the *Code of Federal Regulations* 50.54(f) Regarding Recommendations 2.1, 2.3, and 9.3, of the Near-Term Task Force Review of Insights from the Fukushima Dai-Ichi Accident,'' following the 2011 accident at the Fukushima Dai-Ichi nuclear power plant. As such, the original assessment results have been updated by using the more up-to-date site hazard information.

In addition, to better determine whether seismic loading conditions significantly increases the probability of a break above the TBS in the current NRC assessment, an unconditional mean piping failure probability value has been obtained by convolving a site-specific mean hazard curve with a representative mean large LOCA piping fragility function obtained from the Electric Power Research Institute (EPRI) Report (3002000709), ''Seismic Probabilistic Risk Assessment Implementation Guide.'' The results of this analysis show that failure probabilities of unflawed piping for a limited number of plants considered are well below the TBS frequency criterion. In addition, the study results show that the probabilities of exceedance corresponding to 1 percent probability of failure are all below the TBS threshold, even using the most conservative design stress intensity value and the most conservative failure criterion. Therefore, there is a clear indication that unflawed piping generally has a very low probability of failure attributable to seismic loads, which is consistent with the original NRC assessment conclusion in NUREG–1903 and the excellent performance experience of piping systems observed during past strong damaging earthquakes (''Summary and Evaluation of Historical Strong-Motion Earthquake Seismic Response and Damage to Above-Ground Industrial Piping,'' April 1985).

The NUREG–1903 report also showed that, for the direct flawed piping failure, the probabilities of pipe breaks larger than the TBS are likely to be less than 10^{-5} per year as the critical flaws associated with the stresses corresponding to the 10^{-5} and 10^{-6} probability of exceedance seismic events are generally large. However, considering the limited applicability of the results and the effects of the recent seismic hazard updates on the TBS, this conclusion needs to be verified by an entity on a case-by-case basis under proposed 10 CFR 50.46a(c)(1)(i).

For the two indirect piping failure cases considered in the original NUREG–1903 analysis, the likelihood of indirectly induced piping failures resulting from major component support failures is less than 10^{-5} per year, which was the frequency criterion used to select the TBS. Based on this frequency criterion, the NUREG–1903 report concluded that indirectly induced piping failure is unlikely to govern the combined failure of piping. However, the NRC noted that this conclusion is not necessarily bounding and may not be applicable to all sites because the assessment used generic seismic hazard curves and representative major support fragilities in lieu of plant-specific hazard curves and fragilities. This is further complicated by the recent seismic hazard updates documented in the aforementioned SHSRs. The assessment results documented in NUREG/KM–0017, ''Seismic Hazard Evaluations for U.S. Nuclear Power Plants: Near-Term Task Force Recommendation 2.1 Results,'' dated December 16, 2021, show that some sites have experienced noticeable changes in both seismic exceedance frequencies and Ground Motion Response Spectrum shapes relative to those of the prior assessments. Taken together, these changes affect seismic demand estimates used as an input to fragility analysis of key component supports as well as the resulting unconditional failure probability of indirectly induced piping failure. More details on this effort can be found in the ''White Paper on Continued Applicability of NUREG–1903.'' Because the risk associated with indirect piping failures is plant-specific, the NRC would require in proposed 10 CFR 50.46a(c)(1)(i) that each entity perform an assessment of indirect piping failures using the most up-to-date seismic hazard information. This assessment would be part of the comprehensive risk assessment required to implement 10 CFR 50.46a and graded approaches would be possible depending on the significance of the associated risk. More detailed guidance on this topic would be provided in DG–

1426, ''An Approach for a Risk-Informed Evaluation Process Supporting Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Reactors,'' and DG–1428, ''Plant-Specific Applicability of the Transition Break Size.''

Periodic inservice inspections are a key performance monitoring strategy for verifying that analyses that predict component failure remain accurate through the time the component is analyzed, and they provide a method to identify novel degradation that may impact the analysis and the structural integrity of the component. Reactor coolant boundary piping in PWRs and BWRs is both ASME Class 1 piping and risk significant and is typically inspected by a prescribed inservice inspection program, a risk-informed inspection program, or an augmented inspection program under 10 CFR 50.55a, ''Codes and standards.'' For instance, in PWRs, the dissimilar metal welds that join the hot leg to the reactor pressure vessel nozzle are inspected through ASME Code Case N–770, ''Alternative Examination Requirements and Acceptance Standards for Class 1 PWR Piping and Vessel Nozzle Butt Welds Fabricated With UNS N06082 or UNS W86182 Weld Filler Material With or Without Application of Listed Mitigation Activities,'' as incorporated by reference in 10 CFR 50.55a, which requires different inspection frequencies depending on the type of mitigation employed. Also, the stainless-steel welds in the same piping system are typically covered under Category R.1.20 in ASME Code Case N–716–2, ''Alternative Classification and Examination Requirements,'' as incorporated by reference in 10 CFR 50.55a through RG 1.147, Revision 20, ''Inservice Inspection Code Case Acceptability, ASME section XI, Division 1.'' However, the wording of the code case does not require a minimum number of these welds to be inspected in the overall program (see section 4(b)(2) of Code Case N–716–2). In addition, there is a concerted effort within the ASME code community to use risk arguments to reduce inspections in piping (thereby increasing time between inspections) and other components, such as steam generator shell welds, which may extend to Class 1 piping for cases with no active degradation. This industry, EPRI, and ASME effort is addressed in the 2023 white paper entitled, ''Draft White Paper: Statistical Approach to Optimizing a Performance Monitoring Program.''

The analyses conducted within NUREG–1829 rely on the continuing inservice inspection of the piping considered in predicting LOCA frequencies. The inspections assumed were historical prescribed ASME inspection procedures and frequencies (*e.g.,* once in a 10-year interval). The impact of increasing the time between inspections on the predicted LOCA frequencies estimated in the elicitation is unknown, therefore performance monitoring is needed to confirm the continued adequacy of the analyses used to calculate the LOCA frequencies and identify novel degradation that may challenge the component integrity. To provide appropriate performance monitoring, proposed 10 CFR 50.46a(b)(3) would require that a sampling inspection program be conducted on the welds in piping systems whose diameter is greater than the TBS. Under the proposed rule, credit may be given for those welds inspected as part of an established inspection program (*e.g.,* these welds could be included in the sample inspected in the risk-informed piping inspection programs in lieu of other welds in the same risk-informed category). The dissimilar metal welds in PWRs, which are susceptible to primary water stress corrosion cracking, are inspected periodically per Code Case N–770, while the similar circumferential welds are part of a risk-informed program. Due to the number of similar metal, circumferential, Class 1 welds in a PWR reactor coolant loop, or those circumferential welds in a BWR that are classified as Category A welds (*i.e.,* welds of resistant material as defined in Generic Letter 88–01), it is possible that welds from the systems whose diameter is greater than the TBS might not be included in the sample inspected as part of the risk-informed inspection program. In addition, future ASME code changes might decrease the number of these circumferential welds inspected. Therefore, the proposed rule would require licensees to inspect an NRC-approved risk-informed sample of these similar metal circumferential welds in a PWR or the Category A circumferential welds in a BWR in accordance with 10 CFR 50.55a with the highest failure potential before implementation of proposed 10 CFR 50.46a and every subsequent in-service inspection interval. This proposed requirement, coupled with the ongoing inspection programs, would provide for the appropriate amount of performance monitoring data over the course of the plant's licensed life. Additional technical background supporting this proposed requirement can be found in the ''White Paper on Continued Applicability of NUREG–1829.''

The NRC also considered the possibility that currently licensed AP1000 facilities; other currently certified designs listed in appendices A through G of 10 CFR part 52 (*i.e.,* the AP600, ESBWR, APR1400, System 80+, U.S. Advanced Boiling Water Reactor, and NuScale designs); and other future LWR plants could apply the proposed TBS. The original elicitation effort did not consider these newer reactor designs when developing the LOCA frequencies. The current validation effort also did not consider the effects of design differences between these newer plants and other currently operating PWRs on the TBS. These newer plants may have different piping materials, configurations, and operational and service conditions, among other factors, that may impact the piping break frequencies and, thus, the TBS. Therefore, the NRC decided that the proposed TBS would not be applicable to newer plant designs, and these reactors should collectively be treated as ''new reactors'' as described in section XXXVI.F.(xii), ''Applicability to New Reactor Designs,'' of this document.

(iv) Evaluation of the Plant-Specific Applicability of the Transition Break Size

Because both the NUREG–1829 and NUREG–1903 studies developed representative and not bounding estimates, and the recent validation efforts in the ''White Paper on Continued Applicability of NUREG–1829'' and ''White Paper on Continued Applicability of NUREG–1903'' only confirmed the continued applicability of these representative estimates, unique plant attributes may result in plant-specific LOCA frequencies that are greater than reported in either NUREG–1829 or NUREG–1903. Consequently, proposed 10 CFR 50.46a(c)(1)(i) would require entities applying to implement proposed 10 CFR 50.46a for plants authorized to operate under 10 CFR part 50 on December 31, 2015, to conduct an evaluation to demonstrate the applicability of the TBS as defined in 10 CFR 50.46a(a)(9) to their individual plants. In addition, proposed 10 CFR 50.46a(a)(9) and 10 CFR 50.46a(c)(1)(i) also would allow for an alternate TBS to be proposed and justified. Similarly, proposed 10 CFR 50.46a(c)(2) would require that entities applying to implement proposed 10 CFR 50.46a for all other LWRs submit an analysis demonstrating that the proposed reactor design is similar to the designs of reactors authorized to operate under 10 CFR part 50 on December 31, 2015. This

analysis should demonstrate that the NUREG–1829 and NUREG–1903 results, which supported the development of the proposed TBS definition as described in section XXXVI.F.(iii), ''Determining the Ongoing Validity of the Transition Break Size,'' of this document, are generally applicable to these plant designs. Applicants for all other plants would also need to propose and justify an appropriate TBS.

Additionally, proposed 10 CFR 50.46a(c)(1)(i) for reactors authorized to operate under 10 CFR part 50 on December 31, 2015, and proposed 10 CFR 50.46a(c)(2) for all other LWRs would require demonstration that the TBS as defined in proposed 10 CFR 50.46a(a)(9) remain applicable after initial plant changes such that the TBS remains valid. Proposed 10 CFR 50.46a(d)(4) would require demonstration that subsequent plant changes enacted under this proposed rule also do not invalidate the TBS. Most anticipated plant changes should not impact the TBS, so little, if any, evaluation would be necessary to demonstrate the acceptability of such changes. However, some changes, such as power uprates, have the potential to affect the TBS by increasing operating temperatures, coolant flow rate, and neutronic flux.

Guidance for conducting the plant-specific evaluations to demonstrate the initial applicability of the TBS and the subsequent applicability after implementing changes under this proposed rule is provided in DG–1428.

(v) Alternative ECCS Analysis Requirements and Acceptance Criteria

For breaks at or below the TBS, proposed 10 CFR 50.46a(e)(2)(ii) would specify that acceptance criteria be satisfied to a high level of probability (*i.e.,* 95 percent probability level, as explained in RG 1.157, ''Best-Estimate Calculations of Emergency Core Cooling System Performance''), which is currently required for all breaks under 10 CFR 50.46. Commensurate with the lower probability of breaks larger than the proposed TBS, 10 CFR 50.46a(e)(3) of the proposed rule would specify alternative ECCS analysis requirements in addition to the current 10 CFR 50.46 for breaks larger than the proposed TBS. Therefore, proposed 10 CFR 50.46a(e)(3)(ii) would require entities to analyze ECCS cooling performance for breaks up to and including a double-ended rupture of the largest pipe in the RCS using a relaxed set of criteria compared to current LOCA requirements. These analyses would need to be performed by methods acceptable to the NRC and would need to demonstrate that ECCS cooling performance conforms to the acceptance criteria set forth in the proposed rule.

Additionally, the proposed rule would modify the ECCS acceptance criteria from the current 10 CFR 50.46 to be more performance-based and would address the research findings in RIL–0801 for all breaks. The proposed rule would establish two ECCS performance criteria in proposed 10 CFR 50.46a(e)(1) and fuel system requirements in proposed 10 CFR 50.46a(f).

(a) ECCS Performance Criteria

The SSCs of the ECCS are designed to provide residual heat removal during and following a postulated LOCA. Failure of the ECCS to perform its intended function would result in a loss of coolable geometry followed by core reconfiguration. While the principal ECCS performance requirements are simple in nature (*i.e.,* remove residual heat and maintain a coolable geometry), the system must be designed to achieve specified performance objectives, taking into consideration all degradation mechanisms and any unique performance features of the particular fuel system that the ECCS is intended to cool. Sufficient empirical data must be available for the particular fuel system to enable the entity to identify all degradation mechanisms (*e.g.,* embrittlement, loss of structural integrity) and any unique performance features (*e.g.,* eutectic or exothermic reactions, combustible gas generation). Consideration of applicable degradation mechanisms would in turn allow specification of limits for key parameters (*e.g.,* cladding or fuel temperatures) that would establish the duration for which the ECCS must remove residual heat and ensure that a coolable geometry is maintained. In addition, fuel-specific analytical requirements may be necessary to accurately or conservatively model unique phenomena that impact the ECCS performance demonstration (*e.g.,* fuel rod balloon and burst, cladding inside-diameter oxygen ingress).

Section 50.46a(e)(1) of the proposed rule would establish the following principal ECCS performance requirements:

- Sufficient coolant so that the fuel remains in a coolable geometry during and following the LOCA heatup and quench.
- Sufficient long-term cooling so that decay heat will be removed for the extended period of time required by the long-lived radioactivity remaining in the fuel.

Compliance with these performance requirements would provide reasonable assurance that the overall objective of maintaining a coolable fuel geometry during and after a LOCA. In addition, the proposed rule would dictate specific analytical requirements for demonstrating compliance with the ECCS performance requirements. For instance, to demonstrate compliance with these system performance requirements, ECCS performance would be evaluated using fuel-specific performance objectives and associated analytical limits that take into consideration all known degradation mechanisms and unique performance features of the particular fuel system, along with an acceptable evaluation model.

In previous comments, Framatome suggested changes to the draft final 10 CFR 50.46c rule to make it more performance based. Those changes included two ECCS performance criteria that, according to Framatome, would support new fuel types. The NRC agreed that the performance criteria suggested by Framatome would have benefits such as making those performance requirements more performance based. The two performance criteria in proposed 10 CFR 50.46a(e)(1) align closely with Framatome's recommended performance criteria. The difference between the proposed rule and Framatome's suggestion is also a change from the draft final 10 CFR 50.46c rule (see section XXXV.C.(v)(c), ''10 CFR 50.46c Rulemaking and Cladding Embrittlement Research Findings,'' of this document). In that draft rule, core temperature was the first ECCS performance requirement. In this proposed rule, the NRC replaced core temperature with fuel coolability to potentially allow for a demonstration of coolability and safety of fuel outside of a fuel rod, such as dispersed fine fuel fragments resulting from FFRD.

(b) Fuel Coolability

As explained in section XXXV.C.(v)(a), ''10 CFR 50.46 and Fuel Dispersal,'' of this document, since 1973, the AEC and NRC position has been that the objective of the coolable geometry criterion in 10 CFR 50.46(b)(4) is to maintain fuel pellets within the cladding and fuel rods within the fuel bundle lattice. While fuel dispersal is not explicitly addressed in the NRC's current regulations, the objective of the coolability criterion indicates that significant fuel dispersal during a LOCA is not permitted, as fuel leaving the fuel rod leads to loss of the fuel rod structure and loss of fuel bundle configuration. However, the state-of-knowledge

surrounding LOCAs and the ability to simulate complex phenomena during a LOCA have drastically improved since 1973 and is expected to continue to do so. Therefore, it is appropriate to update the understanding of coolability. Based on the conclusions in NUREG/CR–7307, which describes the NRC-sponsored fuel dispersal consequences PIRT exercise, it is reasonable to conclude that some amount of fuel dispersal could be coolable, and it is expected that this can be demonstrated with the tools and experimental capabilities available today. The PIRT expert panel believed that relatively simple bounding calculations can be performed to address the primary downstream consequences of dispersal.

While core configuration, fuel bundle array geometry, and fuel rod structure have traditionally been considered to be challenged by any significant amount of fuel dispersal, the NRC is open to the possibility that core configuration, fuel bundle array geometry, and fuel rod structure could be shown to remain generally intact even if some amount of fuel is dispersed. While simple bounding calculations may be possible at the present time, the models and testing necessary to perform a more detailed analysis and a more detailed demonstration in support of reactor safety analyses have not been developed and specific limits concerning how much dispersed fuel would be acceptable have not been defined. Therefore, similar to any other LOCA phenomena, prior to approving LOCA analysis methods involving fuel dispersal under both the existing regulations and the proposed rule, the NRC would review the relevant modeling approaches, including their underlying validation and experimental basis, to ensure their credibility. Should fuel dispersal be calculated to occur, an entity would need to provide a technical basis addressing the coolability of both fuel retained in the core and fuel dispersed into the reactor vessel or containment.

The proposed 10 CFR 50.46a provides an explicit risk-informed framework for treatment of breaks above the TBS that could relax required analytic assumptions. The proposed risk-informed framework is not the only permissible way to use risk insights in addressing the ECCS requirements. The NRC will continue to assess regulatory compliance consistent with the existing regulatory framework on risk-informed regulation, including regulatory guidance such as RG 1.174. An acceptable level of defense-in-depth and safety margins should continue to be maintained when applying risk insights. As a result of addressing coolability in a more performance-based way and treating dispersal as not being incompatible with coolability, other licensing pathways may be made possible to address coolability, such as other alternatives postulated in the regulatory basis for this rulemaking or proposed by industry in topical reports.

This proposed rule would represent a change in the Commission's position on coolability to allow for demonstrations of fuel dispersal. This proposed change could result in questions on when the core geometry would no longer be considered coolable. The proposed requirements to demonstrate fuel coolability (in proposed 10 CFR 50.46a(e)(1)(i) and (f)(3)) and address cladding degradation phenomena (in proposed 10 CFR 50.46a(f)(1)) in the ECCS performance analyses would provide reasonable assurance that unacceptable scenarios would not occur. Unacceptable scenarios would include, but would not be limited to the following:

- Widespread brittle cladding failure. Brittle failure of the cladding during a LOCA could lead to the shattering of the cladding and the release of much of the fuel in the rod. While fuel may be dispersed out of a rupture opening of a fuel rod when considering FFRD, less fuel is expected to be dispersed than if PQD is not preserved. Additionally, the general fuel bundle configuration of the core would be lost in the case of widespread brittle cladding failure, which would have major deleterious effects on core coolability. For these reasons, the NRC would maintain PCT and PQD criteria for zirconium-alloy and UO_2 fuel systems in 10 CFR 50.46 but include them in guidance (*i.e.,* DG–1263) to support proposed 10 CFR 50.46a. The PCT and PQD criteria in DG–1263 would address proposed 10 CFR 50.46a(f)(1), which states that cladding degradation phenomena must be addressed.
- Fuel/cladding melt. In addition to ensuring PQD, emergency coolant provided by the ECCS is intended to prevent the fuel from melting during a LOCA. If the ECCS is unable to provide sufficient cooling to prevent the fuel from melting, then this situation could lead to an outcome where the fuel becomes uncoolable. While this rulemaking proposes to recategorize LOCAs above the TBS as beyond-design-basis, the NRC continues to find that avoidance of fuel melting during a LOCA is appropriate to ensure a coolable geometry. Similarly, the fuel dispersal PIRT identified fuel accumulation on the spacer grids as a concern. If fuel particles settle on spacer grids and there is two-sided heating of the cladding, then it could potentially cause the cladding to melt and therefore damage the configuration of the core. This postulated scenario must be avoided. For zirconium-alloy and UO_2 fuel systems that retain their fuel, the PCT criteria in DG–1263, which would address the proposed 10 CFR 50.46a(f)(1) requirement to have NRC-approved limits that address cladding degradation phenomena, would prevent fuel melt during a LOCA.

(c) Acceptable Methodologies and Analysis Assumptions

Proposed 10 CFR 50.46a(e) would retain the requirement in existing 10 CFR 50.46 that ECCS cooling performance must be calculated in accordance with an acceptable evaluation model. Acceptable evaluation models are currently of two types: those that realistically describe the behavior of the RCS during a LOCA, and those that conform with the required and acceptable features specified in appendix K to 10 CFR part 50. Appendix K to 10 CFR part 50 evaluation models incorporate conservatism as a means to justify that the acceptance criteria are satisfied by an ECCS design. In contrast, the realistic or best-estimate models attempt to accurately simulate the expected phenomena while accounting for uncertainty such that there is a high level of probability that the ECCS acceptance criteria will not be exceeded. As a result, comparisons to applicable experimental data must be made and uncertainty in the evaluation model and inputs must be identified and assessed. All these existing requirements are included in proposed 10 CFR 50.46a(e)(2) for breaks at or below the TBS.

As currently required under 10 CFR 50.46, the ECCS analysis performed with realistic modeling must demonstrate with a high level of probability that the acceptance criteria will not be exceeded. The NRC position in RG 1.157 is that 95 percent probability constitutes an acceptably high probability. Section 50.46a(e)(2) of the proposed rule retains this high level of probability as the statistical acceptance criterion for breaks below the TBS. For breaks at or above the TBS, proposed 10 CFR 50.46a(e)(3) would depart from the requirement of high probability to state that assurance to at least a best-estimate level is acceptable. For these breaks, best-estimate would refer to nominal and unbiased analyses. Thus, for realistic evaluation models for breaks above the TBS, entities would not be required to account for the

uncertainty. The best-estimate analyses could also take credit for offsite power, as stated in proposed 10 CFR 50.46a(e)(3).

Proposed 10 CFR 50.46a(e)(2) and (e)(3) would each require a separate determination of the most limiting break scenarios within each of the two break-size regions: (1) breaks at or below the TBS and (2) breaks larger than the TBS up to and including a double-ended rupture of the largest pipe in the RCS. Different methodologies, analytical assumptions, and acceptance criteria could be used for each break size region. Consistent with current 10 CFR 50.46 requirements, entities would be required to analyze breaks at or below the TBS by assuming the worst single failure concurrent with a loss-of-offsite power and only crediting the mitigative capability of safety-related SSCs. For breaks larger than the TBS, entities could credit operation of both safety and non-safety-related SSCs (subject to system availability as supported by plant-specific data or analysis) provided that onsite power could be readily provided to that equipment through manual actions after a loss-of-offsite power (*e.g.,* within approximately 30 minutes). This requirement for non-safety-related equipment would be a defense-in-depth consideration for severe accident management. The SSCs that are credited for such accidents should have at least a pedigree similar to that of the equipment credited in other beyond-design-basis accidents. All non-safety equipment that is credited for analyses of breaks larger than the TBS would need to be identified as such and evaluated whether they should be listed in the plant technical specifications in order to satisfy criterion 4 of 10 CFR 50.36(c)(2)(ii). Criterion 4 of 10 CFR 50.36(c)(2)(ii) states that a technical specification limiting condition for operation must be established for a ''structure, system, or component which operating experience or probabilistic risk assessment has shown to be significant to public health and safety.'' Despite the recategorization of LOCAs greater than the TBS as beyond-design-basis, the NRC still believes that it is significant to public health and safety that such events are able to be mitigated. Criterion 4 of 10 CFR 50.36(c)(2)(ii) is the basis for the establishment of technical specifications for equipment that are used in the mitigation of another beyond-design-basis accident, anticipated transient without scram. For example, in the BWR/6 standard technical specifications in Volume 2 of Revision 5.0 of NUREG–1434, ''Standard Technical Specifications—General Electric BWR/6 Plants,'' the typically non-safety-related anticipated transient without scram recirculation pump trip system is stated as satisfying criterion 4 of 10 CFR 50.36(c)(2)(ii).

(d) Fuel-Specific Performance and Analytical Requirements

Section 50.46a(f) of the proposed rule would include performance requirements for fuel designs. The fuel designs would be required to have NRC-approved limits that do the following:

- Address cladding degradation phenomena.
- Maintain fuel coolability.
- Avoid explosive concentration of combustible gas.
- Demonstrate that, after any calculated successful initial operation of the ECCS, the ECCS must provide sufficient coolant to remove decay heat and prevent further cladding failure for the extended period of time required by the long-lived radioactivity remaining in the fuel.

Means of meeting the requirement to address cladding degradation criteria are provided in DG–1263 for fuel designs consisting of uranium oxide or mixed uranium-plutonium oxide fuel pellets within cylindrical zirconium-alloy cladding. Under this requirement, entities should address the research findings discussed in section XXXV.C.(v)(c), ''10 CFR 50.46c Rulemaking and Cladding Embrittlement Research Findings,'' of this document when establishing criteria on PCT, PQD, and breakaway oxidation, as detailed in DG–1263. The NRC is proposing to not include PCT and PDQ requirements in the proposed 10 CFR 50.46a, unlike the current 10 CFR 50.46(b)(1) and (b)(2). Instead, the NRC proposes to include PCT and PQD criteria in guidance to enable regulatory flexibility. For example, additional criteria for fuel performance above 2200 °F (1204 °C) may be needed to address other high-temperature failure mechanisms that may not occur below 2200 °F (1204 °C). Including the PCT, the maximum local oxidation, and maximum hydrogen generation criteria in DG–1263 rather than codified in proposed 10 CFR 50.46a would provide this flexibility.

Exemptions from proposed 10 CFR 50.46a would not be needed for new fuels to which the current criteria may not be applicable, such as non-zirconium-alloy cladded fuel, since the criteria would be located in guidance. The NRC did not include guidance for fuel designs that do not consist of uranium oxide or mixed uranium-plutonium oxide fuel pellets within cylindrical zirconium-alloy cladding as a part of this rulemaking due to a lack of operational experience on which to base specific criteria and to accelerate the rulemaking schedule. The NRC has determined that these new fuels should be able to be licensed based on technical justifications without the need for exemptions from regulation. For example, since the detailed criteria would be in guidance, justification could be provided for alternative criteria for PCT that exceed the 2200 °F (1204 °C) limit in 10 CFR 50.46(b)(1) and has historically been used for fuel designs consisting of uranium oxide or mixed uranium-plutonium oxide fuel pellets within cylindrical zirconium alloy cladding.

As discussed in section XXXVI.F.(ii), ''Original Determination of the Transition Break Size,'' of this document, some amount of fuel dispersal could be shown to be coolable and therefore acceptable under proposed 10 CFR 50.46a. During FFRD, fuel is dispersed following ductile failure of the cladding (*i.e.,* ballooning and burst) and also can be dispersed from brittle failure of the cladding. Historically, brittle failure of even a single rod has been prevented by ensuring compliance with 10 CFR 50.46(b), as described in section XXXV.C.(v)(a), ''10 CFR 50.46 and Fuel Dispersal,'' of this document. Under this proposed rule, the NRC may review applications for safety demonstrations of FFRD during breaks above the TBS, so it is logical to consider safety demonstrations of fuel dispersed from brittle failure for LOCAs above the TBS. Such brittle failures should be limited so that there is not a widespread loss of the general fuel rod bundle configuration in the core, as widespread destruction of the fuel rod bundle configuration would have significant deleterious effects on core coolability.

There has been little research on the amount of fuel dispersal expected to occur due to brittle failure, but if coolability and safety can be ensured following brittle failure of the cladding, then the NRC may find it to be acceptable for breaks above the TBS. Entities would need to justify the safety case for permitting brittle failure of fuel rods and the resulting fuel dispersal.

Additionally, the criteria in proposed 10 CFR 50.46a(f) may be used as an alternative to the criteria in proposed 10 CFR 50.46(b), as applicable, without having to adopt the rest of proposed 10 CFR 50.46a, as stated in proposed 10 CFR 50.46(a)(3)(i).

The existing regulation in 10 CFR 50.46(b)(5) requires that, for long-term cooling, the calculated core temperature

be maintained at an acceptably low value following any calculated successful initial operation of the ECCS. It also requires that decay heat be removed for the extended period of time required by the long-lived radioactivity remaining in the fuel. Section 50.46a(f)(4) of the proposed rule would retain these requirements from 10 CFR 50.46(b)(4) and specify that cladding failure should be prevented in the extended period of time required by the long-lived radioactivity remaining in the fuel.

(e) Restriction of Reactor Operation

Proposed 10 CFR 50.46a(i) would allow the Director of the NRC's Office of Nuclear Reactor Regulation to impose restrictions on reactor operation if the NRC determines that the evaluations of ECCS cooling performance are not consistent with the requirements for evaluation models and analysis methods specified in proposed 10 CFR 50.46a(e)(1) through (e)(3) and 10 CFR 50.46a(f). Non-compliance could be due to factors such as lack of a sufficient database upon which to assess model uncertainty, use of a model outside the range of an appropriate data base, use of models inconsistent with the requirements of appendix K to 10 CFR part 50, or discovery of phenomena unknown at the time of approval of the methodology. Lack of compliance with methodological requirements would not necessarily mean that the ECCS capability is unacceptable, but only that the analysis results using the methodology in question cannot be relied upon to demonstrate compliance with the appropriate acceptance criteria. Thus, depending upon the specific circumstances, it might be necessary for the NRC to impose restrictions on operation until these issues are resolved. This requirement would be consistent with the current ECCS regulations in existing 10 CFR 50.46(a)(2).

(vi) Risk-Informed Changes to the Facility, Technical Specifications, or Procedures

The proposed 10 CFR 50.46a would designate LOCAs above the TBS as beyond-design-basis, allowing for best-estimate analysis for such LOCAs. The proposed flexibility in ECCS analyses for LOCAs above the TBS would enable a wide range of changes that could be implemented at facilities seeking to apply the proposed 10 CFR 50.46a.

Entities that would request approval to use 10 CFR 50.46a would use a risk-informed evaluation to demonstrate that facility changes would satisfy the risk-informed acceptance criteria in proposed 10 CFR 50.46a(h). Changes that would need to be evaluated would be specified in proposed 10 CFR 50.46a(d)(3) and would include all ''enabled'' changes (*i.e.,* changes that would be permissible if the NRC were to approve the entity's request to use proposed 10 CFR 50.46a) that satisfy the alternative ECCS analysis requirements in proposed 10 CFR 50.46a but do not satisfy the ECCS analysis requirements in current 10 CFR 50.46.

Proposed 10 CFR 50.46a(h)(1), (2) and (3) would require entities to demonstrate in their risk-informed evaluations that increases in plant risk (if any) would meet appropriate risk acceptance criteria, defense-in-depth would be maintained, adequate safety margins would be maintained, and adequate performance-measurement programs would be implemented. All changes to a plant, its technical specifications, or its procedures that would be based upon the analyses of ECCS performance permitted under proposed 10 CFR 50.46a(e)(3)–except for those changes made under proposed 10 CFR 50.46a(h)(1)–would need to be reviewed and approved by the NRC. A wide range of changes could be implemented under proposed 10 CFR 50.46a that, if improperly implemented by entities, could result in significant adverse impacts on public health and safety or common defense and security. NRC review and approval would provide verification that an entity has properly evaluated each proposed change against the acceptance criteria in proposed 10 CFR 50.46a. Existing 10 CFR 50.36(b) requires each license authorizing operation of a production or utilization facility of a type described in 10 CFR 50.21, ''Class 104 licenses; for medical therapy and research and development facilities,'' or 50.22, ''Class 103 licenses; for commercial and industrial facilities,'' to include technical specifications, so changes to the technical specifications require the license to be amended. However, 10 CFR 50.36 does not provide risk thresholds, nor does it require a risk-informed evaluation to demonstrate that the proposed change does not result in significant adverse impacts on public health and safety or common defense and security. Therefore, for technical specifications changes proposed under 10 CFR 50.46a, 10 CFR 50.46a(h)(2) would provide the risk acceptance criteria necessary for entities to evaluate each proposed change, beyond that required in 10 CFR 50.36. Accordingly, the NRC's proposed rule would require NRC review and approval of all changes initiated under proposed 10 CFR 50.46a(h)(2).

An entity other than a design certification applicant or holder of an ML who sought to make certain changes that would be enabled by the proposed rule without prior NRC review and approval would need to submit for NRC review its risk-informed process that would be used in evaluating the acceptability of these changes as described in proposed 10 CFR 50.46a(c)(1)(v). The entity's process would also need to include a means to evaluate the continued applicability of the TBS with the acceptance criteria used in the evaluation described in proposed 10 CFR 50.46a(c)(1)(i) for plants authorized to operate under 10 CFR part 50 on December 31, 2015 or as described in proposed 10 CFR 50.46a(c)(2) for entities other than those authorized to operate under 10 CFR part 50 on December 31, 2015. An entity who would make only a single or a few changes enabled by the rule would not need to submit a risk-informed evaluation process. Instead, that entity would submit only its risk-informed evaluation of each change it has requested. Proposed 10 CFR 50.46a(h)(1) would contain acceptance criteria for self-made changes enabled by the rule. Under the proposed framework, if an entity's initial application to implement proposed 10 CFR 50.46a does not include a risk-informed evaluation process, then that entity could, at any later time, submit another license amendment requesting approval of a risk-informed evaluation process. The DG–1426 would provide guidance for the risk-informed evaluation specified in proposed 10 CFR 50.46a(c)(1)(iv) and the risk-informed evaluation process specified in proposed 10 CFR 50.46a(c)(1)(v).

(a) Requirements for the Risk-Informed Evaluation

The acceptability of all entity-initiated changes made under the rule would be judged in a risk-informed manner. The risk-informed assessment process would include methods for evaluating compliance with the risk criteria, defense-in-depth criteria, safety margin criteria, and performance measurement criteria in proposed 10 CFR 50.46a(h). These attributes have been identified by the NRC in RG 1.174 as a set of risk evaluation tools to ensure that changes to the facility do not endanger public health and safety.

Compliance with the risk criteria would play a key role in the regulatory structure of the proposed rule. Entities would be required to use a risk assessment to determine the change in

risk associated with facility changes. Inasmuch as the Commission's final policy statement on the ''Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities'' (60 FR 42622; August 16, 1995) sets forth the Commission's intention to encourage the use of PRA and to expand the scope of PRA applications in all nuclear regulatory matters to the extent supported by the state-of-the-art in PRA methods and data, 10 CFR 50.46a(h)(4) of the proposed rule would require that a technically acceptable PRA be used to demonstrate compliance with the requirements of proposed 10 CFR 50.46a if the change being assessed could substantively increase risk. Proposed 10 CFR 50.46a(h)(4)(i) through (iv) set forth the four general attributes of an acceptable PRA for the purposes of this proposed -rule. However, the NRC recognizes that nonquantitative PRA assessment methodologies and approaches could also be used to complement or supplement the quantitative aspects of a PRA, especially when performance of a quantitative PRA methodology of the level needed to support a particular plant modification decision would not be justifiable because the safety significance of the decision would not warrant the level of technical sophistication inherent in a PRA. Accordingly, proposed 10 CFR 50.46a(h)(5) would establish the minimum requirements for risk assessment methodologies other than PRA. This proposed requirement would provide flexibility for entities to use the nonPRA risk methodology (or combination of different methodologies) when these methodologies produce results that are sufficient to -determine that the risk acceptance criteria in the proposed rule have been met.

(b) Aggregation of Plant Changes When Evaluating Changes in Risk

Entities often make changes to their facilities, technical specifications, and procedures. Some changes that entities would be able to make after being approved to use this proposed rule would not have been permitted without the proposed 10 CFR 50.46a ECCS requirements (*i.e.,* enabled changes). Other changes would be unrelated insofar as the basis of the changes and NRC approval, when necessary, would rely on regulations, guidelines, or facility priorities that would not depend on the proposed 10 CFR 50.46a ECCS requirements. Unrelated changes would indirectly influence the change in risk of the proposed 10 CFR 50.46a related changes because they would change the risk profile of the facility. If unrelated changes were combined (bundled) with enabled changes in evaluating the proposed 10 CFR 50.46a change in risk estimates, the result would typically be different than if the unrelated changes were considered as part of the baseline risk associated with the current design and operation of the facility. Regulatory guide 1.174 permits bundling changes (referred to as combined changes in RG 1.174) and provides additional acceptance guidelines when combining unrelated plant changes that might decrease risk together with a group of enabled changes to evaluate the total change in risk for comparison to the acceptance guidelines.

Allowing the bundling of unrelated changes into the proposed 10 CFR 50.46a change in risk estimates would encourage entities to use risk-informed methods to take advantage of opportunities to reduce risk. However, in some situations, bundling could mask the creation of significant risk outliers. To ensure that outliers would not be created, the proposed rule would not permit bundling of unrelated changes with enabled changes without NRC review and approval. Specifically, proposed 10 CFR 50.46a(h)(2)(i) and (iii) would allow changes not enabled by proposed 10 CFR 50.46a to be bundled with changes enabled by proposed 10 CFR 50.46a in the calculation of the change in risk when an entity would submit an application for a change under 10 CFR 50.90, ''Application for amendment of license, construction permit, or early site permit.''

(c) NRC approval of an Entity Process for Making Changes to an Entity's Facility or Procedures Without NRC Review and Approval

As a general matter, the proposed rule would require an entity to obtain NRC review and approval through an application for any changes to its facility, technical specifications, or procedures that may be implemented under proposed 10 CFR 50.46a. However, the proposed rule would allow an entity, other than a design certification applicant or holder of an ML, to make a subset of plant and procedure changes without NRC approval if the changes would involve minimal changes in risk and no significant impact upon defense-in-depth capabilities, safety margins, or performance monitoring. Prior NRC review and approval of these changes on an individual basis would be unnecessary if the NRC had previously concluded that the entity other than a design certification applicant or holder of an ML had an adequate technical process for appropriately identifying this subset of changes. Plant changes that would involve minimal changes in risk and have no significant impact upon defense-in-depth, safety margins, and performance monitoring (and do not involve a change to the technical specifications), would not result in significant issues involving public health and safety or common defense and security.

Expending entity resources to prepare, and NRC resources to review and approve, an application for approval of plant changes involving minimal changes in risk would not be efficient uses of resources. Rather, if the NRC would review and approve in advance the entity's processes (including the acceptability of the entity's PRA and other risk assessment methods) and criteria for identifying changes that would have minimal impact on risk and would not significantly affect defense-in-depth, safety margin, performance monitoring, or plant physical security, then there would be no need for the NRC to review and approve each of the individual changes. Accordingly, the NRC is proposing an approach in 10 CFR 50.46a(h)(1) that would allow an entity other than a design certification applicant or holder of an ML to obtain ''pre-approval'' of a process for identifying minimal plant and procedure changes made possible under proposed 10 CFR 50.46a.

Proposed 10 CFR 50.46a(h) would enable an entity other than a design certification applicant or holder of an ML to make changes based upon the provisions of proposed 10 CFR 50.46a, without prior NRC approval, if the requirements in proposed 10 CFR 50.46a(h)(1) and (h)(3) were met. The proposed rule also would require that the change be permitted under the 10 CFR 50.59, ''Changes, tests and experiments.'' Compliance with the 10 CFR 50.59 requirements would be necessary to ensure that facility changes made without NRC approval would not result in plant conditions that could impact public health and safety. Compliance with the proposed 10 CFR 50.46a(h) requirements for risk assessments would be required to ensure that facility changes would result in acceptable changes in risk, that adequate defense-in-depth would be maintained, that safety margins would be maintained, and that adequate performance-measurement programs would be implemented.

Design certification applicants would not be subject to the change process in proposed 10 CFR 50.46a(h)(1), either before or after NRC certification of the design. An applicant for a design certification that has not been approved

by the NRC would not need this provision because it could change the design specified in its application before NRC issuance of a final standard design certification rule for its design. The NRC also has determined that design certification applicants whose designs have been certified should not be allowed to change the certified designs without NRC review and approval via rulemaking. Allowing the design certification applicant to make changes to the certified design without NRC approval through proposed 10 CFR 50.46a(h)(1) would be inconsistent with the purpose of certifying the design in a rulemaking and would effectively reduce the NRC's regulatory control over the design certification. The NRC would review any deviations from the certified design when reviewing the COL application. The NRC also would exclude ML holders from this option to avoid a reduction of NRC regulatory control over the approved manufacturing design, consistent with the requirement in existing 10 CFR 52.171(b)(1) that holder of an ML may not make changes to the design of the nuclear power reactor authorized to be manufactured without NRC approval.

(d) Risk Acceptance Criteria for Plant Changes

To make changes to the facility, technical specifications, or procedures not permitted by proposed 10 CFR 50.46a(h)(1), proposed 10 CFR 50.46a(h)(2) would require the submission of information from the risk-informed evaluation demonstrating, among other things, that the total increases in risk from the proposed change would be very small and that the overall plant risk would remain small. These characterizations of ''very small'' and ''small'' are intended to be consistent with their use in RG 1.174, which introduces surrogate guidelines that provide assurance that overall plant risks remain bounded by the Commission's Policy Statement on ''Safety Goals for the Operations of Nuclear Power Plants'' (51 FR 28044; August 4, 1986).

1. Risk Estimate

To satisfy the Commission's requirement in proposed 10 CFR 50.46a(h)(2)(ii) that the total increases in risk are very small, an entity would need to evaluate the change in risk for each facility change and show that the change meets the acceptance guidelines. If a series of changes were made over time, proposed 10 CFR 50.46a(h)(2)(iii) would require that the cumulative effect of these changes be evaluated and shown to meet the acceptance criteria. Proposed 10 CFR 50.46a(h)(2)(iii) also would permit an entity to combine changes in risk from facility changes not enabled by proposed 10 CFR 50.46a with changes in risk from facility changes that would be enabled by proposed 10 CFR 50.46a for the purposes of meeting the acceptance guidelines. Taken together, this bundled group of enabled changes and unrelated changes would be referred to as the ''changes made under'' proposed 10 CFR 50.46a.

For each change requiring a risk-informed evaluation, the total change in risk from all facility changes made under the proposed 10 CFR 50.46a would need to be evaluated and compared to the ''very small'' acceptance criterion when the change is first made and then with each subsequent enabled change that would result in a greater than minimal increase in risk. Requiring that the total change in risk from all facility changes made under the proposed 10 CFR 50.46a be compared to the proposed 10 CFR 50.46a acceptance criteria instead of allowing the changes in risk to be partitioned and individually compared to the acceptance criteria would ensure that the total risk increase for all changes, as they are implemented over time, would not constitute more than a very small increase in risk. If the total increase in the applicable risk metrics were not compared to the acceptance criteria, then several changes in which each individual change's risk increase was kept below the proposed rule's risk acceptance criteria could, considered cumulatively, result in a significant increase in risk. A significant increase may not satisfy the Commission's proposed criterion that the overall plant risk remains small. Also, comparing the risk increase from each change to the acceptance criteria independently of all previous changes would render the use of the ''very small'' criterion inadequate to monitor and control increases in risk from a series of plant changes implemented over time.

Comparing the total risk increase to the risk increase criterion, and allowing bundling of unrelated changes in the change in risk estimate, would support the NRC's position as stated in RG 1.174 that, consistent with the key principles of risk-informed integrated decision-making, entities should have a risk management approach in which risk insights are not just used to systematically increase risk, but also to help reduce risk where appropriate and where it is shown to be cost effective.

2. Acceptance Criteria

The risk acceptance guidelines proposed in 10 CFR 50.46a(h)(2)(ii) use CDF and large early release frequency (LERF) risk metrics. As discussed in SRM–SECY–98–015, ''Staff Requirements—SECY–98–015—Final General Regulatory Guide and Standard Review Plan for Risk-Informed Regulation of Power Reactors,'' dated May 20, 1998, the Commission approved the use of RG 1.174, which incorporated Commission direction in the March 19, 1998, SRM issued for SECY–97–287, ''Final Regulatory Guidance on Risk-Informed Regulation: Policy Issues,'' dated December 12, 1997. Based on proposals made by the staff, the Commission approved the use of very small increases in CDF and LERF independent of the baseline calculated CDF/LERF, provided that licensees track and NRC staff monitor the cumulative effect of changes. These risk metrics are based on subsidiary objectives derived from the NRC's safety goals and their quantitative health objectives. In particular, the CDF risk metric is used as a surrogate for the individual latent cancer fatality risk, and the LERF risk metric is used as a surrogate for the individual early fatality risk. The NRC has used CDF and LERF in making regulatory decisions for more than 30 years. The NRC endorsed the use of CDF and LERF as appropriate measures for evaluating risk and ensuring safety in nuclear power plants when it adopted RG 1.174 in 1998. Since the adoption of RG 1.174, the NRC has had 27 years of experience in applying risk-informed regulation to support a variety of applications, including amending facility procedures and programs (*e.g.,* inservice testing and inservice inspection programs), amending facility OLs, making changes to the FSAR, and implementing risk-informed technical specifications. Based on this experience, the NRC has determined that CDF and LERF are acceptable measures for evaluating changes in risk as the result of changes to a facility, technical specifications, and procedures, except for certain changes that affect containment performance but do not affect CDF or LERF. Changes that affect containment performance are considered as part of the defense-in-depth evaluation.

In SRM–SECY–07–0082, ''Staff Requirements—SECY–07–0082—Rulemaking to Make Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements; 10 CFR 50.46a, 'Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors,' ''

dated August 10, 2007, the Commission concluded that, to more closely follow the approach presented in RG 1.174, the staff, in the 10 CFR 50.46a draft final rule, should restrict changes to a plant to very small risk increases. As discussed in RG 1.174, a very small risk increase is independent of a plant's overall risk as measured by the current CDF and LERF. Increases in CDF of 10^{-6} per reactor year or less and increases in LERF of 10^{-7} per reactor year or less are very small risk increases for existing reactor facilities. Limiting the acceptance criteria for plant changes enabled under proposed 10 CFR 50.46a to very small risk increases ensures that significant plant changes will not be enabled strictly due to the initiating event frequency for a LOCA greater than the TBS, which is on the order of 10^{-5} and the same as the criteria for small risk increases. In SRM–SECY–12–0081, ''Staff Requirements—SECY–12–0081—Risk-Informed Regulatory Framework for New Reactors'' dated October 22, 2012, the Commission approved the staff's recommendation to transition new reactors from large release frequency to LERF at or before initial fuel load and discontinue regulatory use of large release frequency. Applicants for new reactor OLs under 10 CFR part 50 or COLs under 10 CFR part 52 may need to transition to LERF to demonstrate in the risk-informed evaluation that the proposed changes meet the requirements in proposed 10 CFR 50.46a(h).

Since adopting RG 1.174 in 1998, the NRC has applied the quantitative change in risk guidelines to individual plant changes and to sequences of plant changes implemented over time. The NRC has found these guidelines and the CDF and LERF values (when used together with the defense-in-depth, safety monitoring, and performance measurement criteria) to be capable of differentiating between changes, and sequences of changes, that are not expected to endanger public health and safety and those that might.

When the change does not significantly increase LOCA frequencies or invalidate the evaluation demonstrating the applicability of the TBS to the applicant's facility and the change is permitted under 10 CFR 50.59, 10 CFR 52.98(b), 10 CFR 52.98(c), and 10 CFR 52.98(d), as applicable, proposed 10 CFR 50.46a(h)(1) would permit entities other than a design certification applicant or holder of an ML to make changes without prior NRC approval if the changes involve minimal increases in risk that also have no significant impact upon defense-in-depth capabilities, safety margins, and performance monitoring. A minimal risk increase is one that, when considered qualitatively by itself or in combination with all other minimal increases, would never become significant. A minimal increase in risk is an increase less than 10 percent of the risk increases that would be very small for any licensee. Therefore, a minimal increase is an increase of less than 10^{-7} per reactor year for CDF and an increase in LERF of less than 10^{-8} per reactor year. These values are two orders of magnitude below the maximum allowed risk increase guidelines in RG 1.174 and one order of magnitude less than the very small criterion. Although multiple changes, when evaluated separately, could each be a minimal increase in risk, when combined and evaluated together, they could exceed the very small criterion. Most of these changes would have a much smaller (and, in some cases, an unmeasurable) increase in risk. If an entity other than a design certification applicant or holder of an ML were to implement an unexpectedly large number of minimal risk changes, then the periodic reporting requirements in proposed 10 CFR 50.46a(j)(3) would provide adequate notice to ensure that the NRC is aware of potentially significant changes (or any collective impact), so that the NRC could undertake additional oversight actions as deemed necessary and appropriate.

(e) Defense-in-Depth

Section 50.46a(h)(3)(i) of the proposed rule would require that the risk-informed evaluation demonstrate that defense-in-depth is maintained. Defense-in-depth is an element of the NRC's safety philosophy that employs successive measures to prevent accidents or mitigate damage if a malfunction, accident, or naturally caused event occurs at a nuclear facility. As conceived and implemented by the NRC, defense-in-depth provides, among other things, redundancy in addition to a multiple barrier approach against fission product releases. Defense-in-depth continues to be an effective way to account for uncertainties in equipment and human performance. The NRC has determined that retention of adequate defense-in-depth must be ensured in all risk-informed regulatory activities.

(f) Safety Margins

Proposed 10 CFR 50.46a(h)(3)(ii) would require that adequate safety margins be retained to account for uncertainties. These uncertainties include phenomenology, modeling, plant construction, and plant operation. Without this proposed provision, entities could make plant changes that would inappropriately reduce safety margins, resulting in an unacceptable increase in risk or challenge to plant SSCs. This proposed requirement would ensure that an adequate safety margin exists to account for these uncertainties, such that there would be no unacceptable results or consequences (*e.g.,* structural failure) if an acceptance criterion or limit is exceeded.

(g) Performance Measuring Programs

Section 50.46a(h)(3)(iii) of the proposed rule would require entities to implement adequate performance-measurement programs and feedback strategies to ensure that the risk-informed evaluation continues to reflect actual plant design and operation. The risk-informed evaluation would include the risk assessment, maintenance of adequate defense-in-depth, and maintenance of adequate safety margins. This proposed requirement would require that the monitoring programs be designed to detect degradation of SSCs before plant safety is compromised.

(vii) Leak Detection Requirements

In its SRM on SECY–07–0082, the Commission directed the NRC staff to increase the defense-in-depth against large pipe breaks provided by the 10 CFR 50.46a draft final rule. The SRM also directed the NRC staff to evaluate various approaches for enhancing that draft final rule with requirements for improved leak detection methods. The NRC determined that adequate leak detection capability meeting this direction could enhance defense-in-depth for LOCAs larger than the TBS by reducing the likelihood of pipe breaks in the large break region. Thus, proposed 10 CFR 50.46a(d)(2) would require that licensees have leak detection systems available at the facility and implement actions as necessary to identify, monitor, and quantify leakage to ensure that adverse safety consequences do not result from leaking primary pressure boundary components that are larger than the TBS.

Because proposed 10 CFR 50.46a would not change the design basis of piping and components that are smaller than the TBS, the requirements of proposed 10 CFR 50.46a(d)(2) would apply only to piping and components that are larger than TBS. The NRC recognizes that leakage detection methods that satisfy these proposed requirements may not be capable of determining whether the source of leakage is from piping or a component that is larger or smaller than the TBS.

Discrimination between leaks in pipes larger or smaller than the TBS would be unnecessary as long as adequate leak detection would be provided for all beyond-TBS piping.

(viii) Programmatic Requirements

The proposed rule would include several specific programmatic requirements in proposed 10 CFR 50.46a(d) that would apply to entities who are approved to implement proposed 10 CFR 50.46a. These requirements would remain applicable to such an entity as long as the entity is subject to the proposed 10 CFR 50.46a alternative ECCS requirements until such time as the licensee permanently ceases operations by submitting the certifications required under 10 CFR 50.82(a). The proposed programmatic requirements would require entities implementing proposed 10 CFR 50.46a to do the following:

(a) Maintain ECCS models and/or analysis methods that demonstrate compliance with the ECCS acceptance criteria.

(b) Maintain adequate reactor coolant leak detection equipment available at the facility and identify, monitor, and quantify leakage to ensure that adverse safety consequences do not result from leaking primary pressure boundary components that are larger than the TBS.

(c) Perform a risk-informed evaluation for each potentially risk-significant change (or group of changes) to the facility enabled by proposed 10 CFR 50.46a.

(d) Perform an evaluation to determine the effect of all planned nuclear power plant changes and do not implement any facility change that would invalidate the applicability of the TBS to the facility.

(e) Within 120 days after the outage in which the inspection required in proposed 10 CFR 50.46a(b)(3) has been performed, submit to the NRC a report that details the results of the inspection and any impact these results have on the TBS in accordance with proposed 10 CFR 50.46a(b)(3).

The following discussion describes each of the programmatic requirements.

(a) Maintain ECCS Models and/or Analysis Methods That Demonstrate Compliance With the ECCS Acceptance Criteria

Section 50.46a(d)(1) of the proposed rule would require that calculated results of entity ECCS models and/or analysis methods must demonstrate compliance with the ECCS acceptance criteria as long as the entity is subject to the requirements in proposed 10 CFR 50.46a. Entities also would be required to update ECCS models and/or analysis methods by modifying them as needed to address any error corrections and plant design changes affecting ECCS performance during this time period.

(b) Maintain Adequate Reactor Coolant Leak Detection Equipment Available at the Facility and Identify, Monitor, and Quantify Leakage To Ensure That Adverse Safety Consequences Do Not Result From Leaking Primary Pressure Boundary Components That Are Larger Than the Transition Break Size

The requirement for adequate leak detection capability would be in proposed 10 CFR 50.46a(d)(2) and was discussed in section XXXVI.F.(vii), ''Leak Detection Requirements,'' of this document. Adequate leak detection would be required for all primary coolant pressure boundary piping and other components whose rupture could result in a break larger than the TBS.

(c) Perform a Risk-Informed Evaluation for Each Change (or Group of Changes) to the Facility Enabled by Proposed 10 CFR 50.46a

In addition to meeting all other applicable requirements, entities would be required by proposed 10 CFR 50.46a(d)(3) to perform a risk-informed evaluation for changes enabled by proposed 10 CFR 50.46a. If an entity had a change methodology that was submitted under proposed 10 CFR 50.46a(c)(1)(iv) and approved by the NRC, that licensee would be able to make some changes without NRC approval as long as the acceptance criteria in proposed 10 CFR 50.46a(h)(1) were met. Otherwise, the entity would be required to submit the results of its risk-informed evaluation for NRC review and approval. The entity would need to retain the results of all risk-informed evaluations made under proposed 10 CFR 50.46a(h)(1) and periodically submit a summary of the results to the NRC as required under proposed 10 CFR 50.46a(j)(3).

(d) Perform an Evaluation To Determine the Effect of All Planned Facility Changes and Do Not Implement Any Facility Change That Would Invalidate the Applicability of the TBS to the Facility

For the TBS as defined in 10 CFR 50.46a(a)(9) to properly apply to an entity's facility, that entity would be required to perform an evaluation to demonstrate that the TBS is applicable to that particular facility. For those entities that decide to propose an alternate TBS, a similar evaluation would be needed as part of the basis for the proposed TBS. But after the initial evaluation has demonstrated the applicability of the TBS, an entity could make significant facility changes that would invalidate the initial evaluation. Therefore, after a facility has been approved to use proposed 10 CFR 50.46a, the proposed rule would require the entity to ensure that the TBS remains applicable to the facility by reviewing all subsequent plant changes to ensure that the facility is not modified to the extent that the results impact the applicability of the TBS. Licensees' existing configuration management programs, which contain a process to control plant changes made under 10 CFR 50.59, could be modified, through screening or evaluation, to identify future plant changes that may invalidate the applicability of the NRC's generic studies. Most anticipated plant changes should not impact the TBS, so little, if any, evaluation would be necessary to demonstrate the acceptability of such changes. However, some changes, such as power uprates, would have the potential to affect the TBS by increasing operating temperatures, coolant flow rate, and neutronic flux.

(e) Submit to the NRC a Report Within 120 Days After the Outage When the Inspection Occurred Detailing the Results of the Inspections and Any Impact These Results Have on the TBS in Accordance With Proposed 10 CFR 50.46a(b)(3)

Under proposed 10 CFR 50.46a(b)(3), for RCPB piping whose inner diameter is greater than the TBS, licensees would be required to inspect an NRC-approved risk-informed sample of the similar metal piping circumferential welds in a PWR and the Category A welds (as defined in Generic Letter 88–01) in a BWR in accordance with 10 CFR 50.55a(g) before implementing proposed 10 CFR 50.46a and in every subsequent inservice inspection interval (as defined in 10 CFR 50.55a(y)). Any indications found during this inspection should be dispositioned according to ASME section XI requirements and the effects of any indications on the continued applicability of the TBS should be evaluated.

(ix) Reporting Requirements

(a) ECCS Reporting Requirements

The ECCS reporting requirements currently provided in 10 CFR 50.46(a)(3) were added during the 1988 revision to 10 CFR 50.46 (53 FR 35996; September 16, 1988). The proposed rule (52 FR 6334; March 3, 1987) preceding that final rule prompted several public

comments on the reporting requirements, some of which suggested that the reporting requirements be relaxed or even eliminated (see NRC Summary of Public Comments, ''PR–050—52FR06334—Emergency Core Cooling Systems: Revisions to Acceptance Criteria,'' March 3, 1987).

In response to these comments, the NRC identified several reasons for requiring reporting of changes to, or errors in, ECCS evaluation models or in the applications thereof. First, the Commission believed that significant changes or errors raise potential questions about the adequacy of an evaluation model as a whole. Second, the Commission noted that even minor or inconsequential errors and changes constituted a deviation from what previously had been reviewed and accepted. Finally, the Commission also noted that applications of models to areas not contemplated during initial review of the model could result in errors by extending a model beyond its intended range. The Commission stated that, overall, the reporting requirements were a clarification and relaxation of the then-existing requirements.

More than 20 years later, in its rulemaking efforts for 10 CFR 50.46c, the NRC again received numerous public comments about reporting requirements, some of which suggested that the reporting requirements should be relaxed or eliminated. In response to those public comments, the NRC is proposing in the new 10 CFR 50.46a several relaxations to, and clarifications of, the reporting requirements compared to what currently appears in 10 CFR 50.46(a)(3). However, the NRC proposes to leave the deterministic reporting requirements under the 1988 revision to the ECCS regulations largely intact, with the addition of reporting requirements for changes and error corrections affecting the integral time-at-temperature (*i.e.,* ECR) calculation.

Reporting remains necessary for changes to, or errors in, ECCS evaluation models, and applications thereof, for several reasons. First, considering all safety analyses for DBEs, LOCA analysis requires substantially more complex thermal-hydraulic calculations. The reporting requirements allow minor changes to, and error corrections for, these calculations. Second, the reporting requirements provide a regulatory framework for communicating, and addressing the effects of, these changes and errors. And finally, reporting requirements are less burdensome than an alternative that would include topical report revisions and license amendments to address changes and errors. The NRC considered these benefits, in addition to the original, safety-related justification for the reporting requirements set forth in the 1988 rulemaking, when deciding to retain reporting requirements in proposed 10 CFR 50.46a.

The ECCS reporting criteria in proposed 10 CFR 50.46a(j) generally match the criteria in the 10 CFR 50.46c draft final rule in SECY–16–0033. One of the primary differences would be that an entity could propose an alternative definition for a ''significant change'' for breaks above the TBS. Furthermore, proposed 10 CFR 50.46a(j)(1)(iii) would relax the reporting requirements for applicants for a standard design certification (including applicants after the Commission has adopted a final design certification regulation) or applicants for or holders of a standard design approval under 10 CFR part 52 that are approved to use proposed 10 CFR 50.46a. Under proposed 10 CFR 50.46a(j)(1)(iii), standard design approval holders and applicants and standard design certification applicants that are approved to use the alternative ECCS criteria in proposed 10 CFR 50.46a would be required to internally document the nature and estimated effect of all changes and errors affecting ECCS evaluation models. This documentation would be subject to NRC inspection. Also, if the cumulative effect of changes or errors would result in an inability to ensure compliance with the alternative ECCS criteria in proposed 10 CFR 50.46a(f), then proposed 10 CFR 50.46a(j)(1)(iv) would continue to require NRC notification of the underlying changes or errors and associated corrective actions so that the NRC may evaluate the potential for impacts to the affected standard design approval or standard design certification.

Instead of the existing requirement for the applicant for or holder of a standard design approval or applicant for a standard design certification to report this information to the NRC, the CP, OL, or COL applicant would be responsible for providing an acceptable analysis of the ECCS in its application submitted to the NRC under proposed 10 CFR 50.46a(j)(1)(i)–(iii). The proposed relaxation for applicants for or holders of standard design approvals and applicants for standard design certifications is justified because reporting changes and errors to the NRC before the design is referenced in an application for a CP, OL, or COL would not produce a tangible public health and safety benefit, provided that the changes or errors would not create the potential for the standard design approval or standard design certification to become noncompliant with NRC requirements. There would be no public health and safety benefit because the change or error would not impact the operation of an operating reactor or even the NRC's safety review of an application.

Moreover, instead of the existing 30-day reporting requirements that are in 10 CFR 50.46(a)(3)(ii), the reporting requirements proposed in 10 CFR 50.46a(j)(1)(ii), (j)(1)(iv), (j)(2)(ii), and (j)(2)(iii) would require reports to be submitted to the NRC within 60 days of discovery to better align with the 10 CFR 50.73, ''Licensee event report system,'' report timeframe. As stated in 10 CFR 50.46(a)(3)(ii), discovery of a change or error that exceeds the 10 CFR 50.46 acceptance criteria would be a reportable event as described in paragraph (e) of 10 CFR 50.55, ''Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses''; 10 CFR 50.72, ''Immediate notification requirements for operating nuclear power reactors''; and 10 CFR 50.73. Likewise, discovery of a change or error that exceeds the criteria in proposed 10 CFR 50.46a would also be a reportable event under 10 CFR 50.55(e), 10 CFR 50.72, and 10 CFR 50.73. Since exceeding the proposed 10 CFR 50.46a criteria would be reportable under those regulations, the NRC proposes to align the report required under proposed 10 CFR 50.46a(j)(1) and (2) with the 60-day timeframe in 10 CFR 50.73. The additional time permitted relative to 10 CFR 50.46 would be based on the low initiating event frequency for many of the limiting LOCAs, which would be confirmed on a plant-specific basis in order to employ the proposed 10 CFR 50.46a. The additional time may also result in increased accuracy in the information provided to the NRC in the report required under proposed 10 CFR 50.46a.

The 10 CFR 50.46a proposed rule would clarify existing reporting and corrective action requirements. Proposed 10 CFR 50.46a(j)(1) would distinguish four possible combinations of reporting criteria based upon predicted response, level of significance (*i.e.,* significant or not significant, as defined by the proposed rule), and whether the error, change, or operation would result in any exceedance of acceptance criteria. For each scenario, the proposed rule would provide the required actions, reports, and a time frame for providing the necessary reports.

Presently, the reporting requirements in 10 CFR 50.46(a)(3) require that entities report changes to, or errors in,

an ECCS evaluation model, or in the application of the evaluation model, and the estimated effect of the changes or errors on predicted PCT. Proposed 10 CFR 50.46a would expand the definition of a significant change or error to include integral time-at-temperature (*i.e.,* ECR). Any changes or errors that prolong the temperature transient may further challenge the PQD analytical limits; however, they may not significantly change the predicted PCT. As such, this change or error would not be captured in the existing reporting requirements. The NRC would include the reporting requirements for changes and errors in integral time-at-temperature in proposed 10 CFR 50.46a to improve the content and communications of reports submitted to the NRC. The NRC also proposes this requirement to inform the agency's response to future changes to, or errors discovered in, ECCS evaluation models or in the applications thereof.

A significant change or error would occur when the sum of the absolute magnitudes of the respective changes is greater than 50 °F (10 °C) PCT or 1.0 percent ECR for breaks at or below the TBS, as defined in proposed 10 CFR 50.46a(k)(1). A change of 1.0 percent ECR is correlated to a change in calculated ECR for a 50 °F (10 °C) change in cladding temperature for a typical analysis of record PCT. The definition of significant change in proposed 10 CFR 50.46a(k)(1) would be specific to zirconium-alloy cladding. A new definition of significant change or error may be necessary for other cladding materials. In addition, proposed 10 CFR 50.46a(k)(1)(ii) would require the use of maximum local oxidation (*i.e.,* percent ECR) to evaluate the impact of a change or error on the predicted integral time-at-temperature. In proposed 10 CFR 50.46a(k)(2), for breaks above the TBS, the significant change or error is one that results in a significant reduction in the capability to meet the requirements of proposed 10 CFR 50.46a(e)(1) and (f). For LOCAs above the TBS, this significant change or error is higher level than the criteria for LOCAs at or below the TBS to allow for an entity to define alternative criteria for a significant change. If alternative criteria are not defined, then the same reporting criteria in proposed 10 CFR 50.46(k)(1) would be applied.

Existing reporting requirements in 10 CFR 50.46(a)(3) with respect to any ''change to or error discovered in an acceptable evaluation model or in the application of such a model'' have been a source of confusion. Two areas of common misconceptions are related to (1) the baseline PCT and integral time-at-temperature values when estimating a significant change or error (*i.e.,* greater than 50 °F (10 °C)), and (2) the 30-day reporting requirement including ''a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements.'' Similar to the 10 CFR 50.46c draft final rule, the NRC is proposing in this rulemaking to revise the existing reporting requirements to (1) identify more clearly the baseline values to be used in reporting pursuant to the requirements of proposed 10 CFR 50.46a(j), (2) require under proposed 10 CFR 50.46a(j)(1)(ii) and (iv) that entities include, in a report describing a significant change, a proposed scope and schedule for providing a reanalysis, and (3) distinguish between the requirements for proposing a reanalysis scope and schedule, and for proposing to implement corrective action as may be needed to show compliance with proposed 10 CFR 50.46a(e) requirements.

As is the case with 10 CFR 50.46(a)(3), flexibility would exist in terms of the scope of reanalysis that would be required to comply with proposed 10 CFR 50.46a(j)(1)(ii) and (iv), and with the schedule that the reporting entity may propose. Since the promulgation of the 1988 revision to 10 CFR 50.46, the NRC has accepted multiple evaluations, which have been performed within a scope that has been significantly limited when compared to full-scale implementation of an ECCS evaluation model. In these cases, the NRC has concluded that such evaluations satisfied the requirements of 10 CFR 50.46(a)(3)(ii). The Commission does not propose to change its approach in this regard. In addition, a proposed schedule for reanalysis may also incorporate appropriate flexibility. The NRC has accepted proposed schedules that extend as far as four years into the future and that are managed using regulatory commitments that can be changed or updated as operating conditions require and nuclear safety considerations permit. Proposed 10 CFR 50.46a(j)(1)(ii) and (iv) would retain this flexibility.

Proposed 10 CFR 50.46a(k)(1) would provide threshold values for PCT and integral time-at-temperature for entities to use when estimating the effect of a significant change or error. The baseline predictions used to assess a significant change or error should be the PCT and integral time-at-temperature values documented in a plant's updated final safety analysis report (UFSAR). These values should represent the latest LOCA analyses that were submitted and reviewed by the NRC as part of a license amendment request (*e.g.,* power uprate, fuel transition) or as incorporated into the facility licensing basis in accordance with NRC-approved methods, as amended by subsequent annual reports.

Existing 10 CFR 50.46(a)(3) requires entities to include, in a report describing the nature of a significant error or change and its estimated effect on the predicted PCT, a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with 10 CFR 50.46. This requirement has led to a misconception that, when a significant error is reported that does not cause the predicted PCT to exceed its 2200 °F (1204 °C) acceptance criterion, a proposed schedule for providing a reanalysis is not required and taking other action is not needed to show compliance with the requirements. As explained in the preamble to the 1988 revision of 10 CFR 50.46, it has long been the NRC's position that facility operation in excess of the 10 CFR 50.46 acceptance criteria is an immediate safety concern that requires prompt corrective action and the ''taking other action'' language in the rule was intended to address that concern. This position is underscored by the final sentence of the existing 10 CFR 50.46(a)(3)(iii): ''The affected applicant or holder shall propose immediate steps to demonstrate compliance or bring plant design into compliance with § 50.46 requirements.'' Therefore, the reporting and reanalysis requirements would be further separated into proposed 10 CFR 50.46a(j)(1) and 10 CFR 50.46a(j)(2) to distinguish the requirements that apply when a significant change or error is identified that results in facility operation in excess of the proposed 10 CFR 50.46a acceptance criteria, from the requirements that apply when a significant change or error is identified that does not result in facility operation in excess of the proposed 10 CFR 50.46a acceptance criteria.

When a change to, or error in, an ECCS evaluation model, or in the application of such a model, is discovered, the entity would be responsible for estimating the magnitude of changes in predicted results to (1) determine if immediate steps are necessary to demonstrate compliance or bring plant design or operation into compliance with proposed 10 CFR 50.46a(e) requirements, and (2) identify reporting requirements. Under proposed 10 CFR 50.46a(j), an entity's obligation to report and take corrective action would vary depending upon whether the licensee's

situation falls into one of the following three possible scenarios:

1. *Change or error that does not result in any predicted response that exceeds any acceptance criteria and is itself not significant.*

In this scenario, proposed 10 CFR 50.46a(j)(1)(i) would require the entity to do the following:

a. Submit an annual report documenting the change(s) and/or error(s), along with the estimated magnitudes of changes in predicted results, and the basis for the entity's determination that the change or error is not significant.

b. Revise the UFSAR in accordance with paragraph (e) of 10 CFR 50.71, ''Maintenance of records, making of reports.''

c. Use the revised UFSAR PCT/ECR predictions as a baseline for future evaluations.

2. *Change or error that does not result in any predicted response that exceeds any acceptance criteria but is significant.*

In this scenario, proposed 10 CFR 50.46a(j)(1)(ii) would require the entity to do the following:

a. Within 60 days of making a change, discovering an error, or both, submit a report documenting the change, error, or both, estimated magnitudes of changes in predicted results, the proposed scope and schedule for providing a reanalysis, and a description of and schedule for implementing corrective actions. The reanalysis must be performed within a scope of detail appropriate to address the reported, significant change to, or error in, the ECCS evaluation model, or in its application. The proposed reanalysis schedule should reflect consideration for both the magnitude of the change or error and the available margin to NRC acceptance criteria, once the estimated effect of the change or error is applied to the existing results.

b. In accordance with the schedule proposed in paragraph a., provide the reanalysis to the NRC. This may be accomplished by submitting a subsequent report, pursuant to proposed 10 CFR 50.46a(j)(1), describing the reanalysis and providing the updated results. The reanalysis may be limited in scope but must otherwise be performed using an acceptable evaluation model.

c. Revise the UFSAR to include new evaluation model results in accordance with 10 CFR 50.71(e).

d. Use the revised UFSAR evaluation model results as a baseline for the future evaluations.

3. *Change or error that results in any predicted response that exceeds any of the four acceptance criteria in proposed 10 CFR 50.46a(f).*

In this scenario, proposed 10 CFR 50.46a(j)(1)(iv) and 10 CFR 50.46a(j)(2)(i) would require the entity to do the following:

a. Take immediate actions to bring the plant into compliance with the acceptance criteria.

b. Within 60 days of making a change, discovering an error, or both, submit a report documenting the change, error, or both, estimated magnitudes of changes in predicted results, description of corrective actions and/or compensatory measures, and the proposed scope and schedule for providing a reanalysis, and a description of and schedule for implementing corrective actions. The reanalysis must be performed within a scope of detail appropriate to address the reported change to, or error in, the ECCS evaluation model, or in its application. The proposed reanalysis schedule should reflect consideration for both the magnitude of the change or error and the fact that the change or error has caused the NRC's acceptance criteria to be exceeded. The entity may also need to submit this information in the reports required under 10 CFR 50.55(e), 10 CFR 50.72, and 10 CFR 50.73, as applicable.

c. Provide the reanalysis to the NRC in accordance with the schedule submitted to the NRC. This may be accomplished by submitting a subsequent report, pursuant to proposed 10 CFR 50.46a(j)(1), describing the reanalysis and providing the updated results. The reanalysis must be performed using an acceptable evaluation model. Revise the UFSAR to include new evaluation model results in accordance with 10 CFR 50.71(e).

d. Use the revised UFSAR evaluation model results as the baseline for future evaluations.

As described in scenario 3, proposed 10 CFR 50.46a(j)(1)(iv) and (j)(2)(i) would apply to changes to, or errors in, ECCS evaluation models, or the applications thereof, that affect the predicted performance relative to all of the acceptance criteria contained in proposed 10 CFR 50.46a(f). For example, an error or change in a PWR boron precipitation calculation that invalidates the timing for emergency operating procedures is considered a condition in which a plant's conformance to proposed 10 CFR 50.46a(f)(4) would be uncertain. In this circumstance, the NRC would consider this a potentially serious safety issue in need of immediate attention and potential correction. In proposed 10 CFR 50.46a(j)(2)(i), if a licensee with a COL identifies a change or error that results in the acceptance criteria in proposed 10 CFR 50.46a(f) being exceeded before the Commission has made a finding under paragraph (g) of 10 CFR 52.103, ''Operation under a combined license,'' immediate action to bring a facility into compliance would not be required due to the low safety significance of exceeding the acceptance criteria before the initial startup of the plant. Similarly, in proposed 10 CFR 50.46a(j)(2)(ii) and (iii), for design certification applicants (including an applicant after the Commission has adopted a final design certification regulation) and applicants and holders for standard design approvals, if a change or error correction results in calculated ECCS performance that does not conform to the criteria in proposed 10 CFR 50.46a(e), immediate action would not be required. In this situation, the affected applicant or holder would need to propose appropriate steps to the Commission within 60 days to demonstrate compliance with proposed 10 CFR 50.46a requirements, along with a report of the nature of the changes or errors that resulted in an inability to assure compliance and an estimate of their effect on the limiting transient.

Based upon the complexity of the ECCS performance demonstration, entities may need to report multiple estimated effects on PCT and integral time-at-temperature to assess available margin to analytical limits under the proposed rule. For example, if the fuel rod population in a reactor core is subdivided, analyzed, and judged against different analytical limits (*e.g.,* burnup-dependent fuel rod populations), the entity may need to report multiple estimated effects and estimated available margin to PCT and integral time-at-temperature analytical limits. This would enhance communication with the NRC, especially for understanding the proposed scope and schedule for reanalysis, if required.

(b) Risk-Informed Evaluation Process Reporting

Section 50.46a(j)(3) of the proposed rule would require periodic reports of changes that required a risk-informed evaluation under proposed 10 CFR 50.46a(d)(3) and were implemented without prior NRC approval under proposed 10 CFR 50.46a(h)(1). Proposed 10 CFR 50.46a(j)(3) would not require the submission of a report if no changes involving minimal changes in risk were made under proposed 10 CFR 50.46a(h)(1) during the reporting period.

(c) TBS Applicability Requirements

Section 50.46a(j)(3) of the proposed rule would require an entity to provide a brief summary of the basis for the

entity determination under proposed 10 CFR 50.46a(h)(1)(iii) that each change made under proposed 10 CFR 50.46a(h)(1) would not invalidate the TBS applicability evaluations made under proposed 10 CFR 50.46a(c)(1)(i) for an operating reactor authorized to operate under 10 CFR part 50 on December 31, 2015, or under proposed 10 CFR 50.46a(c)(2) for entities other than those authorized to operate under 10 CFR part 50 on December 31, 2015.

Proposed 10 CFR 50.46a(j)(4) would include reporting requirements for the periodic inspections used to provide assurance that no significant degradation would be occurring in piping systems with an inner diameter greater than the TBS that could undermine the technical basis of the TBS. During each inservice inspection interval, the licensee would be required to submit a summary report within 120 days after completing the outage when the inspections specified in proposed 10 CFR 50.46a(b)(3) are completed. If any reportable indications were found during these inspections, then the licensee's summary report would need to include an evaluation of the impact of these indications on the TBS as well as any other ASME section XI requirement. This report could be combined with the summary report required by 10 CFR 50.55a(b)(2)(xxxii), which has an identical reporting time requirement. The level of detail in the report specified in proposed 10 CFR 50.46a(j)(4) would be consistent with the report specified in 10 CFR 50.55a(b)(2)(xxxii).

(x) Documentation Requirements

Section 50.46a(l) of the proposed rule would require that entities maintain records sufficient to demonstrate compliance with proposed 10 CFR 50.46a requirements. When making changes under proposed 10 CFR 50.46a(h), entities would be required to document the bases for concluding that the acceptance criteria in proposed 10 CFR 50.46a(h)(1) and (h)(2) would be satisfied and would continue to be satisfied as long as the entity is subject to the proposed 10 CFR 50.46a. Entities would be required under proposed part II of appendix K to 10 CFR part 50 to document the bases of evaluation models used to perform ECCS calculations. Entities also would be required to document plant design changes made under proposed 10 CFR 50.46a by updating the FSAR in accordance with the requirements in 10 CFR 50.71(e). All documentation could be reviewed during NRC inspections and/or audits.

(xi) Submittal and Review of Applications

(a) Initial Application for Implementing Proposed 10 CFR 50.46a Requirements

When an entity would first apply to use the proposed 10 CFR 50.46a requirements, that entity would need to submit an application under 10 CFR 50.34, 10 CFR 50.90, or 10 CFR part 52 for NRC review and approval. The initial application would need to contain the information specified in proposed 10 CFR 50.46a(c)(1)(i) through (vii), as applicable. This would include information related to the applicability of the TBS to the facility (if the entity desires to develop an alternate TBS, the information needed in the application would include those items discussed in section XXXVI.F.(xii), Applicability to New Reactor Designs,'' of this document); information identifying the ECCS analysis methods to be used; information describing the risk-informed evaluation for all changes enabled by the proposed rule and proposed in the application; information describing the proposed process for making risk-informed changes without prior NRC approval (if the applicant would seek approval of such a process); information describing non-safety equipment to be credited for compliance with the ECCS acceptance criteria in proposed 10 CFR 50.46a(e); and information describing how the leak detection program would satisfy the criteria in proposed 10 CFR 50.46a(d)(2).

An entity's initial change from its existing ECCS analysis would not need to be reviewed by the entity under the provisions of 10 CFR 50.59 because the proposed rule would require NRC review and approval of the initial application to implement the proposed 10 CFR 50.46a requirements. After the proposed 10 CFR 50.46a evaluation models and initial ECCS LOCA analyses were established by approval of the proposed 10 CFR 50.46a application, subsequent changes to ECCS analyses would be controlled by the process in 10 CFR 50.59 (which provides criteria for determining which changes are within the licensee's authority to make) and the requirements in proposed 10 CFR 50.46a(j) for reporting changes to evaluation models and analysis methods (whether from correction of errors or changes). The initial application could request one or more facility changes.

The initial application also would include a request for NRC approval of a process for evaluating the acceptability of future facility changes enabled by proposed 10 CFR 50.46a using the provisions in proposed 10 CFR 50.46a(h)(1). If approval of a process for evaluating future changes were requested, the application would need to include the information described in proposed 10 CFR 50.46a(c)(1)(iv).

(b) Subsequent Applications for Changes Under Proposed 10 CFR 50.46a

After NRC approval of an entity's initial application addressing ECCS analyses and the risk-informed evaluation processes under the proposed rule, the entity could submit applications for proposed changes under 10 CFR 50.90. These license amendment applications would need to contain the following:

- For licensees, the information required by 10 CFR 50.90;
- Information from the risk-informed evaluation demonstrating that the risk criteria, defense-in-depth criteria, safety margins, and performance monitoring criteria in proposed 10 CFR 50.46a(h)(2) and (h)(3) would be met;
- Information demonstrating that the ECCS acceptance criteria in proposed 10 CFR 50.46a(e)(1) would be met; and
- Information demonstrating that the proposed change would not increase the LOCA frequency of the facility by an amount that would invalidate the applicability of the TBS to the facility.

After reviewing the application with the proposed change, the NRC could approve the change if it complies with the criteria in proposed 10 CFR 50.46a(h)(2) and (h)(3) and all other applicable NRC regulations, including the current requirements for plant physical security. In addition, the NRC would evaluate potential impacts of the proposed change on facility security to ensure that the change would not significantly reduce the ''built-in capability'' of the plant to resist security threats, thus ensuring that the change would not be inimical to the common defense and security and would provide adequate protection to public health and safety.

Entities who would not submit a request for NRC approval of a process for evaluating the acceptability of future changes enabled by proposed 10 CFR 50.46a using the provisions in proposed 10 CFR 50.46a(h)(1) could make such a request at any time by submitting the application containing the information described in proposed 10 CFR 50.46a(c)(1)(iv).

(xii) Applicability to New Reactor Designs

As discussed in sections XXXVI.F.(ii), ''Original Determination of the Transition Break Size,'' and (iii), ''Determining the Ongoing Validity of the Transition Break Size,'' of this

document, the TBS was established in NUREG–1829, which was based on the commercial LWR designs authorized to operate under 10 CFR part 50 on December 31, 2015. LWRs authorized to operate under 10 CFR part 52 or after that date may have different piping materials, configurations, and operational and service conditions, among other factors, that may impact the piping break frequencies and thus the TBS. New LWR reactor designs (*i.e.,* the class of commercial LWR reactors authorized to operate under 10 CFR part 50 after December 31, 2015, or under 10 CFR part 52) may have similar piping materials, service conditions and operational programs, piping designs, and mitigation and control of age-related degradation programs as those found in currently operating plants. There are several new LWR designs for which the NRC expects that the frequency of LOCAs above the TBS could be as low as it is at current LWRs. Thus, applicants can apply the proposed 10 CFR 50.46a requirements to these new reactor designs with adequate justification. New large LWR or small modular reactor entities under 10 CFR part 50 or part 52 who wish to apply proposed 10 CFR 50.46a would have to submit an analysis for NRC approval, as specified in proposed 10 CFR 50.46a(c)(2), demonstrating why it would be appropriate to apply the alternative ECCS requirements and what the appropriate TBS would be in order for the new design to meet the proposed 10 CFR 50.46a rule.

In its analysis, the entity would be required to demonstrate that the proposed reactor facility is similar to reactors authorized to operate under 10 CFR part 50 on December 31, 2015. In addressing similarity of the proposed design to reactors authorized to operate under 10 CFR part 50 on December 31, 2015, the entity should address design, construction and fabrication, and operational factors that include, but are not limited to:

- The similarity of the piping materials of construction and construction techniques for new reactors to those in the operating fleet authorized to operate under 10 CFR part 50 on December 31, 2015;
- The similarity of service conditions and operational programs (*e.g.,* in-service inspection and testing, leak detection, QA, etc.) for new reactors to those for the operating fleet authorized to operate under 10 CFR part 50 on December 31, 2015;
- The similarity of piping design (*e.g.,* pipe sizes and pipe configuration) for new reactors to those found in the operating fleet authorized to operate under 10 CFR part 50 on December 31, 2015;
- Adherence to existing regulatory requirements, regulatory guidance, and industry programs related to mitigation and control of age-related degradation (*e.g.,* aging management, fatigue monitoring, water chemistry, stress corrosion cracking mitigation, etc.); and
- Any plant-specific attributes that may increase LOCA frequencies compared to those used to support the development of the proposed TBS.

Proposed 10 CFR 50.46a(c)(2) would also require that the analysis include a recommendation for an appropriate TBS and a justification that the proposed TBS is consistent with the technical basis for the proposed 10 CFR 50.46a (*i.e.,* the TBS would include sufficient margin to provide assurance that, when considering the limited availability of operating experience data and the uncertainty in the estimation of LOCA frequency, the estimated frequency of breaks larger than the TBS for all initiators would not exceed 10^{-5} per year). For those new reactor (large LWR and small modular reactor) designs that employ design features that effectively increase the break size via opening of specially designed valves to rapidly depressurize the RCS during any size LOCA, justification of the acceptability of a TBS would also be necessary. The justification should consider the integral impacts of fluid conditions such as flow quality at the discharge node(s), which can substantially affect the temperature transient experienced by the fuel. The methodology used to determine the proposed TBS should be described in the justification.

(xiii) Changes to 10 CFR 50.46

The NRC is proposing several changes to 10 CFR 50.46. Proposed 10 CFR 50.46(a) would include a pointer to proposed 10 CFR 50.46a as a voluntary alternative. Proposed 10 CFR 50.46(a)(3)(i) would be revised to permit use of the ECCS criteria in proposed 10 CFR 50.46a(f) instead of 10 CFR 50.46(b). To align with these changes, the applicable ECCS reporting requirements from proposed 10 CFR 50.46a would be added as proposed 10 CFR 50.46(a)(iv) and 50.46(a)(v) for entities that are approved to use proposed 10 CFR 50.46a(f). These changes would not invalidate current exemptions from 10 CFR 50.46 and could reduce the number of exemptions for non-zircaloy and non-ZIRLO claddings due to the allowance to use the fuel technology-neutral proposed 10 CFR 50.46a(f) criteria in place of the prescriptive 10 CFR 50.46(b) criteria.

(xiv) Discussion of Public Comments on the Fuel Dispersal Aspects of the Regulatory Basis

In the public comments on the regulatory basis, representatives of the nuclear power industry did not present a unanimous recommendation among the alternatives provided by the NRC. Alternative 5 would have had the NRC pursue rulemaking to modify 10 CFR 50.46 to allow for insights from piping fracture mechanics to be used to disposition large-break LOCAs and, thus, fuel dispersal during large-break LOCAs. NEI and Westinghouse supported a modified version of alternative 5 that would have aligned with EPRI's ''Alternate Licensing Strategy.'' The EPRI Alternate Licensing Strategy proposed to utilize piping fracture mechanics to show that leaks in large pipes can be detected and operator action taken with sufficient probability before the pipe breaks, such that the larger LOCAs that could challenge fuel integrity would not occur. EPRI submitted its Alternate Licensing Strategy to the NRC via topical reports in April 2024.

NEI also supported, along with the BWR Owners' Group, alternative 4, a rulemaking that would provide a generic bounding assessment of dose and use risk insights for post-FFRD consequences. The former alternative was not viewed by NEI and the BWR Owners' Group as a solution for BWRs since it would utilize the leak-before-break (LBB) concept and LBB has only ever been approved for use in PWRs. Historically, the NRC has not allowed LBB to be applied to ECCS design, containment design, or equipment qualification, as described in the preamble to a 1987 final rule amending GDC 4, ''Environmental and dynamic effects design bases'' (52 FR 41288; October 27, 1987). The PWR Owners' Group and Framatome expressed support for an approach that would employ integrated decision-making as done in the disposition of in-vessel downstream effects associated with generic safety issue (GSI)–191.

Additionally, there was support from NEI, the BWR Owners' Group, and Westinghouse for alternative 2, a rulemaking to recategorize large-break LOCAs as beyond-design-basis accidents, though they recommended that a rulemaking with an updated 10 CFR 50.46c be pursued separately from this increased enrichment rulemaking due to the perceived schedule impact. Aspects of Framatome's response also aligned with this alternative, such as their statement in their proposed path forward that ''the amount of dispersal

and coolability evaluation in a [large-break LOCA] would be based on fully best-estimate models (*i.e.,* conditions consistent with expected, nominal operating conditions without biases or uncertainties).'' Moreover, in response to question 2 posed to the public on fuel dispersal in the regulatory basis **Federal Register** notice, NEI, Westinghouse, and Framatome stated that they believed that with a true best-estimate analysis for large-break LOCAs, it would be reasonable to demonstrate that no high burnup rods rupture and, therefore, disperse fuel, especially when combined with the anticipated benefits from ATF.

Industry recommendations stated schedule as a large reason for their support of particular alternatives. The regulatory basis attempted to qualitatively compare the rulemaking schedule impacts of each alternative. After further consideration of these alternatives, the NRC's accuracy of the estimated impacts has improved and the qualitative schedule estimates presented in the regulatory basis have been updated significantly. The NRC now considers that alternative 2 would take less time than alternatives 4 and 5 because the previous work on the draft 10 CFR 50.46a rulemaking could be leveraged. For example, the technical basis and rule language were already developed by the NRC, so most of the work would be in confirming that the technical basis is still applicable, modernizing the rule, and developing guidance. In addition, the previous work performed on the previous 10 CFR 50.46c rulemaking could be leveraged to develop a performance-based rule with guidance that would facilitate future efforts to pursue other licensing pathways. As such, the risk-informed approach in alternative 2 and the performance-based approach in the previous 10 CFR 50.46c rule have been adapted into this proposed rule.

The Union of Concerned Scientists and two members of the public stated that they did not support any approach that allows for fuel dispersal. Another member of the public recommended that the NRC wait until more research and analysis is performed for fuel dispersal. The NRC considered all these comments, among other factors, as discussed in section XXXVI.F.(i), ''Overview,'' of this document, when deciding to pursue a performance-based alternative 2.

XXXVII. Specific Questions

The NRC is seeking advice and recommendations from the public on the proposed rule, draft guidance documents, and a draft regulatory analysis. The NRC is particularly interested in comments and supporting rationale from the public on the following:

Expedited Construction of Certain Structures, Systems, and Components

Question 1: Should the NRC consider granting one or more general licenses to begin construction activities as part of an existing or future standard design certification rule? If the NRC were to issue such a general license, should the NRC require that the general license holder reference another plant that has completed construction (resulting in the general license excluding first of a kind applicants)? If not, what conditions should the NRC include in the general license to ensure that the construction activities authorized by the general license can be completed safely? Please provide a basis for your response.

Question 2: Would it be useful for the NRC to issue regulations to provide for general licenses related to production and utilization facilities for other activities described under section 109 of the AEA, with the exception of import, export, construction, or operation? Please provide a basis for your response.

Question 3: Does the proposed regulatory change achieve its intended objective of allowing applicants to make business decisions on the appropriate balance between expedited construction and the regulatory risk that changes will be necessary to address safety issues? Are there other approaches that can both provide the needed flexibility while better allowing applicants to structure the degree of regulatory risk they take on through interactions with the NRC staff (*e.g.,* hold-points during construction for NRC inspection)?

Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods

In accordance with Commission direction in the staff requirements memorandum (SRM), dated July 21, 1993, on SECY–93–087, ''Policy, Technical, and Licensing Issues Pertaining to Evolutionary and Advanced Light-Water Reactor (ALWR) Designs,'' dated April 2, 1993, the NRC staff considers common cause failures (CCFs) in digital instrumentation and controls (DI&C) systems to be beyond design-basis events (BDBEs). In addition, SECY–93–087 states that common mode failures could defeat the redundancy achieved by the hardware architectural structure, and could result in the loss of more than one echelon of defense-in-depth provided by the monitoring, control, reactor protection, and engineered safety functions performed by the DI&C systems. Therefore, a CCF could result in ''a malfunction of an SSC important to safety with a different result than any previously evaluated in the final safety analysis report'' (see 10 CFR 50.59 (c)(2)(vi)), and a licensee would have to obtain a license amendment pursuant to 10 CFR 50.90 prior to implementing the proposed DI&C modification.

Question 4: In light of these considerations, do the proposed revisions to 10 CFR 50.59 adequately address issues that may arise from facilities that have transitioned to DI&C? If not, please provide specific comments on changes that would be necessary to address these issues.

Updates to Construction Permit Requirements and Related Licenses

Question 5: Are there any additional requirements in 10 CFR 50.34 that the NRC should consider changing to be more technology-inclusive or provide additional clarity? Should conforming changes to 10 CFR 50.67 be made to be consistent with 10 CFR 50.34 wording updates? Please provide a basis for your response.

Question 6: Are there any requirements in 10 CFR 50.34 that the NRC should consider changing that are posing undue barriers to timely and efficient submittal of CP applications, or which are unnecessary at the CP stage? Please provide a basis for your response.

Establishing Thresholds for Changes to Reactor Designs During Construction and Operation Under 10 CFR Part 52

Question 7: The proposed revisions to the definitions in each of the appendices in 10 CFR part 52 identify the specific sections in the generic DCD that contain the various categories of Tier 1 information (*i.e.,* definitions and general provisions, design descriptions, ITAAC, significant site parameters, and significant interface requirements). The proposed revisions to section VIII in each of the appendices in 10 CFR part 52 describe the change control process associated with each category of Tier 1 information. Will there be adequate regulatory clarity regarding the category of Tier 1 information in the generic DCD such that the change control process can be readily identified? Please provide a basis for your response.

Question 8: The proposed revisions to section VIII.B of appendix D to 10 CFR part 52 would effectively treat Tier 2* information for the AP1000 design as Tier 2 information during construction as well as operation. However, for appendices A (ABWR) and E (ESBWR) Tier 2* information would not be treated as Tier 2 information until after

the plant has achieved full power. The basis for this difference is the construction and licensing experience gained from the COLs referencing the AP1000 design which is lacking for the ABWR and ESBWR designs. Should the flexibility provided to the AP1000 design in appendix D during construction also be extended to the ABWR and ESBWR designs in appendices A and E? Please provide a basis for your response.

Question 9: Paragraph (b) of 10 CFR 53.1535 states ''The holder of a COL under this part for which the NRC has not yet made a finding in accordance with 10 CFR 53.1452(g) must request amendments required by 10 CFR 53.1525 or 53.1550 no later than 45 days from the date the licensee begins the construction of the SSCs to implement the change or departure requiring NRC approval. The licensee proceeds with such changes at its own risk recognizing that there is a possibility that the amendment will not be granted.'' This differs from provisions in 10 CFR part 52 by adopting requirements that explicitly support a change process described in RG 1.237, ''Guidance for Changes During Construction for New Nuclear Plants Being Constructed Under a Combined License Referencing a Certified Design Under 10 CFR part 52.'' Should the provisions in 10 CFR part 52 be revised to also explicitly support this change process? Please provide a basis for your response. Question 10: The proposed revisions to 10 CFR 52.98 and 53.1550 allow holders of an OL or COL that reference a manufacturing license (ML) to make changes to the FSAR without obtaining a license amendment if the changes are identical to changes approved by the Commission by amendment to the ML for the manufactured reactor and upon determining that implementation of the changes will be consistent with the basis for the Commission's approval of the amendment to the ML and not involve any additional changes that would require an amendment to its OL or COL. Should this flexibility be provided to COLs that reference a design certification? Please provide a basis for your response.

Question 11: Should the proposed rule changes to 10 CFR 50.59 described in section XII of this document also be applied to the 10 CFR 50.59-like process in the appendices of 10 CFR part 52? Please provide a basis for your response.

Revision of the Emergency Preparedness Regulations for Nuclear Power Reactors

Conduct of Exercises

The NRC is considering risk-informed revisions to the conduct of exercises in section F, ''Training,'' of appendix E to 10 CFR part 50. Paragraph IV.F.2.b of appendix E to 10 CFR part 50 requires a biennial exercise of the onsite plan to ensure that emergency response organization (ERO) proficiency in key skills is maintained. The NRC is assessing risk-informed revisions to the conduct of exercises to ensure ERO proficiency is maintained through the appropriate frequency of exercises and performance of the exercise cycle as required by paragraph IV.F.2.j of appendix E to 10 CFR part 50. Licensees conduct drills and exercises to develop and maintain key skills such as timely and accurate classification and notification of events; assessment of radiological releases and development of protective actions; planning, analysis, and implementation of mitigative actions; worker protection during emergency conditions; and coordination with offsite response organizations to include dissemination of information to the public through media channels. Following each exercise, licensees perform a critique of their actions to comply with 10 CFR 50.47(b)(14) which states, in part, ''deficiencies identified as a result of exercises or drills are (will be) corrected.'' In 1996, the NRC revised the emergency plan regulations for exercises from annual to biennial (61 FR 30129; June 14, 1996) to allow greater flexibility in licensee emergency planning training activities while maintaining readiness. The NRC is considering another revision to the frequency to either a triennial, or quadrennial basis. For example, a quadrennial exercise cycle could be supplemented with additional drills to ensure that proficiency is maintained between exercise years. Additionally, the NRC is considering additional language in paragraph IV.F.2.c of appendix E to 10 CFR part 50 to allow for the use of tabletop exercises or other performance enhancing methods when offsite authorities are not participating in the exercise of the onsite emergency plan required by paragraph IV.F.2.b. These potential changes could increase scheduling flexibility and reduce the resource burden while maintaining reasonable assurance that ERO proficiency will be maintained. If the exercise frequency is changed to quadrennial for some sites, the NRC is considering a corresponding change to the exercise cycle from 8 to 16 calendar years in paragraph IV.F.2.j.(iii) of appendix E to 10 CFR part 50 to reflect the proposed change to quadrennial exercises. However, a change to the exercise cycle may impact the ability of the ERO to demonstrate proficiency in the key skills necessary to respond to various emergency events, particularly in sites with increased turnover in ERO members. During the 1996 change from annual to biennial, the NRC received several comments about the ability of licensees to maintain proficiency with a longer gap between exercises and how this increased gap could also affect the performance of State and local responders. These comments were ultimately resolved and the NRC determined that reasonable assurance remained with the change in exercise frequency. With an additional three decades of experience, advances in all-hazards emergency preparedness, and a range of potential new advanced reactor designs in the future, the NRC is again interested in comments on the conduct of exercises. The NRC urges stakeholders to provide comments on the following questions:

Question 12: What are the potential benefits and challenges of a change to the conduct of exercises to applicants and licensees and offsite response organizations? Please provide a basis for your response.

Question 13: What specific criteria related to maintaining onsite ERO proficiency should be considered in evaluating whether a biennial, triennial, or quadrennial exercise is appropriate? Please provide a basis for your response.

Question 14: How would a potential change impact the conduct of exercises of the offsite plans required under paragraph IV.F.2.c of appendix E to 10 CFR part 50? Please provide a basis for your response.

Question 15: If there was a change to the exercise frequency, should the exercise cycle be changed or otherwise be revised to ensure there is adequate opportunity for the ERO to demonstrate adequate performance under paragraph IV.F.2.j of appendix E to 10 CFR part 50? Please provide a basis for your response.

Considerations for Emergency Planning Zones

The proposed change to 10 CFR 50.33(g)(1) would provide certainty for a site-boundary EPZ for facilities less than 300 MWt. This proposed change is based on NRC staff review of available technical analyses that estimate radiological consequences for a variety of reactor designs and design power levels. The NRC is considering factors that may obviate the need for applicants of certain reactor designs to perform

detailed analyses to support a site-boundary EPZ determination or reach a determination that no EPZ is needed. Such factors may include use of novel fuel forms or the performance of functional containment that may generically demonstrate that predetermined, prompt protective measures are unwarranted. The NRC is also considering factors that may necessitate additional analysis by the applicant for facilities less than 300 MWt.

Question 16: Are there additional design factors or analyses that should be considered to provide certainty on EPZ determinations? Please address within the comment the technical basis for consideration and how they relate to EPZ determinations and, specifically, the criteria of 10 CFR 50.33(g)(2).

Question 17: Should design features, other than power level, or site attributes be considered for determining when additional analysis by the applicant is necessary to justify site-boundary EPZ for facilities less than 300 MWt? Please provide the basis for your response.

Optional Submittal of Operational Programs

The NRC is proposing to add a new provision in 10 CFR 52.158(c) that will allow an applicant for an ML to voluntarily submit standardized operational program information for approval and to revise 10 CFR 52.171 to provide finality for such information that is approved by the NRC in the ML review. The NRC is proposing these changes in response to stakeholder interest in the context of deployment of factory-fabricated reactors.

Question 18: Should the NRC consider making similar changes to the requirements in 10 CFR 52.47, 52.63, 53.1239, and 53.1263 for design certifications? Please provide a basis for your response.

Question 19: If the NRC were to add a provision for the optional submittal of standardized operational program information in a design certification application, please describe how change control should be accounted for as a part of certifying the design.

Early Site Permit for Nuclear Power Plants

Question 20: With the proposed change to remove the requirement for renewal, all changes to update the early site permit (ESP) must be made by amendment. What other options could the staff consider to increase the useability of an ESP? Could the provisions in the, ''Commission Policy Statement on Deferred Plants,'' (52 FR 38077; October 14, 1987) be applied to ESPs? Please provide a basis for your response.

Question 21: For a COL application that references an ESP, the changes proposed in 10 CFR 52.39 and 53.1188 would limit finality on safety and environmental issues to 20 years following ESP issuance or approval of an update amendment. Because the proposed rule would also retain the requirement for applicants to review for new and significant information when referencing an ESP, the NRC requests input on whether limiting finality to 20 years is necessary to ensure that all relevant environmental information is considered in licensing decisions.

Manufacturing License Term Extension

Question 22: The manufacturing license term extension aligns with the recently promulgated July 2, 2025, direct final rule, ''Revising the Duration of Design Certifications,'' where the NRC replaced the 15-year duration for design certifications with a 40-year duration period. The Commission is interested in determining if a manufacturing license or design certification term limit is necessary. Should the NRC eliminate time limits for manufacturing licenses, design certifications, or both? Please provide a basis for your response.

Nuclear Power Plant License Renewal

Safety Guidance

The NRC currently has separate safety guidance for initial and subsequent renewal to address 40 to 60 years and 60 to 80 years of operation, respectively. In addition, some licensees may soon apply for a third renewal, for which no guidance has yet been developed. One option would be to maintain a single set of safety guidance that represents the state-of-the-art for aging management, covering initial renewal, subsequent renewal, and periods beyond. This guidance would identify an acceptable approach for managing aging and evaluating time-limited aging analyses, regardless of the renewal period. The question below applies to the Generic Aging Lessons Learned Report for initial (NUREG–1801) and subsequent (NUREG–2191) license renewal and the Standard Review Plan for initial (NUREG–1800) and subsequent (NUREG–2192) license renewal.

Question 23: Should the NRC consolidate its safety guidance into one collection that is time-independent (*i.e.,* the same guidance applying to all periods of extended operation), instead of having separate guidance for initial renewal, subsequent renewal, and the upcoming third renewal term? Is there a different approach that should be considered? Please provide a basis for your response.

Implementation of Aging Management

Question 24: With the proposed change to use a 40-year ''tack-on'' license, what regulatory approach should the NRC take with respect to aging management activities that are currently required to be implemented prior to the period of extended operation? Should conditions that are currently included in the renewed license be revised or instead imposed by different means? Please provide a basis for your response.

Considerations for Shorter License Renewal Term

Question 25: Should the NRC retain an option for licensees seeking shorter renewals (those that would not exceed 40 years when combined with the number of years remaining on an existing license) to apply for a ''supersession'' license?

Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors

Expansion of 10 CFR 71.55(g) Enrichment Levels

The NRC is proposing to change 10 CFR 71.55(g) to expand the exception from 10 CFR 71.55(b) for enrichment levels between 5.0 and 10.0 weight percent U–235. The NRC is not considering expanding the exception for enrichments from 10.0 weight percent U–235 up to but less than 20.0 weight precent U–235 for two reasons: (1) limited technical data with respect to overall mechanisms and consequences of a canister breach allowing water in-leakage that would provide additional risk insights; and (2) the current transportation package certification path using 10 CFR 71.55(c) adequately addresses the potential need to ship UF_6 enriched above 10.0 weight percent U–235, has no enrichment limitation, and is technology neutral.

Question 26: 10 CFR 71.55(c) provides a certification pathway that has limited prescriptive requirements and no enrichment limitations. Should the NRC add another option to the exception in 10 CFR 71.55(g) to account for enrichment levels from 10.0 weight percent U–235 up to but less than 20.0 weight percent U–235? Please provide a basis for your response.

Regulatory Certainty of Performance-Based ECCS Rod Embrittlement Criteria

Question 27: Will there be adequate regulatory certainty if the fuel system criteria for uranium oxide or uranium-

plutonium oxide pellets within cylindrical zirconium-based cladding are located in guidance and 10 CFR 50.46a(f) of the proposed rule is performance-based? Please provide a basis for your response.

Inspection Requirements

The NRC is proposing to add non-destructive evaluation inspection requirements for circumferential welds in piping systems with inner diameters that are larger than the TBS to provide assurance that an acceptable level of performance monitoring is maintained in these systems such that breaks larger than the TBS remain highly unlikely.

The NRC has evaluated several sampling schemes to determine the most effective approach for providing assurance against breaks larger than the TBS in these systems. These inspections may support plant-specific applicability of the TBS. The option in this proposed rule is:

- Inspecting a smart sample of those welds with attributes (*e.g.,* operating temperature, type of welding, fabrication history) most conducive to degradation and having the highest failure potential before implementation of the proposed rule and in every subsequent inservice inspection interval thereafter.

Other schemes include:

- Inspecting all welds at least one-time over the plant's remaining licensing period.
- Inspecting a random sample of the weld population before implementation of the proposed rule and in every subsequent inservice inspection interval thereafter.

Question 28: Please provide feedback on the effectiveness of the proposed sampling scheme in providing assurance against breaks larger than the TBS in these systems. Are there pros and cons to the other sampling schemes, an alternative sampling scheme, or a holistic approach relying on existing performance monitoring strategies that the NRC should consider, and why? Should the sampling scheme be required before or as plants enter into extended operation beyond what is currently authorized in the operating fleet (*e.g.,* if authorized beyond 80 years)?

The NRC is also proposing a requirement to evaluate the effect of any identified indications found during inspections required by this proposed rule on the TBS. The NRC recognizes that any such findings must be dispositioned under ASME section XI, which would require a demonstration that the indications remain acceptable for continued service or are repaired before placing the component back into service. However, the NRC has not included criteria in this proposed rule regarding what constitutes an acceptable additional evaluation of any inspection findings. The NRC is considering that an acceptable additional evaluation would consist of two parts. The first part would be a deterministic or probabilistic fracture mechanics analysis to demonstrate that the failure likelihood of any indications identified during the inspection resulting in a likelihood of ruptures greater than the TBS is less than 10^{6} per year. The second part would, if the indications are evidence that active degradation is occurring, recharacterize the risk-informed inspection examination category for the population of all similar welds to be commensurate with the expected degradation mechanism. All future inspections of this weld population would then be performed according to the ASME section XI requirements associated with that inspection category.

Question 29: The NRC is interested in obtaining feedback on the efficacy of this proposed evaluation method and more broadly on what an acceptable additional evaluation of any indications found during the inspection should entail.

DG–1261—Breakaway Oxidation

Question 30: The DG–1261, Revision 1, ''Measuring Breakaway Oxidation Behavior,'' contains breakaway oxidation testing criteria. The NRC is interested in obtaining feedback on this regulatory position. Please provide a basis for your response. The NRC is interested in specific information on how quality assurance practices and industry operating experience have evolved since the underlying research was published, and whether these developments should inform potential adjustments to this provision.

Regulatory Analysis

Question 31: The NRC is interested in feedback on the draft regulatory analysis, in particular, the benefits associated with power uprates under the proposed 10 CFR 50.46a. Please provide a basis for your response.

DG–1426—Risk-Informed Evaluation and Risk-Informed Evaluation Process

An entity that wishes to make changes under the proposed rule would have to perform a risk-informed evaluation and demonstrate that the proposed change meets the acceptance criteria in proposed 10 CFR 50.46a(h). The acceptance criteria in the proposed rule would include that the total increases in core damage frequency (CDF) and large early release frequency (LERF) due to the proposed change are very small and that the overall plant baseline risk remains small. ''Small'' and ''very small'' are defined in RG 1.174 and DG–1426. The acceptance criteria are limited to very small changes instead of small changes, in part, because the TBS initiating event frequency is the same as the limit for small changes (*i.e.,* change in CDF of approximately 1×10^{-5}). If the acceptance criteria were limited to small changes, a PRA would show that not mitigating a TBS or DEGB LOCA is always less than the small threshold, making the risk assessment unnecessary and overly burdensome.

An entity seeking to make changes under the proposed rule without prior NRC approval would have to have an NRC-approved risk-informed evaluation process and demonstrate that any increases in the estimated risk are minimal. The proposed acceptance criteria for proposed changes that may be made without prior NRC approval were chosen to be an order of magnitude lower than the acceptance criteria for changes that require prior NRC approval for consistency with other established risk-informed programs.

The DG–1426 contains draft guidance that would be acceptable to the NRC for performing a risk-informed evaluation and establishing a risk-informed evaluation process that satisfies the requirements of the proposed rule. This DG follows the structure for risk-informed changes in RG 1.174. Entities would be able to leverage changes made for previous risk-informed amendments, such as 10 CFR 50.69, ''Risk-informed categorization and treatment of structures, systems and components for nuclear power reactors,'' or Technical Specification Task Force Traveler 505, ''Provide Risk-Informed Extended Completion Times—RITSTF Initiative 4B,'' when performing the risk-informed evaluation. Therefore, the NRC does not expect that the risk-informed evaluation would be burdensome.

Under current 10 CFR 50.59, ''Changes, tests and experiments,'' a licensee would need to obtain a license amendment if there would be more than a minimal increase in frequency or consequences of accidents or malfunctions. As described in the preamble for the 10 CFR 50.59 final rule (64 FR 53582; October 4, 1999), PRAs (*i.e.,* total increases in CDF and LERF) may not be used to determine if the minimal increase standard is met because 10 CFR 50.59 concerns DBEs, while RG 1.174 includes risk from severe accidents beyond the design basis. Similar to the change in proposed

10 CFR 50.59 as described in section XII, ''Discussion—Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods,'' of this document, the risk-informed evaluation process in proposed 10 CFR 50.46a would provide additional flexibility by allowing a licensee to use the total increases in CDF and LERF to determine if the increase in risk associated with a change enabled by this proposed rule would be minimal.

In this proposed rule, the NRC is including the risk-informed evaluation and risk-informed evaluation process that were included in the previously proposed but discontinued 10 CFR 50.46a rulemaking in SECY–10–0161. As part of the development of that previous rule, the NRC received comments from the public and the Advisory Committee on Reactor Safeguards on the risk-informed evaluation and risk-informed evaluation process related to, among other things, the use of the ''very small'' threshold for changes, the definition of ''minimal increase in risk,'' PRA maintenance and upgrade, the evaluation of cumulative risk, and the relationship of the risk-informed evaluation process to 10 CFR 50.59. In addition, the NRC staff received direction from the Commission in SRM–SECY–07–0082 to use the ''very small'' threshold for changes. While some of these issues are addressed in this proposed rule, the NRC is seeking additional information to identify if further changes are needed.

Question 32: The NRC is interested in any additional considerations or feedback on the risk-informed evaluation and risk-informed evaluation process proposed in 10 CFR 50.46a and the implementing guidance in DG–1426, including whether they should be modified or removed from the proposed rule in their entirety. Specifically, what are the advantages and disadvantages of including a risk-informed evaluation as a necessary part of implementing the rule? In addition, what are the advantages and disadvantages of restricting all changes to very small risk increases? Would the risk-informed evaluation, restricting changes to very small risk increases, or both, make it burdensome to implement changes under the proposed rule? What are the advantages and disadvantages of removing the risk-informed evaluation and risk-informed evaluation process from the proposed rule? If the NRC removed the risk-informed evaluation and risk-informed evaluation process from the proposed rule, how should changes that could impact the risk calculation be evaluated? Please provide any supporting basis or justification for your response.

New Reactor Applicability

Question 33: The proposed rule would establish a TBS based on nuclear power reactor licensees' operating experience with piping materials, piping designs, service conditions, operational programs, and mitigation and control of age-related degradation programs. The proposed rule would allow new reactors to submit for NRC approval an alternate TBS that includes a demonstration that the proposed reactor design is similar to the designs of reactors authorized to operate under 10 CFR part 50 on December 31, 2015. This provision might not be applicable to some new reactor designs, including small modular reactors, due to fundamental design differences. For example, some of the new reactor designs may have novel LOCA mitigation strategies, such as passive features or use of valves and associated flanges in the piping system to ensure coolant inventory retention. Some applicants may be able to demonstrate that the failure frequencies at particular locations in the piping system are extremely low and can be maintained extremely low during plant operation. In lieu of the TBS, the failure frequencies of the piping system may be established and maintained extremely low during the plant operation to justify relaxation of the required assumptions for the analyses similar to the proposed rule (*e.g.,* a realistic treatment of defense-in-depth features and best-estimate analyses). The NRC is interested in receiving feedback on the applicability of the proposed rule to such new reactor designs. Please include in your feedback whether it is appropriate to risk-inform the LOCA requirements in light of novel design features, and language that would appropriately allow entities to treat breaks at particular locations in the piping systems for new reactor designs similarly to break sizes larger than the TBS in the proposed rule. Please also include in your feedback whether the option for a non-size-based TBS would improve the applicability of the proposed rule to these designs along with any supporting basis or justification for your response.

Alternate Transition Break Size

Question 34: The NRC incorporated in the proposed rule enabling language to allow currently operating power reactor licensees to recommend and justify an alternative TBS. The NRC is interested in feedback on this option. Please include in your feedback the potential advantages that could be realized by this alternative and if potential benefits are more likely to be realized generically or for individual plants. Please also provide any disadvantages that may result from a loss of regulatory consistency if similar plants have different TBS values and any potential impacts on fulfilling the inspection requirements in proposed 10 CFR 50.46a(b)(3). Please also describe the impact of any associated costs necessary to develop a risk-informed technical basis for an alternative TBS and the associated uncertainties due to the lack of current guidance for developing this basis.

Alternative 10 CFR 50.46a Licensing Pathways

Question 35: This proposed rule would add a voluntary alternative to 10 CFR 50.46 designed to provide flexibility by allowing licensees to adopt tailored approaches for ECCS performance evaluations. This flexibility is proposed in 10 CFR 50.46(a)(1), which would provide applicants and licensees the ability to select between two acceptance criteria pathways. The first is presented in proposed 10 CFR 50.46(b), which is the current 10 CFR 50.46 acceptance criteria. The second is presented in proposed 10 CFR 50.46a(f), which contains the new performance-based acceptance criteria. The NRC expects that the performance-based requirements in proposed 10 CFR 50.46a(f) would facilitate implementation of potential alternative approaches to FFRD such as those described in the regulatory basis for this rulemaking, some of which are already being considered by the NRC. These alternatives could be beneficial for licensees that elect not to pursue the remainder of proposed 10 CFR 50.46a. Please comment on any elements of the proposed rule that could have unintended consequences for implementation of these alternatives.

ECCS Reporting Requirements

Question 36: The industry has proposed that a graded approach could be used to relax the ECCS reporting requirements based on context beyond the current 10 CFR 50.46 criteria. Please provide thoughts on how a graded approach could be applied to relax the ECCS reporting requirements in 10 CFR 50.46 and proposed 10 CFR 50.46a. Please provide a basis for your response.

Threshold for Significance Determination

Question 37: The proposed fixed 50-degree peak clad temperature (PCT)

threshold for significant errors can either overstate or understate the safety significance of a change depending on available margin to the acceptance criterion. Further, it does not consider designs where a parameter other than PCT is proposed as the acceptance criterion. Alternative approaches, such as a margin-based threshold can more accurately reflect actual risk significance. Please provide your thoughts, with justification and any supporting information, on alternative approaches for determining the significance of errors in the LOCA evaluation model (*e.g.,* percent reduction in the margin between the acceptance criteria and the approved maximum value of the acceptance parameter).

ECCS Performance

Question 38: The proposed rule explicitly only provides the TBS-based approach to address FFRD. The TBS-based approach may not provide enough margin to demonstrate coolability at the upper end of the burnup range allowed by the proposed rule and therefore, could result in implementation and licensing challenges. The NRC previously included a dose consequence-based approach to addressing FFRD in the regulatory analysis for the Increased Enrichment Rule (Docket ID: NRC–2020–0034). What are the advantages and disadvantages of including an explicit option in the performance-based ECCS acceptance criteria in proposed 10 CFR 50.46a(f) that is based on dose-consequence? What implementation challenges (*e.g.,* acceptance threshold) would need to be addressed for such an option? Please provide the rationale and any supporting information for your response.

Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Question 39: Appendix T of 10 CFR is intended to address nuclear supply chain constraints by providing a graded approach for additional QA flexibilities and aligning with international standards. The proposed rule limits the applicability of appendix T to nth-of-a-kind (NOAK) plants referencing a first-of-a-kind (FOAK) plant constructed and operated under appendix B. How can the NRC expand the applicability of appendix T to FOAK plants and existing licensees, including any guardrails or restrictions that may be desirable (*e.g.,* vendor inspections for FOAK and new suppliers for NOAK)? Should the NRC consider alternative approaches to appendix T such as endorsement of ISO 19443 or changes to appendix B? Please provide the basis for your recommendations, including any unintended consequences.

Question 40: The change process for the Quality Management System (QMS) in proposed 10 CFR 50.54(a)(5) requires changes to the QMS be submitted to the NRC for NRC approval prior to implementation. Should the change process have a graded approach or mirror 10 CFR 50.54(a)(4) in which only changes that reduce the commitments be submitted to the NRC for prior approval? Please explain if there is a preferred method.

Alternative Risk-Informed and Performance-Based Acceptance Criteria for 10 CFR Parts 50 and 52

Question 41: The NRC is seeking views on increasing the flexibility provided by the proposed rule. The rule currently does not include the allowance for a licensee or applicant to adopt a previously approved alternative without submitting an application to the NRC, provided that the basis for the staff's approval is demonstrated and documented to be applicable to the adoptee's plant or facility. Would adding such flexibility increase or accelerate the use of the proposed rule? What are some viable approaches to resolve any conflicts of such flexibility with the requirements in 10 CFR 50.59?

Siting

Question 42: The proposed rule introduces a new graded approach to siting that provides entry criteria for the less restrictive requirements in subpart A to 10 CFR part 100 (*i.e.,* demonstrating an unmitigated consequence of less than 25 rem (0.25 Sv) TEDE at the site exclusion area boundary) as an alternative to the prescriptive siting requirements in subpart B. The associated draft guidance provides detailed information on how to evaluate this entry criteria. Given the significance of this new graded approach to siting, are there implications in terms of implementation of this new approach that should be further explored in guidance or addressed at the final rule stage?

XXXVIII. Regulatory Flexibility Certification

As required by the Regulatory Flexibility Act of 1980, 5 U.S.C. 605(b), the Commission certifies that this rule, if adopted, will not have a significant economic impact on a substantial number of small entities. This proposed rule affects only the licensing and operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of ''small entities'' set forth in the Regulatory Flexibility Act or the size standards established by the NRC (10 CFR 2.810).

XXXIX. Regulatory Analysis

The NRC has prepared a draft regulatory analysis on this proposed regulation. The analysis examines the costs and benefits of the alternatives considered by the NRC. The NRC requests public comment on the draft regulatory analysis. The draft regulatory analysis is available as indicated in the ''Availability of Documents'' section of this document. Comments on the draft analysis may be submitted to the NRC as indicated under the **ADDRESSES** caption of this document.

XL. Backfitting and Issue Finality

This section describes the backfitting and issue finality implications of this proposed rule and the draft guidance documents described in section XLVII, ''Availability of Guidance,'' of this document, as applied to pertinent NRC approvals and certain applicants that reference NRC approvals in their applications. The NRC's backfitting provisions associated with nuclear power plants licensed under 10 CFR part 50 appear in 10 CFR 50.109, ''Backfitting.'' Issue finality provisions (analogous to the backfitting provisions in 10 CFR 50.109) for approvals under 10 CFR part 52 are located in various provisions of 10 CFR part 52. The NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests,'' describes the Commission's policies on backfitting and issue finality.

Part 53 of 10 CFR contains backfitting and issue finality provisions. Those provisions apply to NRC actions that would affect 10 CFR part 53 licensees and certain applicants that reference NRC approvals under 10 CFR part 53. The NRC has not issued any licenses or other approvals under 10 CFR part 53, so no licensees or applicants under 10 CFR part 53 could be affected by this proposed rule. Therefore, this proposed rule's changes to 10 CFR part 53 would not constitute backfitting under 10 CFR part 53 or affect the issue finality of an approval issued under 10 CFR part 53.

''Backfitting'' is defined in 10 CFR 50.109(a)(1) as, in relevant part, a modification of or addition to the systems, structures, and components or design of a facility; or the design approval or manufacturing license (ML) of a facility; or the procedures or organization required to design, construct, or operate a facility, which

results from a new or amended provision in the Commission's regulations. The issue finality provision for combined licenses (COLs) located in 10 CFR 52.98 provides, in relevant part, that the Commission may not modify, add, or delete any term or condition of a COL except in accordance with the provisions of 10 CFR 50.109. Essentially, if a change does not constitute backfitting, then the change does not affect the issue finality of a COL.

Part 52 of 10 CFR contains an issue finality provision for MLs. No entity holds an ML under 10 CFR part 52. Therefore, the proposed changes to 1) amend 10 CFR 52.173 to change the duration of an ML to a maximum of 40 years, 2) amend 10 CFR 52.181 to change the duration of a renewed ML to a maximum of 40 years, 3) amend 10 CFR 50.71(f) regarding final safety analysis report (FSAR) updates by ML holders, and 4) amend 10 CFR 52.171(b)(1) to allow the holder of an ML to use the regulations in 10 CFR 50.59 to determine whether changes to the facility or procedures as described in the FSAR would require prior Commission approval of an amendment to the ML, would not affect the issue finality of an ML.

Similarly, the proposed change to amend 10 CFR 52.98, which would allow COL holders who reference an ML to use the applicable change processes in 10 CFR part 50 to determine whether changes to the facility or procedures as described in the FSAR would require prior Commission approval, would not affect the issue finality of a COL referencing an ML because there are no MLs for a COL to reference. Also, the proposed change to amend 10 CFR 50.59 to allow the holder of an operating license (OL) under 10 CFR part 50 or a COL under 10 CFR part 52 that references a reactor manufactured under an ML to make changes in the facility or procedures as described in the FSAR without requesting a license amendment if the changes would be the same as changes approved by amendment to the ML and upon a determination that implementing the changes would be consistent with the basis for the Commission's approval of the amendment to the ML and would not involve any additional changes that would require an amendment to the OL or COL, would not constitute backfitting of a 10 CFR part 50 operating license or affect the issue finality of a 10 CFR part 52 COL referencing an ML because there are no MLs for an OL or a COL to reference.

Two sets of proposed changes would affect the issue finality of standard design certifications under 10 CFR part 52. First, the NRC proposes to clarify the definitions of Tier 1 information in section II.D of appendices A, D, E, F, and G to 10 CFR part 52 by identifying specific sections and tables within the generic design certification documents that correspond to each of these categories of Tier 1 information. Second, the NRC proposes to amend sections II.F and VIII.B of appendices A and E to 10 CFR part 52 to revert all Tier 2* information to Tier 2 status after the plant first achieves full power. These proposed changes would modify the certification information of the certified standard designs in those appendices. The issue finality provision for design certifications is in 10 CFR 52.63(a)(1) and prohibits the modification of certification information unless the Commission determines in a rulemaking that certain criteria are met. In this case, the Commission determines that these proposed changes would reduce unnecessary regulatory burden and maintain protection to public health and safety and the common defense and security in accordance with 10 CFR 52.63(a)(1)(iii). Therefore, the NRC may propose to make these changes.

Under 10 CFR 52.63(a)(2), in a rulemaking performed under 10 CFR 52.63(a)(1)(iii), the Commission will give consideration to whether the benefits justify the costs for plants that are already licensed or for which an application for a permit or license is under consideration. The NRC prepared an analysis addressing whether the benefits of the proposed changes would justify the costs for plants that are already licensed or for which an application for a permit or license is under consideration (see section XXXIX, ''Regulatory Analysis,'' of this document).

Other proposed changes to the standard design certifications under 10 CFR part 52 would not affect the issue finality of those certified designs or COL holders referencing the certified designs because the proposed changes would not amend certification information of the designs. The Commission explained in the 2007 10 CFR part 52 final rule that 10 CFR 52.63(a) applies to changes to the certification information (*i.e.,* the information in the generic design control document incorporated by reference in a design certification appendix in 10 CFR part 52) but does not apply to changes to the certified design rule language (72 FR 49381; August 28, 2007). Therefore, deleting section IX of appendix D to 10 CFR part 52 because it is redundant with 10 CFR 52.99 and 52.103 would not affect the issue finality of the existing design certification or COLs referencing the existing certified design because the proposed change would not amend certification information of the design.

Of the other proposed changes, many would not constitute backfitting under 10 CFR part 50 or affect the issue finality of a COL under 10 CFR part 52 because they would be non-mandatory relaxations of existing requirements. As explained in MD 8.4, non-mandatory relaxations of regulations generally do not meet the definition of ''backfitting'' in 10 CFR 50.109(a)(1). Thus, these proposed changes would not constitute backfitting under 10 CFR part 50 or affect the issue finality of a COL under 10 CFR part 52. The following proposed changes would be non-mandatory relaxations of existing requirements:

- Amending paragraphs IV.F.2.a.(i) through (iii) of appendix E to 10 CFR part 50 and paragraphs 10 CFR 50.160(c)(1) and (c)(2) to remove the requirement to demonstrate compliance within 2 years before issuance of an OL under 10 CFR part 50 or the scheduled date of initial loading of fuel for a 10 CFR part 52 COL. A 10 CFR part 50 OL applicant or 10 CFR part 52 COL holder could conduct the initial exercise within 2 years of the respective milestones and would comply with the proposed rule.
- Amending paragraph IV.D.3 of appendix E to 10 CFR part 50 to revise requirements for when backup alert and notification system methods are required. Licensees could continue to have a single primary method and a single backup method and would comply with the proposed rule.
- Amending 10 CFR 50.33(g), 50.47(c)(2), and 50.160(b)(3) to ensure the plume exposure pathway emergency planning zone (EPZ) is no larger than needed to implement predetermined, prompt protective measures. Licensees could continue to have a plume exposure pathway EPZ of an area about 10 miles (16 km) in radius and would comply with the proposed rule.
- Eliminating the requirement to define an ingestion pathway EPZ by removing references to the ingestion pathway EPZ in 10 CFR 50.33(g)(1), 50.47(b)(10), 50.47(c)(2), and paragraph IV.F.2.a.(i) and footnote 1 of appendix E to 10 CFR part 50. Licensees could continue to have an ingestion pathway EPZ of an area about 50 miles (80 km) in radius and would comply with the proposed rule.
- Amending paragraph IV.E.8.b of appendix E to 10 CFR part 50 to require the emergency plan to specify the location of the emergency operations facility in relation to the EPZ boundary. A licensee could continue to locate its

emergency operation facility between 10 and 25 miles (16 and 40 km) of the nuclear power reactor site, or a primary facility less than 10 miles (16 km) from the nuclear power reactor site and a backup facility between 10 and 25 miles (16 and 40 km) of the nuclear power reactor site, based on the current 10-mile (16-km) EPZ requirement, and would comply with the proposed rule.

- Amending 10 CFR 50.54(t) to eliminate the requirement for licensees to ensure that all program elements are reviewed by people who have no direct responsibility for implementation of the emergency preparedness (EP) program. Licensees could continue to have their EP program elements reviewed by people who have no direct responsibility for implementation of the EP program and would comply with the proposed rule.
- Amending paragraphs IV.5, IV.6, and IV.7 of appendix E to 10 CFR part 50 to eliminate certain requirements related to updates of evacuation time estimates. Licensees could continue to update their EPZ permanent resident population estimates and evacuation time estimate analysis, and would comply with the proposed rule.
- Amending paragraph IV.E.9.d of appendix E to 10 CFR part 50 to eliminate the requirement for monthly tests of communications between the licensee and the appropriate NRC Regional Office Operations Center. Licensees could try to communicate monthly with their NRC Regional Office Operations Center and would comply with the proposed rule.
- Amending 10 CFR 71.55 to expand the exception from 10 CFR 71.55(b) for packages containing enrichment levels between 5.0 and 10.0 weight percent U–235. Packages could contain enrichment levels below 5.0 weight percent U–235 and would comply with the proposed rule.
- Amending 10 CFR 50.67 and General Design Criterion (GDC) 19 of appendix A to 10 CFR part 50 to increase the numerical value of the control room design criteria from 5 to 10 rem (0.05 to 0.10 Sv) and enable a higher control room design criteria, ranging from 10 to 25 rem (0.10 to 0.25 Sv) TEDE, for licensees whose facility-specific risk profiles warrant them. Licensees could meet the current control room habitability design requirements and would comply with the proposed rule.
- Removing the restriction limiting proposed alternatives to paragraphs (b) through (h) of 10 CFR 50.55a so that proposed alternatives would now be permitted for all regulatory requirements in 10 CFR 50.55a using the existing criteria in paragraphs (z)(1) and (2) of 10 CFR 50.55a. Licensees could continue to propose alternatives to only paragraphs (b) through (h) of 10 CFR 50.55a and would comply with the proposed rule.
- Amending appendix A to 10 CFR part 50 to clarify that (1) deviations from GDC could be identified and justified within licensing submittals, with no need for a separate exemption request; and (2) demonstrating compliance with GDC 28 of appendix A to 10 CFR part 50 could be based on a different design basis accident than the control rod ejection or control rod drop accident. Licensees could continue to submit an exemption request or demonstrate compliance with GDC 28 using an evaluation of control rod ejection or control rod drop accidents and would comply with the proposed rule.
- Amending 10 CFR 54.37(b) to only require that the final safety evaluation report include a summary description of aging management activities that addresses newly identified SSCs, as appropriate, consistent with what is required in the renewal application.

Some of the changes in this proposed rule would not constitute backfitting under 10 CFR part 50 or affect the issue finality of an approval under 10 CFR part 52 because the proposed changes would provide a voluntary alternative set of requirements. Licensees could continue to comply with the current applicable requirement and would not be required to comply with the proposed rule. The following proposed changes would not require holders of 10 CFR part 50 or 52 approvals to comply with the proposed rule changes:

- Amending various regulations to allow applicants and licensees under 10 CFR parts 50 and 52 the option to use 10 CFR 50.160.
- Amending 10 CFR 52.26 to remove the requirement for an ESP to include a fixed term and making related conforming changes to subpart A of 10 CFR part 52.
- Amending 10 CFR 50.68(b)(7) to allow enrichment above 5.0 weight percent U–235.
- Amending 10 CFR 50.46a and making conforming changes to provide alternative acceptance criteria for emergency core cooling systems for light-water reactors.
- Adding 10 CFR 50.221 to establish an optional verification, validation, and uncertainty quantification (VVUQ) program.
- Adding appendix T to 10 CFR part 50 to establish an alternative to the current quality assurance requirements in appendix B to 10 CFR part 50.
- Amending various paragraphs in 10 CFR 50.4, 50.34, 50.54, 50.55, and 52.79 to make conforming changes to reflect the addition of appendix T to 10 CFR part 50.
- Adding 10 CFR 50.220 and 52.220 to allow licensees and applicants to voluntarily submit and use technology-inclusive, risk-informed, or performance-based acceptance criteria as alternatives to existing prescriptive requirements.

Several of the proposed changes would apply to only future applicants and to current licensees at their discretion, and therefore would not constitute backfitting under 10 CFR part 50 or affect the issue finality of a 10 CFR part 52 approval. Applicants and potential applicants (for licenses, permits, and other regulatory approvals) generally are not within the scope of the backfitting or issue finality regulations. Those regulations include language delineating when those provisions begin; in general, the backfitting and issue finality regulations begin upon the issuance of the license, permit, or other approval. The following proposed changes would apply to only future applicants and to current licensees at their discretion:

- Amending paragraph I.5 of appendix E to 10 CFR part 50 to determine the degree to which compliance with the requirements in certain sections of appendix E is necessary on a case-by-case basis for power reactors with a site-boundary EPZ or no EPZ.
- Amending 10 CFR 50.33(g), 50.47(c)(2), and 50.160(b)(3) to simplify EPZ determinations.
- Amending 10 CFR 50.33(g) to eliminate the requirement to submit response plans of State, local, and participating Tribal governmental entities.
- Amending 10 CFR 50.34(a)(10) and sections I.1, I.2, and II of appendix E to 10 CFR part 50 to remove the requirements for applicants to submit preliminary plans for coping with emergencies in the preliminary safety analysis report.
- Amending 10 CFR 52.158 and 52.171 to allow ML applicants the option to submit essentially complete operational program information with their applications and to provide finality to such program information that is reviewed and approved by the NRC as part of the ML review.
- Amending 10 CFR 54.31 to extend the maximum renewal period for a license to 40 years.
- Adding 10 CFR 54.21(a)(4) to allow applicants to voluntarily propose risk-informed and performance-based

alternatives to the current prescriptive requirements of the aging management review.

- Amending 10 CFR 54.17(c) to remove the 20-year limit on applying for license renewal.
- Amending 10 CFR 54.21(c)(2) to remove the requirement to submit a list of plant-specific exemptions granted under 10 CFR 50.12 that are based on time-limited aging analyses and a justification for continuing those exemptions during the extended operating period.
- Amending 10 CFR 54.22 to remove the requirement that applicants include and justify any technical specification changes needed to manage the effects of aging.
- Amending 10 CFR part 100 to allow power reactor applicants under 10 CFR part 50 or 52 to have greater flexibility to determine the appropriate level of site characterization.
- Amending or adding 10 CFR 50.10, 50.34(b), 50.57, 50.58, 51.4, 52.79(a), 52.85, 52.97(d), and 52.98 to revise the definition of construction to better focus the definition on safety-significant matters and reduce the cost impact of the current definition, to allow certain applicants to request generic finality, and to allow certain construction activities under a general license.
- Amending 10 CFR 50.2 to add definitions for the terms ''design basis events'' and ''beyond design basis events'' and making a conforming change to 10 CFR 50.49(b)(1)(ii).
- Adding a new paragraph (b)(2) to 10 CFR 50.75 to allow new reactor applicants and licensees to use an alternative decommissioning funding assurance pathway.
- Amending 10 CFR 50.75(c)(1) to delete language in the table of minimum amounts that requires reactors of less than 1200 MWt to use the certification amount for a 1200 MWt reactor.
- Amending 10 CFR 50.75(e) to include ''applicant or'' in all appropriate places where currently only ''licensee'' is referenced.
- Amending 10 CFR 50.34(a)(4) and (b)(4) and footnote 1 of 10 CFR 50.34(a) regarding construction permit and OL application requirements and making conforming changes to 10 CFR 52.47, 52.79, 52.137, and 52.157.
- Amending paragraph (a)(1)(ii)(D) and footnotes 3 and 6 of 10 CFR 50.34 to use technology-inclusive language and making conforming changes to 10 CFR 52.17, 52.47, 52.79, 52.137, and 52.157.
- Amending footnote 4 of 10 CFR 50.34(a)(1)(ii)(D)(*1*) to remove outdated information regarding recommendations included in a 1959 National Bureau of Standards handbook.
- Amending 10 CFR 52.1 to add the definitions of Tier 1, Tier 2, and Tier 2*, which would apply to design certifications issued after the effective date of the proposed rule (if finalized).

The remaining proposed changes in this proposed rule would not constitute backfitting under 10 CFR part 50 or affect the issue finality of a 10 CFR part 52 COL, and they would not be non-mandatory relaxations of existing requirements, voluntary alternative requirements, or applicable to only future applicants. These proposed changes would not require a licensee to modify or add to systems, structures, components, or the design of a facility; or the design approval or ML of a facility; or the procedures or organization required to design, construct, or operate a facility. Therefore, the proposed changes would not meet the 10 CFR 50.109 definition of ''backfitting'' and, thus, would not constitute backfitting and would not affect the issue finality of a 10 CFR part 52 COL. The following proposed rule changes would fall into this category:

- Amending 10 CFR 50.160(b)(1)(iv)(A)(*2*) and paragraph IV.D.2 of appendix E to 10 CFR part 50 to use modern terminology.
- Amending 10 CFR 50.54(q) to revise and risk-inform the emergency plan change process. The criteria to determine whether the licensee's emergency plan change would require prior NRC approval and the process to obtain that approval in 10 CFR 50.54(q) are not within the scope of ''backfitting'' as defined in 10 CFR 50.109(a)(1) because they are part of an NRC-designed administrative change process that is not required to design, construct, or operate a facility. In addition, the procedures a licensee might use to decide whether to change its emergency plan are not required to design, construct, or operate a facility. Other proposed changes that would amend a change process are the following:
  - Adding 10 CFR 50.59(e) to establish a risk-informed alternative to the existing 10 CFR 50.59 change process.
  - Amending 10 CFR 50.59(c)(2)(viii) to allow licensees to implement certain changes to analytical methods described in the FSAR (as updated) without prior NRC approval, provided those changes are undertaken pursuant to an NRC-approved VVUQ program under 10 CFR 50.221.
  - Amending section VIII.A of appendices A, D, E, F, and G to 10 CFR part 52 to revise the change process for licensee-requested changes to Tier 1 design description information and Tier 1 ITACC information, and to revise the change process for changes and departures during commercial operation.
  - Amending section VIII.B.5.c of appendices A, D, E, F, and G to 10 CFR part 52 to amend the change process criteria used to determine if a proposed departure from Tier 2 information affecting the resolution of an ex-vessel severe accident design feature identified in the plant-specific DCD requires a license amendment.
  - Amending section VIII.B of appendix D to 10 CFR part 52 to allow the use of the 10 CFR 50.59-like criteria in sections VIII.B.5.b and B.5.c to determine if licensees who reference appendix D to 10 CFR part 52 may depart from Tier 2* information without prior NRC approval.
- Amending table S–3 in 10 CFR 51.51(b). The information in table S–3 provides the basis for evaluating the contribution of the environmental effects of the uranium fuel cycle to support the NRC's NEPA obligations at the time of a nuclear reactor licensing action. Because table S–3 only provides information about the environmental effects away from a nuclear reactor, the NRC's proposed revision to table S–3 would not result in a modification or addition that meets the definition of ''backfitting'' in 10 CFR 50.109(a)(1).
- Amending table S–4 in 10 CFR 51.52. The information in table S–4 provides the basis for evaluating the contribution of the environmental impacts of the transportation of fuel and waste to and from a nuclear reactor to support the NRC's NEPA obligations at the time of a nuclear reactor licensing action. Because table S–4 only provides information about the environmental impacts away from a nuclear reactor, the NRC's proposed revisions to table S–4 would not result in a modification or addition that meets the definition of ''backfitting'' in 10 CFR 50.109(a)(1).
- Amending the terminology in 10 CFR 50.67 and GDC 19 of appendix A to 10 CFR part 50 to clarify the regulations.
- Amending current 10 CFR 50.34, 50.46, 50.46a, and 50.69; GDC 17, 35, 38, 41, 44 and 50 of appendix A to 10 CFR part 50; appendix K to 10 CFR part 50; 10 CFR 52.47, 52.54, 52.79, 52.137, and 52.157; and appendix G to 10 CFR part 52 to reflect the proposed 10 CFR 50.46a. Many of these proposed changes would support implementation of the proposed 10 CFR 50.46a, which would offer voluntary alternative criteria for emergency core cooling systems for light-water reactors. These proposed conforming changes would not meet the definition of backfitting for the same

reasons why the proposed 10 CFR 50.46a—voluntary alternative requirements—would not meet the definition of backfitting. The other proposed conforming changes would affect regulations for applicants and, therefore, would not constitute backfitting under 10 CFR part 50 or affect the issue finality of a 10 CFR part 52 approval.

- Removing footnote 3 from 10 CFR 50.49(b)(1) and redesignating footnote 4 as footnote 1.
- Amending 10 CFR 50.75(e), (g), and (h) to make editorial corrections.
- Amending 10 CFR 52.63(a)(1)(vii) to eliminate ''increased standardization'' as a criterion that the Commission must meet before modifying, rescinding, or imposing new requirements on certification information by rulemaking.
- Amending 10 CFR 52.63(a)(4)(ii) to eliminate whether special circumstances outweigh any decrease in safety that may result from a reduction in standardization as a criterion that the Commission must meet before imposing new requirements on a design by plant-specific order.
- Amending 10 CFR 52.63(b)(1) to eliminate the requirement for the Commission to review the impact of a requested exemption on standardization.
- Amending 10 CFR 52.93 and 52.171 to eliminate the requirement for the Commission to discuss the impact of a change on standardization as a criterion for the justification for departures from ML information.

As described in the ''Availability of Guidance'' section of this document, the NRC is issuing 24 draft guidance documents that, if finalized, would provide guidance on the methods acceptable to the NRC for complying with aspects of this proposed rule. Further, as discussed in the guidance documents, applicants and licensees would not be required to comply with the positions set forth in the guidance. Therefore, issuance of the guidance documents as final guidance would not constitute backfitting under 10 CFR parts 50 and 53 or affect the issue finality of any approval issued under 10 CFR parts 52 and 53.

XLI. Cumulative Effects of Regulation

The NRC seeks to minimize potential negative consequences resulting from the cumulative effects of regulation (CER). The NRC believes that the deregulatory impacts of this rulemaking activity are unlikely to cause implementation challenges for stakeholders. In addition, during the pendency of this rulemaking, the NRC is deprioritizing issuance of regulatory actions that might influence the implementation date for the new rule requirements (*e.g.,* orders, generic communications, license amendment requests, and inspection findings of a generic nature).

To fully understand any potential CER implications that could result from this rulemaking, the NRC is asking the following questions. Response to these questions is voluntary and any input will be considered during development of the final rule.

1. The NRC is proposing an effective date that will be 30 days after the date of publication of a final rule. Does this provide sufficient time to implement the proposed requirements? Please provide a rationale for your response.

2. Are there unintended consequences related to this rulemaking and how should they be addressed? Please provide a rationale for your response.

3. Please comment on the NRC's cost and benefit estimates in the regulatory analysis that supports this proposed rule.

XLII. Plain Writing

The Plain Writing Act of 2010 (Pub. L. 111–274) requires Federal agencies to write documents in a clear, concise, and well-organized manner. The NRC has written this document to be consistent with the Plain Writing Act as well as the Presidential Memorandum, ''Plain Language in Government Writing,'' published June 10, 1998 (63 FR 31885). The NRC requests comment on this document with respect to the clarity and effectiveness of the language used.

XLIII. National Environmental Policy Act

The Commission proposes to determine under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in subpart A of 10 CFR part 51, that this rule, if adopted, would not be a major Federal action significantly affecting the quality of the human environment, and an environmental impact statement is not required. The basis of this proposed determination regarding potential environmental impacts is the implementation of the proposed rule for the regulations described in this **Federal Register** notice would not have a significant impact on the environment. The proposed requirements would be administrative in application or matters of procedure or provide an equivalent level of safety as existing requirements; therefore, there would be similar environmental impacts from the implementation of the regulations in this proposed rule as there are for existing requirements.

The proposed determination of this draft environmental assessment is that there will be no significant effect on the quality of the human environment from this action. Public stakeholders should note, however, that comments on any aspect of this environmental assessment may be submitted to the NRC as indicated under the **ADDRESSES** caption. The draft environmental assessment is available as indicated under the ''Availability of Documents'' section of this document. This environmental assessment and proposed finding of no significant impact can be tracked with identification number NEPA ID EAXX–429–00–000–1770782365.

XLIV. Paperwork Reduction Act

This proposed rule contains new or amended collections of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et *seq.*). This proposed rule has been submitted to the Office of Management and Budget for review and approval of the information collections.

Type of submission: New.

The title of the information collection: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices.

OMB approval numbers: 3150–0008, 3150–0011, 3150–0093, 3150–0151, 3150–0155, 3150–0264, and 3150–0274.

The form number if applicable: Not applicable.

How often the collection is required or requested: Collections are submitted one-time, on-occasion, and periodically. The frequency of collections changes by adding new periodic reporting under 10 CFR50.46a, introducing event-driven submissions for quality management system (QMS) changes and EP framework transitions, while reducing EP program reviews from annual to biennial under 10 CFR50.54(t). Changes to the QMS must be maintained for three years, while other records are generally required to be maintained for the length of license.

Who will be required or asked to respond: The proposed rule would affect a range of entities that apply for or hold licenses from the NRC. The affected entities encompass both new applicants and current licensees operating under 10 CFR parts 50, 52, 53, 54, 71, and 100 and 10 CFR 50.55a.

An estimate of the number of annual responses: 2,075.1 (2,063.1 reporting responses, 10.3 recordkeeping responses for 10 CFR part 50; 1.7 reporting responses for 10 CFR part 53).

The estimated number of annual respondents: 130 (120 for 10 CFR part 50, 5 for 10 CFR part 53, 5 for 10 CFR part 100).

An estimate of the total number of hours needed annually to comply with the information collection requirement or request: 33,321.6 (83,116.6 reporting + 6,150 recordkeeping for 10 CFR part 50; −835 reporting for 10 CFR part 53; −55,110 reporting for 10 CFR part 100).

Abstract: The NRC is proposing to amend its regulations to modernize reactor licensing, safety oversight, and siting practices. The proposed rule introduces voluntary risk-informed and performance-based alternatives, updates EP requirements, streamlines quality assurance criteria through a new appendix T to 10 CFR part 50, and revises siting criteria to incorporate risk insights. These changes affect information collections associated with license applications, license amendment requests, periodic reporting, and recordkeeping. New collections include ECCS evaluation model reporting and monitoring under 10 CFR50.46a, QMS change approvals under 10 CFR50.54(a)(5), 50.55(f)(5), and 53.1565, and EP framework transition requests under 10 CFR50.160. The proposed rule also reduces burden by eliminating duplicative requirements, such as prescriptive EP content in CP applications and ESP renewal provisions, and by simplifying seismic/geologic siting criteria under 10 CFR part 100. Overall, the proposed rule results in a net increase in burden due to additional technical analyses and documentation required for voluntary alternatives, balanced by targeted reductions from modernization and streamlining initiatives.

This proposed action includes amendments to several requirements in 10 CFR 50.55a and parts 50, 52, 53, 54, 71, and 100. The proposed changes to 10 CFR parts 2 and 51 do not contain any new or amended collections of information subject to the Paperwork Reduction Act of 1995.

The NRC is seeking public comment on the potential impact of the information collections contained in this proposed rule and on the following issues:

1. Is the proposed information collection necessary for the proper performance of the functions of the NRC, including whether the information will have practical utility? Please explain your response.

2. Is the estimate of the burden of the proposed information collection accurate? Please explain your response.

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected? Please explain your response.

4. How can the burden of the proposed information collection on respondents be minimized, including the use of automated collection techniques or other forms of information technology?

A copy of the Office of Management and Budget (OMB) clearance package and proposed rule are available in the ''Availability of Documents'' section of this document or may be viewed free of charge by contacting the NRC's Public Document Room reference staff at 1–800–397–4209, at 301–415–4737, or by email to *PDR.Resource@nrc.gov.*

You may obtain information and comment on submissions related to the OMB clearance package by searching on *https://www.regulations.gov* under Docket ID NRC–2025–0975.

You may submit comments on any aspect of these proposed information collections, including suggestions for reducing the burden and on the above issues, by the following method:

- *Federal rulemaking website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2025–0975.

Submit comments by August 17, 2026.

Public Protection Notification

The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the document requesting or requiring the collection displays a currently valid OMB control number.

XLV. Executive Orders

The following are Executive orders that are related to this proposed rule:

A. Executive Order 12866: Regulatory Planning and Review (as Amended by Executive Order 14215, Ensuring Accountability for All Agencies)

The Office of Information and Regulatory Affairs (OIRA) has determined that this proposed rule is an economically significant regulatory action under section 3(f) of E.O. 12866. Accordingly, NRC submitted this proposed rule to OIRA for review. NRC is required to conduct an economic analysis in accordance with section 6(a)(3)(B) of E.O. 12866. More can be found in section XXXIX, ''Regulatory Analysis,'' of this document.

B. Executive Order 14154: Unleashing American Energy

NRC has examined this proposed rule document and has determined that it is consistent with the policies and directives outlined in E.O. 14154.

C. Executive Order 14192: Unleashing Prosperity Through Deregulation

This action is tentatively determined to be a deregulatory action as defined by E.O. 14192. Details on the estimated costs of this proposed rule document can be found in section XXXIX, ''Regulatory Analysis,'' of this document.

D. Executive Order 14267: Reducing Anti-Competitive Regulatory Barriers

Executive Order 14267 requires the NRC to identify anti-competitive regulations for recission or modification.

The NRC identified 10 CFR 50.34, and related portions of 10 CFR part 52, because these regulations could create a barrier to market participation by using language that may not be clear on the minimum level of information needed to be submitted for a construction permit and uses overly prescriptive language that is not technology inclusive. The proposed recission/modification of the regulations would support the objectives of E.O. 14267 by removing regulatory requirements that could create unnecessary barriers to entry for new market entrants. See section XVIII, ''Discussion—Updates to Construction Permit Requirements and Related Licenses,'' of this document for more information.

The NRC identified 10 CFR 50.54 because this regulation has an anticompetitive effect by raising barriers to entry. It also serves an important regulatory goal as many portions of this regulation are necessary for reasonable assurance of adequate protection. The proposed modifications of the regulation would support the objectives of E.O. 14267 by adding alternatives to enhance entry for new market entrants. The proposed amendments to 10 CFR 50.54 would be conforming changes to reflect the addition of performance-based QA criteria in the proposed appendix T to 10 CFR part 50 as an alternative to appendix B to 10 CFR part 50 for eligible applicants. See section XVI, Discussion—Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' of this document for more information.

The NRC identified 10 CFR 50.160 because this regulation creates a barrier to market participation by limiting use of performance-based emergency preparedness standards to small modular reactors less than 1000 MWt, non-light water reactors, and other new technologies. The proposed modification of the regulation would support the objectives of E.O. 14267 by making performance-based regulations available to all new market entrants. See section XXIV, ''Discussion—Revision of the Emergency Preparedness Regulations for Nuclear Power

Reactors,'' of this document for more information.

The NRC identified 10 CFR 100.3 because this regulation creates a barrier to market participation by limiting available potential facility sites, especially for designs that do not require low population zones beyond site boundaries. The proposed recission/modification of the regulation would support the objectives of E.O. 14267 by removing regulatory requirements that could create unnecessary barriers to entry for new market entrants. See section XXXIV, ''Discussion—Enhancing Flexibility of Reactor Site Criteria,'' of this document for more information.

XLVI. Voluntary Consensus Standards

The National Technology Transfer and Advancement Act of 1995, Public Law 104–113, requires that Federal agencies use technical standards that are developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or otherwise impractical. In this proposed rule, the NRC would revise the regulations associated with the usage of increased enrichment of conventional and ATF designs for LWRs in 10 CFR parts 50, 51, 52, and 71. This action would not constitute the establishment of a standard that contains generally applicable requirements.

XLVII. Availability of Guidance

The NRC is issuing for comment 24 draft guidance documents to support the implementation of the proposed requirements in this rulemaking. You may obtain information and comment submissions related to the draft guidance by searching on *http://www.regulations.gov* under Docket ID NRC–2025–0975. You may submit comments on these draft guidance documents by the methods outlined in the **ADDRESSES** section of this document.

1. The DG–1261, Revision 1, ''Measuring Breakaway Oxidation Behavior,'' would be a new regulatory guide.

2. The DG–1262, Revision 1, ''Determining Post-Quench Ductility,'' would be a new regulatory guide.

3. The DG–1263, Revision 1, ''Establishing Analytical Limits for Zirconium-Based Alloy Cladding,'' would be a new regulatory guide.

4. The DG–1425, ''Alternative Radiological Source Terms for Evaluating Design-Basis Accidents at Nuclear Power Reactors,'' would be Revision 2 to the existing RG 1.183.

5. The DG–1426, ''An Approach for a Risk-Informed Evaluation Process Supporting Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Reactors,'' would be a new regulatory guide.

6. The DG–1428, ''Plant-Specific Applicability of the Transition Break Size,'' would be a new regulatory guide.

7. The DG–1430, ''Performance-Based Emergency Preparedness,'' would be Revision 1 to the existing RG 1.242.

8. The DG–1434, ''Addressing the Consequences of Fuel Dispersal in Light-Water Reactor Loss-of-Coolant Accidents,'' would be a new regulatory guide.

9. The DG–1454, ''Implementation of Determinate and Data-Backed Thresholds for Reactor Safety Assessments,'' would be a new regulatory guide.

10. The DG–1456, ''Emergency Response Planning and Preparedness for Nuclear Power Reactors,'' would be Revision 8 to the existing RG 1.101.

11. The DG–1457, ''Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors,'' would be Revision 2 to the existing RG 1.219.

12. The DG–1460, ''Applications for Nuclear Power Plants,'' would be Revision 2 to the existing RG 1.206.

13. The DG–1461, ''Guidance for Changes During Construction for New Nuclear Power Plants Being Constructed Under a Combined License Referencing a Certified Design Under 10 CFR part 52,'' would be Revision 1 to the existing RG 1.237.

14. The DG–1462, ''A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion,'' would be Revision 1 to the existing RG 1.208.

15. The DG–1463, ''Meteorological Monitoring Programs for Nuclear Power Plants,'' would be Revision 2 to the existing RG 1.23.

16. The DG–1464, ''Guidance for Content of Applications Under 10 CFR 50.220 and 52.220 Proposing Risk-Informed and Performance-Based Alternative Acceptance Criteria,'' would be a new regulatory guide.

17. The DG–1465, ''Guidance for a Technology Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors,'' would be Revision 1 to the existing RG 1.253.

18. The DG–1466, ''Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments,' '' would be Revision 4 to the existing RG 1.187.

19. The DG–1467, ''Assuring the Availability of Funds for Decommissioning Nuclear Reactors,'' would be Revision 3 to the existing RG 1.159.

20. The DG–1468, ''Guidance for Implementation of 10 CFR 50.221, 'Credibility Requirements for Modeling and Simulation,' '' would be a new regulatory guide.

21. The DG–4036, ''Graded Approach to Site Characterization for New Reactor Applications,'' would be a new regulatory guide.

22. The DG–4037, ''Preparation of Environmental Reports for Nuclear Power Stations,'' would be Revision 5 to the existing RG 4.2.

23. LR–ISG–2026–01, ''Updated Review Criteria for License Renewal,'' would be new interim staff guidance.

24. NUREG–0800, Chapter 14, Section 14.3, ''Inspections, Tests, Analyses, and Acceptance Criteria,'' would be a revision to the existing standard review plan (issued March 2007).

Draft regulatory guide updates beyond this rulemaking are included in DG–1425. These additional updates to DG–1425 include the following:

- Updated steady-state release fractions for accidents other than the maximum hypothetical accident (loss-of-coolant accident), based on American National Standards Institute/American Nuclear Society 5.4, ''Method for Calculating the Fractional Release of Volatile Fission Products from Oxide Fuel,'' May 2011, extending the applicability to higher burnups and increased enrichments;

- Additional guidance for modeling BWR main steam isolation valve (MSIV) leakage and fission product removal by suppression pool scrubbing;

- Guidance for crediting holdup and retention of MSIV leakage within the main steamlines and condenser for BWRs; and

- Guidance for use of best estimate plus uncertainty approaches to determining inputs to radiological models.

XLVIII. Availability of Documents

The documents identified in the following table are available to interested persons through one or more of the following methods, as indicated.

BILLING CODE 7590–01–P

DOCUMENT	ADAMS ACCESSION NO. / WEB LINK / *FEDERAL REGISTER* CITATION
Proposed Rule Documents	
Regulatory Analysis for the Proposed Rule: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices	ML26181A099
Environmental Assessment for the Proposed Rule: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices	ML26181A100
OMB Supporting Statement for Proposed Rule: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices	ML25328A182
OMB Burden Tables for Proposed Rule: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices	ML26034C042
Unofficial Redline Rule Language for the Proposed Rule: Modernizing Reactor Licensing, Safety Oversight, and Siting Practices (NRC-2025-0975; RIN 3150-AL44) dated July 2026	ML26029A079
Draft Guidance Documents	
DG-1261, Revision 1, "Measuring Breakaway Oxidation Behavior," July 2026	ML24284A338
DG-1262, Revision 1, "Determining Post-Quench Ductility," July 2026	ML24284A340
DG-1263, Revision 1, "Establishing Analytical Limits for Zirconium-Based Alloy Cladding," July 2026	ML24304A946
DG-1425, "Alternative Radiological Source Terms for Evaluating Design-Basis Accidents at Nuclear Power Reactors," July 2026	ML24185A179
DG-1426, "An Approach for a Risk-Informed Evaluation Process Supporting Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Reactors," July 2026	ML24284A342
DG-1428, "Plant-Specific Applicability of the Transition Break Size," July 2026	ML24341A154
DG-1430, "Performance-Based Emergency Preparedness," July 2026	ML25289A302
DG-1434, "Addressing the Consequences of Fuel Dispersal in Light-Water Reactor Loss-of-Coolant Accidents," July 2026	ML24304A951
DG-1454, "Implementation of Determinate and Data-Backed Thresholds for Reactor Safety Assessments," July 2026	ML25283A021
DG-1456, "Emergency Response Planning and Preparedness for Nuclear Power Reactors," July 2026	ML25289A309
DG-1457, "Guidance on Making Changes to Emergency Plans for Nuclear Power Reactors," July 2026	ML25289A351
DG-1460, "Applications for Nuclear Power Plants," July 2026	ML25255A088
DG-1461, "Guidance for Changes During Construction for New Nuclear Power Plants Being Constructed Under a Combined License Referencing a Certified Design Under 10 CFR Part 52," July 2026	ML25258A248
DG-1462, "A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion," July 2026	ML25259A323

DG-1463, "Meteorological Monitoring Programs for Nuclear Power Plants," July 2026	ML25259A209
DG-1464, "Guidance for Content of Applications Under 10 CFR 50.220 and 52.220 Proposing Risk-Informed and Performance-Based Alternative Acceptance Criteria," July 2026	ML25258A147
DG-1465, "Guidance for a Technology Inclusive Content of Application Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," July 2026	ML25260A526
DG-1466, "Guidance for Implementation of 10 CFR 50.59, 'Changes, Tests, and Experiments,'" July 2026	ML25272A138
DG-1467, "Assuring the Availability of Funds for Decommissioning Nuclear Reactors," July 2026	ML25273A081
DG-1468, "Guidance for Implementation of 10 CFR 50.221, 'Credibility Requirements for Modeling and Simulation,'" July 2026	ML25269A145
DG-4036, "Graded Approach to Site Characterization for New Reactor Applications," July 2026	ML25272A272
DG-4037, "Preparation of Environmental Reports for Nuclear Power Stations," July 2026	ML25268A122
LR-ISG-2026-01, "Updated Review Criteria for License Renewal," July 2026	ML25258A002
NUREG-0800, Chapter 14, Section 14.3, "Inspections, Tests, Analyses, and Acceptance Criteria," July 2026	ML25276A087
Other References	
Expedited Construction of Certain Structures, Systems, and Components	
Federal Register Notice, Final Rule – "Limited Work Authorizations for Nuclear Power Plants," dated October 9, 2007	72 FR 57416
Federal Register Notice, Final Rule – "Limited Work Authorizations for Nuclear Power Plants," Description of Supplemental Proposed LWA Rule, dated October 9, 2007	72 FR 57429
RG 1.233, Revision 0, "Guidance for a Technology-Inclusive, Risk-Informed, and Performance-Based Methodology to Inform the Licensing Basis and Content of Applications for Licenses, Certifications, and Approvals for Non-Light-Water Reactors," dated June 2020	ML20091L698
Determinate and Data-Backed Thresholds for Reactor Safety Assessments	
NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition"	https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/index
RG 1.76, Revision 1, "Design-Basis Tornado and Tornado Missiles for Nuclear Power Plants," dated March 2007	ML070360253
RG 1.208, "A Performance-Based Approach to Define the Site-Specific Earthquake Ground Motion," dated March 2007	ML070310619
RG 1.221, "Design-Basis Hurricane and Hurricane Missiles for Nuclear Power Plants," dated October, 2011	ML110940300
Removal of IEEE-323-1974 Reference in Footnote 3 of 10 CFR 50.49	
Federal Register Notice – Final Rule, "Environmental Qualification of Electric Equipment	48 FR 2733

Important to Safety for Nuclear Power Plants," dated January 21, 1983	
IEEE Std 308-2020, "IEEE Standard Criteria for Class 1E Power Systems for Nuclear Power Generating Stations," dated March 2020	https://store.accuristech.com/standards/ieee-308-2020?product_id=2033437
IEEE Std 323-1974, "IEEE Standard for Qualifying Class IE Equipment for Nuclear Power Generating Stations," dated September 1974	https://ieeexplore.ieee.org/stamp/stamp.jsp?tp=&arnumber=6568022
RG 1.32, "Criteria for Power Systems for Nuclear Power Plants," dated January 2025	ML24306A036
Expanded Alternative Requests under 10 CFR 50.55a(z)	
Federal Register Notice – Final Rule, "American Society of Mechanical Engineers Code Cases and Update Frequency," dated July 17, 2024	89 FR 58039
Federal Register Notice – Final Rule, "Approval of American Society of Mechanical Engineers' Code Cases," dated November 5, 2014	79 FR 65776
Federal Register Notice – Final Rule, "Codes and Standards for Nuclear Power Plants," dated March 15, 1984	49 FR 9711
Federal Register Notice Final Rule, "Codes and Standards for Nuclear Power Plants," dated June 12, 1971	36 FR 11423
SECY-23-0061 "Clarification of the Staff's Position on Certain American Society of Mechanical Engineers Code Alternatives For More Than One 10-Year Inservice Inspection Interval Under Title 10 of the *Code of Federal Regulations* 50.55a," dated July 21, 2023	ML23094A178
Risk-Informing 10 CFR 50.59 and Allowing Flexibility for Changes to Methods	
Federal Register Notice – Final Rule, "Changes, Tests, and Experiments," dated October 4, 1999	64 FR 53582
Federal Register Notice – Final Rule, "Changes, Tests, and Experiments," Final Rule Language, dated October 4, 1999	64 FR 53598
NFPA 805, "Performance-Based Standard for Fire Protection for Light Water Reactor Electric Generating Plants," dated 2025	https://www.nfpa.org/product/nfpa-805-standard/p0805code
RG 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," dated January 2018	ML17317A256
SECY-97-035, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests and Experiments)," dated February 12, 1997	https://www.nrc.gov/sites/default/files/doc_library/cdn/legacy/reading-rm/doc-collections/commission/secys/1997/secy1997-035/1997-035scy.pdf
FDA-2021-D-0980, "Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions," dated November 17, 2023,	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/assessing-credibility-computational-modeling-and-simulation-medical-device-submissions
Minimum Decommissioning Funding Assurance Requirements for Non-Large Light-Water Reactors	
Federal Register Notice - Final Rule, "General Requirements for Decommissioning Nuclear Facilities," dated June 27, 1988	53 FR 24018
SRM-SECY-23-0021: Enclosure 4, "Table of Typographical errors and Inconsistencies," dated March 4, 2024	ML24064A052
Incorporation of Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants	

ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications," dated 2024	https://www.asme.org/codes-standards/find-codes-standards/quality-assurance-requirements-for-nuclear-facility-applications
Federal Register Notice – Final Rule, "Quality Assurance Criteria for Nuclear Power Plant," dated June 27, 1970	35 FR 10498
ISO 19443, "Quality management systems – Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety [ITNS]," Edition 1, 2018	https://www.iso.org/standard/64908.html
ISO 9001, "Quality Management System - Requirements," Edition 5, 2015	https://www.iso.org/standard/62085.html
Updates to Construction Permit Requirements and Related Licenses	
Federal Register Notice – Final Rule, "Technical Specifications for Facility Licenses; Safety Analysis Reports," dated December 17, 1968	33 FR 18610
Federal Register Notice – Proposed Rule, "Backfitting of Production and Utilization Facilities; Construction Permits and Operating Licenses," dated April16, 1969	34 FR 6540
Federal Register Notice – Final Rule, "Backfitting of Production and Utilization Facilities; Construction Permits and Operating Licenses," dated March 31, 1970	35 FR 5317
Federal Register Notice – Final Rule, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors," dated April 18, 1989	54 FR 15372
Federal Register Notice – Final Rule, "Licenses, Certifications, and Approvals for Nuclear Power Plants," dated August 28, 2007	72 FR 49352
Alternative Risk-Informed and Performance-Based Acceptance Criteria for 10 CFR Parts 50 and 52	
Federal Register Notice – Final Rule, "Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors," dated November 22, 2004	69 FR 68008
SRM-SECY-98-144, "Staff Requirements – SECY-98-144 – White Paper on Risk-Informed and Performance-Based Regulation," dated March 1, 1999	ML003753601
Establishing Thresholds for Changes to Reactor Designs During Construction and Operation under 10 CFR Part 52	
SECY-17-0075, "Planned Improvements in Design Certification Tiered Information Designations," dated July 24, 2017	ML16196A321
SECY-19-0034, "Improving Design Certification Content," dated April 8, 2019	ML19080A032
Nuclear Energy Institute (NEI) 96-07, Appendix C, "Guideline for Implementation of Change Processes for New Nuclear Power Plants Licensed under 10 CFR Part 52," Revision 0-Corrected, dated March 2014	ML14091A739
"10 CFR Part 52 Construction Lessons Learned Report," dated January 16, 2024	ML23325A202
Submittal of NEI 15-02, Draft A of Revision 0, Industry Guideline for the Development of Tier 1 and ITAAC Under 10 CFR Part 52, dated May 27, 2015	ML15147A670

Summary of September 20, 2023, Meeting with Southern Nuclear Operating Company, dated October 12, 2023	ML23275A088
1-15-2025 Public Meeting - Options for Regulatory Flexibility in Part 52 during Construction and Operational Phases	ML24358A012
SECY-22-0052, "Proposed Rule: Alignment of Licensing Processes and Lessons Learned from New Reactor Licensing (RIN 3150 AI66), dated June 6, 2022	ML21159A055
SRM-SECY-22-0052, "Staff Requirements – SECY-22-0052 – Proposed Rule: Alignment of Licensing Processes and Lessons Learned From New Reactor Licensing (Rin 3150-AI66), dated November 20, 2024	ML24326A003
SECY-12-0081, "Risk-Informed Regulatory Framework for New Reactors," dated June 6, 2012	ML12117A012
SRM-SECY-12-0081, "Staff Requirements – SECY-12-0081 – Risk-Informed Regulatory Framework for New Reactors," dated October 22, 2012	ML12296A158
NRC Letter, "Vogtle Electric Generating Plant, Units 3 and 4 — Issuance of Amendments and Granting of Exemptions Re: Changes to the Tier 2* Departure Evaluation Process (LAR 17-037) (EPID L-2017-LLA-0421)," dated September 20, 2018	ML18235A030
Southern Nuclear Operating Company Vogtle Electric Generating Plant Units 3 and 4, "Request for Exemption and License Amendment regarding Changes to Tier 2* Information (LAR 14-008)," dated August 7, 2014	ML14219A579
Southern Nuclear Operating Company Vogtle Electric Generating Plant Units 3 and 4, "Withdrawal of Request for Exemption and License Amendment Regarding Changes to Tier 2* Information (LAR 14-008)," dated December 15, 2014	ML14349A624
NRC Letter, "Issuance of Combined Licenses and Limited Work Authorizations for Vogtle Electric Generating Plant (VEGP) Units 3 and 4," dated February 10, 2012	ML113540620
NRC Letter, "Issuance of Tier 2 License Amendment No. 44 (LAR 15-007) for Vogtle, Units 3 and 4," dated February 1, 2016	ML15191A128
Southern Nuclear Operating Company Vogtle Electric Generating Plant Units 3 and 4, "Request for License Amendment and Exemption: Changes to Tier 2* Departure Evaluation Process (LAR-17-037)," dated December 21, 2017	ML17355A416
NRC Letter, "Vogtle Electric Generating Plant, Units 3 and 4 - Issuance of Amendments 142 and 141 and Granting of Exemptions RE: Changes to The Tier 2* Departure Evaluation Process (LAR 17-037)," dated September 20, 2018	ML18235A029
Southern Nuclear Operating Company Vogtle Units 3 and 4, "License Amendment Request and Exemption Request: Remove Tier 1 and Tier 2* Requirements," dated July 25, 2024	ML24207A108
Southern Nuclear Operating Company Vogtle Electric Generating Plant Units 3 and 4, "Withdrawal of License Amendment Request and	ML24269A253

Exemption Request: Remove Tier 1 and Tier 2* Requirements," dated September 25, 2024	
Federal Register Notice – Final Rule, "Early Site Permits: Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors," dated April 18, 1989	54 FR 15372
Federal Register Notice – Policy Statement, "Nuclear Power Plant Standardization," dated September 15, 1987	52 FR 34884
Federal Register Notice – Final Rule, "Economic Simplified Boiling-Water Reactor Design Certification," dated October 15, 2014	79 FR 61944
Federal Register Notice – Final Rule, "Licenses, Certifications, and Approvals for Nuclear Power Plants," dated August 28, 2007	72 FR 49352
Federal Register Notice – Final Rule, "Licenses, Certifications, and Approvals for Nuclear Power Plants," Section 52.63, Finality of Standard Design Certifications, dated August 28, 2007	72 FR 49381
Revision of the Emergency Preparedness Regulations for Nuclear Power Reactors	
Federal Register Notice Final Rule, "Production and Utilization Facilities; Emergency Planning and Preparedness Exercise Requirements," dated June 14, 1996	61 FR 30129
SECY-06-0200, "Results of the Review of Emergency Preparedness Regulations and Guidance," dated September 20, 2006	ML061910707
SRM-SECY-14-0038, "Staff Requirements – SECY-14-0038 - Performance-Based Framework for Nuclear Power Plant Emergency Preparedness Oversight," dated August 2, 2015	ML14259A589
Federal Register Notice – Final Rule, "Emergency Preparedness for Small Modular Reactors and Other New Technologies," dated November 16, 2023	88 FR 80050
NUREG/CR-7285, "Nonradiological Health Consequences from Evacuation and Relocation," dated September 2021	ML21252A104
NUREG-0396, "Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants," dated December 1978	ML051390356
NUREG/CR-7160, "Emergency Preparedness Significance Quantification Process: Proof of Concept," dated June 2013	ML13164A285
NSIR-2017-002, "Analyses Informing Emergency Planning Zone Size Determinations: Identification of Parameter Sensitivities," dated December 2019	ML19338E460
SAND2022-3706, "Scoping Analysis of MACCS Modeling Improvements for the Study of Protective Action Recommendations, dated March 2022	ML22096A090
SAND2025-08913, "Dose Exceedance Distance Sensitivity Based on Parametric Uncertainty," dated July 2025	https://www.osti.gov/servlets/purl/2585516
EPA, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents," dated January 2017	https://www.epa.gov/sites/default/files/2017-01/documents/epa_pag_manual_final_revisions_01-11-2017_cover_disclaimer_8.pdf

IAEA Safety Standards in General Safety Requirements (GSR) No. 7, "Preparedness and Response for a Nuclear or Radiological Emergency"	https://www-pub.iaea.org/MTCD/Publications/PDF/P_1708_web.pdf
NUREG-0654/FEMA-REP-1, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants: Guidance for Protective Action Strategies," Revision 1, dated November 2011	ML113010596
NUREG/CR-7002, "Criteria for Development of Evacuation Time Estimate Studies," Revision 1, dated February 2021	ML21013A504
Optional Submittal of Operational Programs	
SECY-24-0008, "Micro-Reactor Licensing and Deployment Considerations: Fuel Loading and Operational Testing at a Factory," dated January 24, 2024	ML23207A252
NEI Letter to Mirela Gavrilas, "Regulation of Rapid High-Volume Deployable Reactors in Remote Applications (RHDRA) and Other Advanced Reactors," dated July 31, 2024	ML24213A337
NEI letter to Mike King, "Supplement to the NEI Proposal Paper "Regulation of Rapid High-Volume Deployable Reactors in Remote Applications (RHDRA) and Other Advanced Reactors," dated July 14, 2025	ML25195A307
SECY-25-0052, "Nth-of-a-Kind Microreactor Licensing and Deployment Considerations," dated June 18, 2025	ML24309A266
SRM-SECY-25-0052, "Staff Requirements – SECY-25-0052 – Nth-of-a-Kind Microreactor Licensing and Deployment Considerations," dated November 13, 2025	ML25317A650
Early Site Permit for Nuclear Power Plants	
NRC Webpage, "Early Site Permit Applications for New Reactors"	https://www.nrc.gov/reactors/new-reactors/large-lwr/esp
Federal Register Notice – Final Policy Statement, "Commission Policy Statement on Deferred Plants," dated October 14, 1987	52 FR 38077
Federal Register Notice – Final Rule, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors," dated April 18, 1989	54 FR 15372
NRC Letter, "Issuance of Early Site Permit for Exelon Generation Company, LLC (ESP-001)," dated March 15, 2007	ML070670140
NRC Letter, "Issuance of Early Site Permit (ESP) for System Energy Resources, Inc. - Grand Gulf ESP Site (ESP-002)," dated April 5, 2007	ML070780457
Dominion Nuclear North Anna, LLC.; North Anna ESP Site Docket No. 52-008; Early Site Permit, ESP Permit No. ESP-003, dated November 27, 2007	ML073180440
Southern Nuclear Operating Company Vogtle Electric Generating Plant ESP Site Docket No. 52-011; Early Site Permit And Limited Work Authorization; Early Site Permit No. ESP-004, dated August 26, 2009	ML092290157
PSEG Power, LLC and PSEG Nuclear, LLC PSEG Site Early Site Permit Docket No. 52-043; Early Site	ML16084A798

Permit Early Site Permit No. ESP-005, dated May 5, 2016	
Tennessee Valley Authority Clinch River Nuclear Site Early Site Permit Docket No. 52-047; Early Site Permit No. ESP-006, dated December 19, 2019	ML19352D868
Manufacturing License Term Extension	
Federal Register Notice – Final Rule, "Licenses, Certifications, and Approvals for Nuclear Power Plants," dated August 28, 2007	72 FR 49352
Federal Register Notice – Direct Final Rule, "Revising the Duration of Design Certifications," dated July 2, 2025	90 FR 28869
Nuclear Power Plant License Renewal	
Federal Register Notice – Final Rule, "Nuclear Power Plant License Renewal," dated December 13, 1991	56 FR 64943
Federal Register Notice – Final Rule, "Nuclear Power Plant License Renewal," Renewal Finding and Hearing Scope, dated December 13, 1991	56 FR 64960
Federal Register Notice – Final Rule, "Nuclear Power Plant License Renewal; Revisions," dated May 8, 1995	60 FR 22461
NUREG-2191, "Generic Aging Lessons Learned for Subsequent License Renewal (GALL-SLR) Report, Volume 1 and 2," dated July 2025	https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr2191/r1/index
NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants"	https://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1437/index
SECY-22-0109, "Proposed Rule: Renewing Nuclear Power Plant Operating Licenses—Environmental Review (RIN 3150-AK32; NRC-2018-0296)," dated December 6, 2022	ML22165A004
SRM-SECY-98-144, "Staff Requirements – SECY-98-144 – White Paper on Risk-Informed and Performance-Based Regulation," dated March 1, 1999	ML003753601
NRC Regulatory Issue Summary (RIS) 2007-16, Revision 1, "Implementation of the Requirements of 10 CFR 54.37(b) for Holders of Renewed Licenses," dated April 28, 2010	ML100250279
Resolution of Public Comments on Draft Regulatory Issue Summary (RIS) 2007-16, Revision 1, "Implementation of the Requirements of 10 CFR 54.37(b) for Holders of Renewed Licenses," dated March 29, 2010	ML100250316
Enhancing Flexibility of Reactor Site Criteria	
Federal Register Notice – Final Rule, "Risk-Informed, Technology-Inclusive Regulatory Framework for Advanced Reactors," dated March 30, 2026	91 FR 15696
Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors	
13th AEC Air Cleaning Conference, "Nuclear Power Plant Control Room Ventilation System Design for Meeting General Criterion 19," dated 1974	ML19116A064
ACRS Full Committee Brief, "RG 1.200, Revision 3," dated November 5, 2020	ML20293A488
Addendum to NUREG-1061, Vol. 2., "Summary and Evaluation of Historical Strong-Motion Earthquake	ML20117D247

Seismic Response and Damage to Above-Ground Industrial Piping," dated April 1985	
ANSI N14.1-2023, "Nuclear Materials – Uranium Hexafluoride - Packagings for Transport," dated 2023	https://webstore.ansi.org/standards/pcc/ansin142023?source=blog&_gl=1*q53tae*_gcl_au*MTg4MTY4MDQzLjE3MjM4MDk5NDI
ANSI/ANS-58.21-2007, "External Events in PRA Methodology," dated March 2007	https://webstore.ansi.org/standards/ansi/ansians58212007
ASME RA-S-1.1, "Standard for Level 1/Large Early Release Frequency Probabilistic Risk Assessment for Nuclear Power Plant Applications," dated 2024	https://www.asme.org/codes-standards/find-codes-standards/standard-for-level-1-large-early-release-frequency-probabilistic-risk-assessment-for-nuclear-power-plant-applications/2024/pdf
"Backgrounder on NRC Response to Lessons Learned from Fukushima," dated September 2018	https://www.nrc.gov/reading-rm/doc-collections/fact-sheets/japan-events.html
Commission Opinion Paper, "Rulemaking Hearing: Acceptance Criteria for Emergency Core Cooling Systems for Light-Water-Cooled Nuclear Power Reactors: Opinion of the Commission," dated December 28, 1973	ML20236U832
DOE Article, "New Railcar Designed to Transport Spent Nuclear Fuel Cleared for Operation," dated June 4, 2024	https://www.energy.gov/ne/articles/new-railcar-designed-transport-spent-nuclear-fuel-cleared-operation
EPA-400/R-17/001, "PAG Manual: Protective Action Guides and Planning Guidance for Radiological Incidents," dated January 2017	ML17044A073
EPA-402-R-93-081, Federal Guidance Report No. 12, "External Exposure to Radionuclides in Air, Water, and Soil," dated September 1993	https://www.epa.gov/sites/default/files/2015-05/documents/402-r-93-081.pdf
EPA-520/1-88-020, Federal Guidance Report No. 11, "Limiting Values of Radionuclide Intake and Air Concentration and Dose Conversion Factors for Inhalation, Submersion, and Ingestion," dated September 1988	https://www.epa.gov/sites/default/files/2015-05/documents/520-1-88-020.pdf
EPRI Technical Report (3002000709), "Seismic Probabilistic Risk Assessment Implementation Guide," dated December 2013	https://restservice.epri.com/publicdownload/000000003002000709/0/Product
EPRI's Topical Report Submittal for their Alternate Licensing Strategy Regarding Loss-of-Coolant Accident Induced Fuel Fragmentation, Relocation, and Dispersal, dated May 9, 2024	ML24121A203
Federal Register Notice – Final Rule, "Acceptance Criteria for Emergency Core Cooling Systems for Light Water-Cooled Nuclear Power Reactors," dated January 4, 1974	39 FR 1001
Federal Register Notice - Policy Statement, "Safety Goals for the Operations of Nuclear Power Plants," dated August 4, 1986	51 FR 28044
Federal Register Notice – Final Rule, "Changes, Tests, and Experiments," dated October 4, 1999	64 FR 53582
Federal Register Notice – Final Rule, "Compatibility with IAEA Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments," dated January 26, 2004	69 FR 3698
Federal Register Notice – Final Rule, "Criticality Accident Alarm Systems," dated November 5, 1974	39 FR 39020
Federal Register Notice – Final Rule, "Criticality Accident Requirements," dated November 12, 1998	63 FR 63127
Federal Register Notice – Direct Final Rule, "Criticality Control of Fuel Within Dry Storage	71 FR 66648

Casks or Transportation Packages in a Spent Fuel Pool," dated November 16, 2006	
Federal Register Notice – Final Rule, "Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Reactors," dated April 18, 1989	54 FR 15372
Federal Register Notice Final Rule, "Emergency Core Cooling Systems; Revisions to Acceptance Criteria," dated September 16, 1988	53 FR 35996
Federal Register Notice – Final rule, "General Design Criteria for Nuclear Power Plants," dated February 20, 1971	36 FR 3255
Federal Register Notice – Final Rule, "Modification of General Design Criterion 4 Requirements for Protection Against Dynamic Effects of Postulated Pipe Ruptures," dated October 27, 1987	52 FR 41288
Federal Register Notice – Final Rule, "Power Reactor Security Requirements," dated March 27, 2009	74 FR 13926
Federal Register Notice – Final Rule, "Reactor Site Criteria Including Seismic and Earthquake Engineering Criteria for Nuclear Power Plants," dated December 11, 1996	61 FR 65157
Federal Register Notice – Final Rule, "Standards for Protection Against Radiation," dated May 21, 1991	56 FR 23360
Federal Register Notice – Proposed Rule, "Emergency Core Cooling Systems; Revisions to Acceptance Criteria," dated March 3, 1987	52 FR 6334
Federal Register Notice – Proposed Rule, "General Design Criteria for Nuclear Power Plant Construction Permits," dated July 11, 1967	32 FR 10213
Federal Register Notice – Regulatory Basis, "Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors," dated September 8, 2023	88 FR 61986
Federal Register Notice – Final Policy Statement, "Use of Probabilistic Risk Assessment Methods in Nuclear Regulatory Activities; Final Policy Statement," dated August 16, 1995	60 FR 42622
Final Rulemaking Package, SECY-16-0033, "SECY-16-0033 Final Draft Rulemaking—10 CFR 50.46c: Emergency Core Cooling Systems Performance During Loss-of-Coolant Accidents," dated March 16, 2016	ML15238A947
GAO/RCED-99-95, "Nuclear Regulation: Strategy Needed to Regulate Safety Using Information on Risk," dated March 19, 1999	https://www.gao.gov/products/rced-99-95
IAEA STI/PUB/1710, "The Fukushima Daiichi Accident," dated 2015	https://www.iaea.org/publications/10962/the-fukushima-daiichi-accident
IAEA Portable Digital Assistant for First Responders to a Radiological Emergency, "Emergency worker turn-back dose guidance," dated 2024	https://www-pub.iaea.org/mtcd/publications/pdf/epr-first_res-pda/html/ti2-turn-back-dose.htm#ftn.10
ICRP Publication 109, "Application of the Commission's Recommendations for the Protection of People in Emergency Exposure Situations," dated 2009	https://www.icrp.org/publication.asp?id=ICRP%20Publication%20109
ICRP Publication 23, "Report of the Task Group on Reference Man," dated 1975	https://journals.sagepub.com/pb-assets/cmscontent/ANI/P_023_1975_Report_on_the_Task_Group_on_Reference_Man_rev0.pdf

ICRP Publication 26, "Recommendations of the ICRP," dated 1977	https://www.icrp.org/publication.asp?id=ICRP%20Publication%2026
Investigation Committee on the Accident at the Fukushima Nuclear Power Stations of Tokyo Electric Power Company, "Final Report," dated July 2012	http://www.cas.go.jp/jp/seisaku/icanps/eng/final-report.html
Management Directive 8.4, "Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests," dated September 20, 2019	ML18093B087
Memorandum from Arthur T. Howell to William F. Kane, "Degradation of the Davis-Besse Nuclear Power Station Reactor Pressure Vessel Head Lessons-Learned Report," dated September 30, 2002	ML022740211
Memorandum from D. H. Dorman to M. M. Doane, "Implementing Commission Direction on Applying Risk-Informed Principles in Regulatory Decision Making," dated November 18, 2019	ML19319C832
Ministry of Health, Labour and Welfare (Japan), "Responses and Actions Taken by the Ministry of Health, Labour and Welfare of Japan on Radiation Protection at Works Relating to the Accident at TEPCO's Fukushima Daiichi Nuclear Power Plant 7th Edition (Fiscal Year of 2019)," dated January 2020	https://www.mhlw.go.jp/english/topics/2011eq/workers/ri/gr/gr_200131.pdf
National Research Council Committee on the Biological Effects of Ionizing Radiation, "Health Effects of Exposure to Low Levels of Ionizing Radiation," dated 1990	https://www.ncbi.nlm.nih.gov/books/n/nap1224/pdf/
National Research Council of the National Academies, "Lessons Learned from the Fukushima Nuclear Accident for Improving Safety of U.S. Nuclear Plants," dated 2014	https://nap.nationalacademies.org/catalog/18294/lessons-learned-from-the-fukushima-nuclear-accident-for-improving-safety-of-us-nuclear-plants
NCRP Report No. 180, "Management of Exposure to Ionizing Radiation: Radiation Protection Guidance for the United States," dated 2018	https://ncrponline.org/shop/reports/report-no-180-management-of-exposure-to-ionizing-radiation-radiation-protection-guidance-for-the-united-states-2018-2018/
NEI 00-02, Revision 1, "Probabilistic Risk Assessment (PRA) Peer Review Process Guidance," dated May 2006	ML061510619
NEI 06-09, Revision 0, "Risk-Informed Technical Specifications Initiative 4b, Risk-Managed Technical Specifications (RMTS) Guidelines," dated November 2006	ML12286A322
NEI 06-12, Revision 2, "B.5.b Phases 2 & 3 Submittal Guideline," dated December 2006	ML070090060
NEI 12-06, Revision 4, "Diverse and Flexible Coping Strategies (FLEX) Implementation Guide," dated December 2016	ML16354B421
NEI 12-16 Revision 4, "Guidance for Performing Criticality Analyses of Fuel Storage at Light-Water Reactor Power Plants," dated September 2019	ML19269E069
NEI White Paper, "The Economic Benefits and Challenges with Utilizing Increased Enrichment and Fuel Burnup for Light-Water Reactors," dated February 2019	ML21259A191
NRC Generic Letter No. 88-01, "NRC Position on IGSCC in BWR Austenitic Stainless-Steel Piping," dated January 25, 1988	ML031130463

NRC Generic Letter No. 88-20, "Individual Plant Examination for Severe Accident Vulnerabilities - 10 CFR 50.54(f)," dated November 23, 1988	ML031470299
NRC Letter, "Request for Information Pursuant to Title 10 *Code of Federal Regulations* 50.54(f) Regarding Recommendation 2.1, 2.3 and 9.3 of the Near-Term Task Forces Review of Insights from the Fukushima Dai-Ichi Accident," dated March 12, 2012	ML12053A340
NRC Memoranda, "Questions and Answers from Eight Sets of Questions and Answers on the Major Revision of 10 CFR Part 20," dated June 15, 1994	ML12166A179
NRC Memoranda, "Update to Research Information on Cladding Embrittlement Criteria in 10 CFR 50.46," dated December 29, 2011	ML113050484
NRC Order EA-12-049, "Order Modifying Licenses with Regard to Requirements for Mitigation Strategies for Beyond-Design-Basis External Events (Effective Immediately)," dated March 12, 2012	ML12056A045
NRC Project Plan, Version 1.2, "Project Plan to Prepare the U.S. Nuclear Regulatory Commission for Efficient and Effective Licensing of Accident Tolerant Fuels," dated September 2021	ML21243A298
NRC Summary of Public Comments, "PR-050 – 52FR06334 – Emergency Core Cooling Systems: Revisions to Acceptance Criteria," dated March 3, 1987	ML23151A468
NRC White Paper, "White Paper on Continued Applicability of NUREG-1829," dated November 13, 2024	ML24205A015
NRC White Paper, "Draft White Paper: Statistical Approach to Optimizing a Performance Monitoring Program," dated September 26, 2023	ML23272A168
NRC White Paper, "White Paper on Continued Applicability of NUREG-1903," dated November 18, 2024	ML24323A205
NUREG/BR-0006, Revision 9, "Instructions for Completing Nuclear Material Transaction Reports," dated August 2020	ML20240A155
NUREG/BR-0007, Revision 8, "Instructions for the Preparation and Distribution of Material Status Reports," dated August 2020	ML20240A181
NUREG/CR-4792, Volume 1, Summary Report, "Probability of Failure in BWR Reactor Coolant Piping," dated December 1988	ML033450494
NUREG/CR-6674, "Fatigue Analysis of Components for 60-Year Plant Life," dated June 2000	ML003724215
NUREG/CR-6967, "Cladding Embrittlement during Postulated Loss-of-Coolant Accidents," July 2008	ML082130389
NUREG/CR-7009, "MACCS Best Practices as Applied in the State-of-the-Art Reactor Consequence Analyses (SOARCA) Project," dated August 2014	ML14234A148
NUREG/CR-7110, Volume 1, Revision 1, "State-of-the-Art Reactor Consequence Analyses Project: Peach Bottom Integrated Analysis," dated May 2013	ML13150A053
NUREG/CR-7219, "Cladding Behavior During Postulated Loss-of-Coolant Accidents," dated July 31, 2016	ML16211A004

NUREG/CR-7307, "Phenomena Identification and Ranking Tables on High Burnup Fuel Fragmentation, Relocation, Dispersal, and Its Consequences for Design-Basis Accidents in Pressurized- and Boiling-Water Reactors," dated May 2024	ML24155A058
NUREG/KM-0017, "Seismic Hazard Evaluations for U.S. Nuclear Power Plants: Near-Term Task Force Recommendation 2.1 Results," dated December 2021	ML21344A126
NUREG-0116, Supplement 1 to WASH-1248, "Environmental Survey of the Reprocessing and Waste Management Portions of the LWR Fuel Cycle: A Task Force Report," dated October 1976	ML14098A013
NUREG-0313, "Technical Report on Material Selection and Processing Guidelines for BWR Coolant Pressure Boundary Piping," dated January 1988	ML031470422
NUREG-0654/FEMA-REP-1, Revision 2, "Criteria for Preparation and Evaluation of Radiological Emergency Response Plans and Preparedness in Support of Nuclear Power Plants," dated December 2019	ML19347D139
NUREG-0713, Volume 43, "Occupational Radiation Exposure at Commercial Nuclear Power Reactors and Other Facilities 2021: 54th Annual Report," dated February 2024	ML24060A017
NUREG-0737, "Clarification of TMI Action Plan Requirements," dated November 1980	ML051400209
NUREG-0800, SRP Section 11.1, Revision 4, "Coolant Source Terms," dated January 2016	ML15029A022
NUREG-0933, "Resolution of Generic Safety Issues," dated September 2021	ML21251A113
NUREG-1150, Volume 1, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants," dated December 1990	ML120960691
NUREG-1430, Revision 5, Volume 1, Specifications, "Standard Technical Specifications – Babcock and Wilcox Plants," dated September 2021	ML21272A363
NUREG-1430, Revision 5, Volume 2, Bases, "Standard Technical Specifications – Babcock and Wilcox Plants," dated September 2021	ML21272A370
NUREG-1431, Revision 5, Volume 1, Specifications, "Standard Technical Specifications – Westinghouse Plants," dated September 2021	ML21259A155
NUREG-1431, Revision 5, Volume 2, Bases, "Standard Technical Specifications – Westinghouse Plants," dated September 2021	ML21259A159
NUREG-1432, Revision 5, Volume 1, Specifications, "Standard Technical Specifications – Combustion Engineering Plants," dated September 2021	ML21258A421
NUREG-1432, Revision 5, Volume 2, Bases, "Standard Technical Specifications – Combustion Engineering Plants," dated September 2021	ML21258A424
NUREG-1433, Revision 5, Volume 1, Specifications, "Standard Technical Specifications – General Electric Plants (BWR/4)," dated September 2021	ML21272A357
NUREG-1433, Revision 5, Volume 2, Bases, "Standard Technical Specifications – General Electric Plants (BWR/4)," dated September 2021	ML21272A358

NUREG-1434, Revision 5, Volume 1, Specifications, "Standard Technical Specifications – General Electric BWR/6 Plants," dated September 2021	ML21271A582
NUREG-1434, Revision 5, Volume 2, Bases, "Standard Technical Specifications – General Electric BWR/6 Plants," dated September 2021	ML21271A596
NUREG-1437, Revision 1, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants: Final Report," dated June 2013	ML13106A241
NUREG-1465, "Accident Source Terms for Light-Water Nuclear Power Plants," dated February 1995	ML041040063
NUREG-1488, "Revised Livermore Seismic Hazard Estimates for Sixty-Nine Nuclear Power Plant Sites East of the Rocky Mountains," dated April 1994	ML052640591
NUREG-1829, "Estimating Loss-of-Coolant Accident (LOCA) Frequencies through the Elicitation Process," dated April 2008	ML082250436
NUREG-1855, Revision 1, "Guidance on the Treatment of Uncertainties Associated with PRAs in Risk-Informed Decisionmaking," dated March 2017	ML17062A466
NUREG-1903, "Seismic Considerations for the Transition Break Size," dated February 2008	ML080880140
NUREG-2119, "Mechanical Behavior of Ballooned and Ruptured Cladding," dated February 2012	ML12048A475
NUREG-2121, "Fuel Fragmentation, Relocation, and Dispersal During the Loss-of-Coolant Accident," dated March 2012	ML12090A018
NUREG-2194, Revision 1, Volume 1, Specifications, "Standard Technical Specifications – Westinghouse Advanced Passive 1000 (AP1000) Plants," dated January 2024	ML24026A214
NUREG-2194, Revision 1, Volume 2, Bases, "Standard Technical Specifications – Westinghouse Advanced Passive 1000 (AP1000) Plants," dated January 2024	ML24026A234
NUREG-2266, Revision 0, "Environmental Evaluation of Accident Tolerant Fuels with Increased Enrichment and Higher Burnup Levels," dated July 2024	ML24207A210
WASH-1238, "Environmental Survey of Transportation of Radioactive Materials to and from Nuclear Power Plants," dated December 1972	ML14092A626
NUREG-75/038, Supplement 1 to WASH-1238, "Environmental Survey of Transportation of Radioactive Materials to and from Nuclear Power Plants," dated April 1975	ML14091A176
ORNL/TM-2024/3350, "Scoping Studies on the Impacts of Increased Enrichment on Nuclear Criticality Safety," dated May 2024	ML24163A016
Pacific Earthquake Engineering Research Center, PEER Report 2000/09, "Structural Engineering Reconnaissance of the August 17, 1999 Earthquake: Kocaeli (Izmit), Turkey," dated December 2000	https://peer.berkeley.edu/publications/2000-09
Presentation at the Japan Atomic Energy Agency's Fuel Safety Research Meeting, "Overview of Recent and Planned Halden Reactor Project LOCA Experiments," dated May 16-17, 2007	ML081370546
Public Meeting Announcement, "Notice of Public Meeting to Discuss the Regulatory Basis for	ML23278A141

Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors (RIN 3150-AK79; NRC-2020-0034)," dated October 25, 2023	
Public Meeting Announcement, "NRC's Annual Higher Burnup Workshop V on September 3, 2024," dated July 18, 2024	ML24243A162
Public Meeting Summary, "June 22, 2022, Summary of Public Meeting to Discuss the Proposed Rulemaking on Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors," dated July 21, 2022	ML22208A001
Public Meeting Summary, "October 25, 2023, Public Meeting: Regulatory Basis for Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors," dated November 21, 2023	ML23319A259
Regulatory Basis, "Increased Enrichment of Conventional and Accident Tolerant Fuel Design for Light-Water Reactors," dated September 2023	ML23032A504
RG 1.147, Revision 20, "Inservice Inspection Code Case Acceptability, ASME Section XI, Division 1," dated December 2021	ML21181A222
RG 1.157, "Best-Estimate Calculations of Emergency Core Cooling System Performance," dated May 1989	ML003739584
RG 1.174, Revision 3, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," dated January 2018	ML17317A256
RG 1.201, Revision 1, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to their Safety Significance," dated May 2006	ML061090627
RG 1.240, "Fresh and Spent Fuel Pool Criticality Analyses," dated March 2021	ML20356A127
RG 1.3, Revision 2, "Assumptions Used for Evaluating the Potential Radiological Consequences of a Loss of Coolant Accident for Boiling Water Reactors," dated June 1974	ML003739601
RG 1.4, Revision 2, "Assumptions Used for Evaluating the Potential Radiological Consequences of a Loss of Coolant Accident for Pressurized Water Reactors," dated June 1974	ML003739614
RG 8.29, Revision 1, "Instruction Concerning Risks from Occupational Radiation Exposure," dated February 1996	ML003739438
RIL 0801, "Technical Basis for Revision of Embrittlement Criteria in 10 CFR 50.46," dated May 30, 2008	ML081350225
RIL 2021-13, "Interpretation of Research on Fuel Fragmentation, Relocation, and Dispersal at High Burnup," dated December 2021	ML21313A145
SAND 2011-0128, "Accident Source Terms for Light-Water Nuclear Power Plants Using High-Burnup or MOX Fuel," dated January 1, 2011	ML20093F003
SAND 2023-01313, "High Burnup Fuel Source Term Accident Sequence Analysis," dated April 2023	ML23097A087
SECY-10-0161, "Final Rule: Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements	ML102210460

(10 CFR 50.46a) (RIN 3150-AH29)," dated December 10, 2010	
SECY-15-0148, "Evaluation of Fuel Fragmentation, Relocation and Dispersal Under Loss-of-Coolant Accident (LOCA) Conditions Relative to the Draft Final Rule on Emergency Core Cooling System Performance During a LOCA (50.46c)," dated November 30, 2015	ML15230A200
SECY-21-0109, "Rulemaking Plan on Use of Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors," dated December 20, 2021	ML21232A237
SECY-97-155, "Staff's Action Regarding Exemptions from 10 CFR 70.24 for Commercial Nuclear Power Plants," dated July 21, 1997	ML20211L130
SECY-R-143, "Amendment to 10 CFR 50—General Design Criteria for Nuclear Power Plants," dated January 28, 1971	ML072420278
SRM-SECY-07-0082, "Staff Requirements – SECY-07-0082 – Rulemaking to Make Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements; 10 CFR 50.46a, 'Alternative Acceptance Criteria for Emergency Core Cooling Systems for Light-Water Nuclear Power Reactors,'" dated August 10, 2007	ML072220595
SRM-SECY-10-0161, "Staff Requirements – SECY-10-0161 – Final Rule: Risk-Informed Changes to Loss-of-Coolant Accident Technical Requirements (10 CFR 50.46a) (RIN-3150-AH29)," dated April 26, 2012	ML12117A121
SRM-SECY-12-0081, "Staff Requirements – SECY-12-0081 – Risk-Informed Regulatory Framework for New Reactors," dated October 22, 2012	ML12296A158
SRM-SECY-16-0033, "Staff Requirements – SECY-16-0033 – Draft Final Rule – Performance-Based Emergency Core Cooling System Requirements and Related Fuel Cladding Acceptance Criteria," dated April 11, 2024	ML24102A281
SRM-SECY-21-0109, "Staff Requirements – SECY-21-0109 Rulemaking Plan on Use of Increased Enrichment of Conventional and Accident Tolerant Fuel Designs for Light-Water Reactors," dated March 16, 2022	ML22075A103
SRM-SECY-97-287, "Staff Requirements – SECY-98-287 – Final Regulatory Guidance On Risk-Informed Regulation: Policy Issues," dated March 19, 1998	ML003753490
SRM-SECY-98-015, "Staff Requirements – SECY-98-015 – Final General Reg Guide & Std Review Plan for Risk-Informed Regulation of Power Reactors," dated May 20, 1998	ML20248A848
SRM-SECY-98-144, "Staff Requirements – SECY-98-144 – White Paper on Risk-Informed and Performance-Based Regulation," dated March 1, 1999	ML003753601
Technical Report, "Method for Graded Risk-Informed Performance-Based Control Room Design Criteria Framework," dated September 2024	ML24150A080

TLR-RES/DE/REB-2021-09, "Probabilistic Leak-Before-Break Evaluation of Westinghouse Four-Loop Pressurized-Water Reactor Primary Coolant Loop Piping using the Extremely Low Probability of Rupture Code," dated August 13, 2021	ML21217A088
TLR-RES/DE/REB-2021-14, "Probabilistic Leak-Before-Break Evaluations of Pressurized-Water Reactor Piping Systems using the Extremely Low Probability of Rupture Code," dated September 28, 2021	ML21266A045
TSTF-18-07, Revision 2, "TSTF Comments on Draft Safety Evaluation for Traveler TSTF-505, 'Provide Risk-Informed Extended Completion Times' and Submittal of TSTF-505," dated July 2, 2018	ML18183A493
Other Documents	
Executive Order 12866, "Regulatory Planning and Review," October 4, 1993	58 FR 51735
Executive Order 14154, "Unleashing American Energy," January 29, 2025	90 FR 8353
Executive Order 14192, "Unleashing Prosperity Through Deregulation," February 6, 2025	90 FR 9065
Executive Order 14215, "Ensuring Accountability for All Agencies," February 24, 2025	90 FR 10447
Executive Order 14267, "Reducing Anti-Competitive Regulatory Barriers," April 15, 2025	90 FR 15629
Executive Order 14300, "Ordering the Reform of the Nuclear Regulatory Commission," May 29, 2025	90 FR 22587
Presidential Memorandum, "Plain Language in Government Writing," June 10, 1998	63 FR 31885

BILLING CODE 7590–01–C

The NRC prepared an unofficial redline strikeout version of the proposed changes to regulatory text that is intended to help the readeridentifythe changes. The NRC is providing the unofficial redline as a reader tool only, and this document is listed in the ''Availability of Documents'' section of this document. Comments on the rule text should be made in this proposed rule.

The NRC may post materials related to this document, including public comments, on the Federal rulemaking website at *https://www.regulations.gov* under Docket ID NRC–2025–0975. In addition, the Federal rulemaking website allows members of the public to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) navigate to the docket folder (NRC–2025–0975); (2) click the ''Subscribe'' link; and (3) enter an email address and click on the ''Subscribe'' link.

List of Subjects

10 CFR Part 2

Administrative practice and procedure, Antitrust, Byproduct material, Classified information, Confidential business information, Freedom of information, Environmental protection, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Penalties, Reporting and recordkeeping requirements, Sex discrimination, Source material, Special nuclear material, Waste treatment and disposal.

10 CFR Part 50

Administrative practice and procedure, Antitrust, Backfitting, Classified information, Criminal penalties, Education, Emergency planning, Fire prevention, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Penalties, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Whistleblowing.

10 CFR Part 51

Administrative practice and procedure, Environmental impact statements, Hazardous waste, Nuclear energy, Nuclear materials, Nuclear power plants and reactors, Reporting and recordkeeping requirements.

10 CFR Part 52

Administrative practice and procedure, Antitrust, Combined license, Early site permit, Emergency planning, Fees, Inspection, Issue finality, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Probabilistic risk assessment, Prototype, Reactor siting criteria, Redress of site, Penalties, Reporting and recordkeeping requirements, Standard design, Standard design certification.

10 CFR Part 53

Administrative practice and procedure, Antitrust, Backfitting, Construction permit, Combined license, Classified information, Criminal penalties, Early site permit, Emergency planning, Fees, Fire prevention, Fire protection, Inspection, Intergovernmental relations, Limited work authorization, Manufacturing license, Nuclear power plants and reactors, Operating license, Penalties, Prototype, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements, Standard design, Standard design certification, Training programs.

10 CFR Part 54

Administrative practice and procedure, Age-related degradation, Backfitting, Classified information,

Criminal penalties, Environmental protection, Nuclear power plants and reactors, Penalties, Radiation protection, Reporting and recordkeeping requirements.

10 CFR Part 71

Criminal penalties, Hazardous materials transportation, Intergovernmental relations, Nuclear materials, Packaging and containers, Penalties, Radioactive materials, Reporting and recordkeeping requirements.

10 CFR Part 100

Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is proposing to amend 10 CFR parts 2, 50, 51, 52, 53, 54, 71, and 100:

PART 2—AGENCY RULES OF PRACTICE AND PROCEDURE

■ 1. The authority citation for part 2 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 29, 53, 62, 63, 81, 102, 103, 104, 105, 161, 181, 182, 183, 184, 186, 189, 191, 234 (42 U.S.C. 2039, 2073, 2092, 2093, 2111, 2132, 2133, 2134, 2135, 2201, 2231, 2232, 2233, 2234, 2236, 2239, 2241, 2282); Energy Reorganization Act of 1974, secs. 201, 206 (42 U.S.C. 5841, 5846); Nuclear Waste Policy Act of 1982, secs. 114(f), 134, 135, 141 (42 U.S.C. 10134(f), 10154, 10155, 10161); Administrative Procedure Act (5 U.S.C. 552, 553, 554, 557, 558); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note. Section 2.205(j) also issued under Sec. 31001(s), Pub. L. 104–134, 110 Stat. 1321–373 (28 U.S.C. 2461 note).

§ 2.109 [Amended]

■ 2. In § 2.109, remove and reserve paragraph (c).

PART 50—DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

■ 3. The authority citation for part 50 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 102, 103, 104, 105, 108, 122, 147, 149, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; ADVANCE Act of 2024, sec. 301 (42 U.S.C. 2133 note).

■ 4. In § 50.2, add in alphabetical order the definitions ''*Beyond design basis event*'' and ''*Design basis event*'' to read as follows:

§ 50.2 Definitions.

* * * * *

Beyond design basis event means an initiating event with a frequency below the threshold for a design basis event, but greater than or equal to a threshold for credibility that provides an appropriate level of safety and is deemed acceptable by the NRC, or an event (other than a design basis event) that is specifically required by regulation to be considered in the licensing basis. This definition, along with the corresponding definition of ''design basis event,'' applies to applications submitted on or after [DATE 180 DAYS AFTER THE EFFECTIVE DATE OF FINAL RULE] for construction permits and operating licenses under this part, as well as for early site permits, standard design certifications, combined licenses, standard design approvals, and manufacturing licenses under part 52 of this chapter. Applicants for or holders of licenses, permits, standard design certifications, or standard design approvals under this part or part 52 of this chapter who are not subject to this requirement may propose to adopt this definition and the corresponding definition of ''design basis event'' by submitting a request for NRC approval in an application, through a license amendment request under § 50.90, or through the applicable change process under part 52 of this chapter.

* * * * *

Design basis event means an initiating event with a frequency greater than or equal to a determinate, data-backed threshold that provides an appropriate level of safety and is deemed acceptable by the NRC. This definition, along with the corresponding definition for ''beyond design basis event,'' applies to applications submitted on or after [DATE 180 DAYS AFTER THE EFFECTIVE DATE OF FINAL RULE] for construction permits and operating licenses under this part, as well as for early site permits, standard design certifications, combined licenses, standard design approvals, and manufacturing licenses under part 52 of this chapter. Applicants for or holders of licenses, permits, standard design certifications, or standard design approvals under this part or part 52 of this chapter who are not subject to this requirement may propose to adopt this definition and the corresponding definition of ''beyond design basis event'' by submitting a request for NRC approval in an application, through a license amendment request under § 50.90, or through the applicable change process under part 52 of this chapter.

* * * * *

■ 5. In § 50.4, add paragraph (b)(7)(iii) to read as follows:

§ 50.4 Written Communications.

* * * * *

(b) * * *

(7) * * *

(iii) A change to the Safety Analysis Report quality management system under § 50.54(a)(5) or § 50.55(f)(5), or a change to a licensee's NRC-accepted quality management system topical report under § 50.54(a)(5) or § 50.55(f)(5), must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility. If the communication is on paper, the signed original must be sent.

* * * * *

■ 6. In § 50.10, revise paragraphs (a) and (c), and add paragraph (h) to read as follows:

§ 50.10 License required; limited work authorization.

(a) *Definitions.* As used in this section, *construction* means the activities in paragraph (a)(1) of this section.

(1) Activities constituting construction are the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, or in-place assembly, erection, fabrication, or testing, which may impact the required functions of:

(i) Safety-related structures, systems, or components (SSCs) of a facility, as defined in § 50.2;

(ii) SSCs that perform safety-significant functions; and

(iii) SSCs necessary to comply with part 73 of this chapter.

(2) With respect to production or utilization facilities, other than testing facilities and nuclear power plants, required to be licensed under section 104a. or section 104c. of the Act, construction does not include the erection of buildings which will be used for activities other than operation of a facility and which may also be used to house a facility (*e.g.,* the construction of a college laboratory building with space for installation of a training reactor).

(3) Any activities that are determined to be outside the scope of those defined in § 50.10(a)(1) and that are undertaken by an applicant or on its behalf are entirely at the risk of the applicant and has no bearing on the issuance of a license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act.

* * * * *

(c) *Requirement for construction permit, early site permit authorizing limited work authorization activities, combined license, or limited work authorization.* Except as provided in paragraph (h) of this section, no person may begin the construction of a production or utilization facility on a site on which the facility is to be operated until that person has been issued either a construction permit under this part, a combined license under part 52 of this chapter, an early site permit authorizing the activities under paragraph (d) of this section, or a limited work authorization under paragraph (d) of this section.

* * * * *

(h) *Issuance of general license.* A general license is hereby issued to an applicant for a construction permit or combined license for a utilization facility under 10 CFR part 50 or 52 for construction activities on a site that is specified in the application, subject to the following conditions:

(1) The applicant has submitted and the Commission has docketed a construction permit or combined license application for a utilization facility under 10 CFR part 50 or 52 that meets the following criteria:

(i) The application references a reactor design for which the Commission issued an operating license or issued a combined license and made the finding under § 52.103(g) of this chapter and for which the Commission afforded generic finality under § 50.57(d) or § 52.97(d);

(ii) The operating license or combined license described in paragraph (h)(1)(i) of this section met the criteria for a categorical exclusion or resulted in a finding of no significant impact from an environmental assessment in accordance with part 51 of this chapter;

(iii) The application utilizing the general license includes a plan for redress of any adverse environmental impact from conduct of activities under the general license should such redress be necessary; and

(iv) The application must contain information demonstrating that the site characteristics are bounded by the site parameters postulated for the approval of generic finality.

(2) The applicant may perform construction only upon notification to the NRC Director of NRR using instructions in § 50.4 before the start of construction. The notice must state that all applicable permits, licenses, approvals, and other entitlements in connection with the proposed action have been obtained. The notice may be in the form of a letter, but must contain the applicant's name, address, and the name and means of contacting a person responsible for providing additional information concerning construction under this general license.

(3) All applicable Federal environmental consultations have been completed.

(4) The general license authorizes construction of those generic aspects of the design of the commercial nuclear plant for which the Commission afforded generic finality and does not authorize installation of the reactor vessel, the reactor coolant system, or associated reactivity control and heat removal systems;

(5) The applicant must allow for NRC inspections that the Commission deems necessary related to activities performed under the general license.

(6) Any activities undertaken by the applicant or on its behalf under the general license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act.

■ 7. In § 50.33, remove footnotes 1 and 2 and revise paragraph (g) to read as follows:

§ 50.33 Contents of applications; general information.

* * * * *

(g)(1) If the application is for an operating license or combined license for a nuclear power reactor, or if the application is for an early site permit and contains plans for coping with emergencies under § 52.17(b)(2)(ii) of this chapter, the applicant must coordinate radiological emergency preparedness activities with offsite organizations with responsibilities for coping with emergencies including State, local, and Tribal governmental agencies, as applicable. Specifically, the applicant must ensure that these response organizations are aware of the potential radiological consequences of the facility and have been consulted on appropriate protective measures including the extent of any emergency planning zone (EPZ) for implementing predetermined, prompt protective measures. The application must include information that describes the extent of the applicant's interaction with these response organizations. If the application is for an early site permit that, under § 52.17(b)(2)(i) of this chapter, proposes major features of the emergency plans describing the EPZ, then the description of the EPZ must meet the requirements of this paragraph (g)(1). Generally, the plume exposure pathway EPZ for nuclear power reactors shall consist of an area about 2 to 10 miles (3.2 to 16 km) in radius. For reactors with an authorized power level less than 300 MW thermal, the plume exposure pathway EPZ may be established at the site boundary. The need for and size of the EPZ may also be determined on a case-by-case basis as described in § 50.33(g)(2). The exact size and configuration of the EPZ surrounding a particular nuclear power reactor shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. Emergency plans must describe such actions as are appropriate to avoid or reduce dose within and beyond the EPZ or site boundary and to protect the ingestion pathway.

(2) For a case-by-case EPZ determination, the applicant or licensee must submit an analysis used to determine whether the criteria in § 50.33(g)(2)(i)(A) and (B) are met and, if they are met, the size of the plume exposure pathway EPZ.

(i) The plume exposure pathway EPZ is the area within which:

(A) Dose to an individual is projected to exceed 1 rem (10 mSv) total effective dose equivalent over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology; and

(B) Pre-determined, prompt protective measures are necessary.

(ii) [Reserved]

* * * * *

■ 8. In § 50.34,

■ a. Remove the text ''LOCA's'' wherever it appears, and add, in its place, the text ''LOCAs'';

■ b. Remove the text ''PWR's'' wherever it appears, and add, in its place, the text ''PWRs'';

■ c. Remove the text ''BWR's'' wherever it appears, and add, in its place, the text ''BWRs'';

■ d. Revise paragraphs (a)(1) introductory text, (a)(1)(ii)(D), (a)(7), (b)(6)(ii), (b)(6)(v), (b)(10), (b)(11), and footnotes 1, 3, 4, and 6;

■ e. Remove the last sentence of paragraphs (a)(4) and (b)(4);

■ f. Remove and reserve paragraph (a)(10);

■ g. In paragraph (a)(12), remove the phrase ''On or after January 10, 1997, stationary power'' and add in its place ''Power''.

■ h. Add paragraph (b)(14); and

■ i. Revise paragraph (f)(3)(ii).

The revisions and additions are to read as follows:

§ 50.34 Contents of applications; technical information.

(a) *Preliminary safety analysis report.* Each application for a construction permit shall include a preliminary safety analysis report. The minimum information [1] to be included shall consist of the following:

(1) Power reactor applicants for a construction permit shall comply with paragraph (a)(1)(ii) of this section. All other applicants for a construction permit shall comply with paragraph (a)(1)(i) of this section.

* * * * *

(ii) * * *

(D) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release [3] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(1) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [4] (0.25 Sv) total effective dose equivalent (TEDE).

(2) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE;

* * * * *

(7) A description of the quality assurance program or a quality management system to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Appendix B to this part, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth the requirements for quality assurance programs for nuclear power plants and fuel reprocessing plants. Appendix T to this part, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth streamlined requirements for quality assurance programs for nuclear power plants and fuel reprocessing plants that an eligible construction permit applicant may voluntarily use as an alternative to appendix B to this part. The description of the quality assurance program for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of appendix B will be satisfied or for eligible construction permit applications, the quality management system for a nuclear power plant or fuel reprocessing plant shall include discussions of how the applicable requirements of appendix T will be satisfied.

* * * * *

(10) [Reserved]

* * * * *

(b) * * *

(6) * * *

(ii) Managerial and administrative controls to be used to assure safe operation. Appendix B to this part, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth the requirements for such controls for nuclear power plants and fuel reprocessing plants. Appendix T to this part, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth streamlined requirements for such controls for nuclear power plants and fuel reprocessing plants that an eligible operating license applicant may voluntarily use as an alternative to appendix B to this part. The information on the controls to be used for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of appendix B to this part will be satisfied or, for eligible operating license applications, the quality management system for a nuclear power plant or fuel reprocessing plant shall include discussions of how the applicable requirements of appendix T to this part will be satisfied.

* * * * *

(v) Plans for coping with emergencies. The applicant must provide the offsite response organizations that are expected to respond in an emergency with the opportunity to provide input on the emergency plan before submitting it to the NRC. The application must contain any input on the emergency plan received from offsite response organizations.

* * * * *

(10) Power reactor applicants who apply for an operating license, as partial conformance to General Design Criterion 2 of appendix A to this part, shall comply with the earthquake engineering criteria of appendix S to this part.

(11) Power reactor applicants who apply for an operating license shall provide a description and safety assessment of the site and of the facility as in § 50.34(a)(1)(ii).

* * * * *

(14) An applicant may include in its application a request for generic finality, to generic aspects of the design under this part, such that information in the application, if approved by the NRC, is considered resolved in other proceedings where information approved for generic finality is referenced. An application for an operating license that requests generic finality must include applicable site parameters postulated for the design, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

* * * * *

(f) * * *

(3) * * *

(ii) Ensure that the quality assurance (QA) list required by Criterion II of appendix B and appendix T of 10 CFR part 50 includes all structures, systems, and components important to safety. (I.F.1)

* * * * *

[1] This paragraph specifies the minimum required technical information to be included in a preliminary safety analysis report, while §§ 50.35(a)(1) through (4), 50.40, and 50.50 specify required findings for issuance of a construction permit. The level of detail provided in a preliminary safety analysis report to satisfy the minimum technical information requirements in paragraph (a) of this section will be deemed sufficient if the provided information enables the Commission to make the findings for issuance of a construction permit in §§ 50.35(a)(1) through (4), 50.40, and 50.50. The applicant may provide information

required by this paragraph in the form of a discussion, with specific references, of similarities to and differences from, facilities of similar design for which applications have previously been filed with the Commission.

* * * * *

[3] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[4] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that such designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

* * * * *

[6] The fission product release assumed for these calculations should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

■ 9. Revise and republish § 50.46 to read as follows:

§ 50.46 Acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.

(a) Each boiling or pressurized light-water nuclear power reactor must be provided with an emergency core cooling system (ECCS) that is designed under requirements described in this paragraph.

(1) The requirements of this section or § 50.46a must be satisfied for:

(i) Holders of an operating license under this part authorized to operate on December 31, 2015;

(ii) Holders of an operating license under this part authorized to operate after December 31, 2015, and whose reactor design is demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015;

(iii) Holders of a construction permit issued under this part whose reactor design is demonstrated under § 50.46a(c)(2) to be similar to the design of reactors authorized to operate under this part on December 31, 2015;

(iv) Holders of a combined license, standard design approval, or manufacturing license under part 52 of this chapter whose reactor design is demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015;

(v) Applicants for a construction permit or operating license under this part whose reactor design is demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015; and

(vi) Applicants for a combined license, standard design approval, manufacturing license, or standard design certification (including such applicants after NRC issuance of a final standard design certification rule) under part 52 of this chapter whose reactor design is demonstrated under § 50.46a(c)(2) of this section to be similar to the designs of reactors authorized to operate under this part on December 31, 2015.

(2) The requirements of this section must be satisfied for:

(i) Holders of an operating license under this part that were authorized to operate after December 31, 2015, and whose reactor design is not demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015;

(ii) Holders of a construction permit issued under this part whose reactor design is not demonstrated under § 50.46a(c)(2) to be similar to the design of reactors authorized to operate under this part on December 31, 2015;

(iii) Holders of a combined license, standard design approval, or manufacturing license under part 52 of this chapter whose reactor design is not demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015;

(iv) Applicants for a construction permit or operating license under this part whose reactor design is not demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015; and

(v) Applicants for a combined license, standard design approval, manufacturing license, or standard design certification (including such applicants after NRC issuance of a final standard design certification rule) under part 52 of this chapter whose reactor design is not demonstrated under § 50.46a(c)(2) to be similar to the designs of reactors authorized to operate under this part on December 31, 2015.

(3) (i) The ECCS system must be designed so that its calculated cooling performance following postulated loss-of-coolant accidents (LOCAs) conforms to the criteria set forth in paragraph (b) of this section or § 50.46a(f). ECCS cooling performance must be calculated in accordance with an acceptable evaluation model and must be calculated for a number of postulated LOCAs of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated LOCAs are calculated. Except as provided in paragraph (a)(3)(ii) of this section, the evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a LOCA. Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated. This uncertainty must be accounted for, so that, when the calculated ECCS cooling performance is compared to the criteria set forth in paragraph (b) of this section or § 50.46a(f), as applicable, there is a high level of probability that the criteria would not be exceeded. Section II, ''Required Documentation,'' of appendix K to this part, sets forth the documentation requirements for each evaluation model. This section does not apply to a nuclear power reactor facility for which the certifications required under § 50.82(a)(1) or § 52.110(a) of this chapter have been submitted.

(ii) Alternatively, an ECCS evaluation model may be developed in conformance with the required and acceptable features of appendix K to this part, ''ECCS Evaluation Models.''

(4) The Director of Nuclear Reactor Regulation may impose restrictions on reactor operation if it is found that the submitted evaluations of ECCS cooling performance are not consistent with paragraphs (a)(3)(i) and (ii) of this section.

(5) (i) Each applicant for or holder of an operating license or construction permit issued under this part, applicant for a standard design certification under part 52 of this chapter (including an applicant after the Commission has adopted a final design certification regulation), or an applicant for or holder of a standard design approval, a combined license, or a manufacturing license issued under part 52 of this chapter, must estimate the effect of any change to or error in an acceptable evaluation model or in the application of such a model to determine if the change or error is significant. For this purpose, a significant change or error is one which results in a calculated peak

fuel cladding temperature different by more than 50 °F from the temperature calculated for the limiting transient using the last acceptable model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 °F.

(ii) For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the applicant or holder of a construction permit, operating license, combined license, or manufacturing license must report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission at least annually as specified in § 50.4 or § 52.3 of this chapter, as applicable. If the change or error is significant, the applicant or licensee must provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements. This schedule may be developed using an integrated scheduling system previously approved for the facility by the NRC. For those facilities not using an NRC-approved integrated scheduling system, a schedule will be established by the NRC within 60 days of receipt of the proposed schedule. Any change or error correction that results in a calculated ECCS performance that does not conform to the criteria set forth in paragraph (b) of this section is a reportable event as described in §§ 50.55(e), 50.72, and 50.73. The affected applicant or licensee must propose immediate steps to demonstrate compliance or bring plant design or operation into compliance with § 50.46 requirements.

(iii) For each change to or error discovered in an acceptable evaluation model or in the application of such a model that affects the temperature calculation, the applicant or holder of a standard design approval or the applicant for a standard design certification (including an applicant after the Commission has adopted a final design certification rule) must report the nature of the change or error and its estimated effect on the limiting ECCS analysis to the Commission and to any applicant or licensee referencing the standard design approval or standard design certification at least annually as specified in § 52.3 of this chapter. If the change or error is significant, the applicant or holder of the standard design approval or the applicant for the standard design certification must provide this report within 30 days and include with the report a proposed schedule for providing a reanalysis or taking other action as may be needed to show compliance with § 50.46 requirements. The affected applicant or holder must propose immediate steps to demonstrate compliance or bring plant design into compliance with § 50.46 requirements.

(iv) For entities that are approved to use § 50.46a(f) instead of paragraph (b) of this section, changes or errors discovered in an acceptable evaluation model should be reported in accordance with § 50.46a(j)(1) and (2).

(b) The ECCS system of each boiling or pressurized light-water nuclear power reactor fueled with uranium oxide pellets within cylindrical zircaloy or ZIRLO cladding must be designed so that its calculated cooling performance following postulated LOCAs conforms to the following criteria:

(1) *Peak cladding temperature.* The calculated maximum fuel element cladding temperature must not exceed 2200 °F.

(2) *Maximum cladding oxidation.* The calculated total oxidation of the cladding may nowhere exceed 0.17 times the total cladding thickness before oxidation. As used in this subparagraph total oxidation means the total thickness of cladding metal that would be locally converted to oxide if all the oxygen absorbed by and reacted with the cladding locally were converted to stoichiometric zirconium dioxide. If cladding rupture is calculated to occur, the inside surfaces of the cladding must be included in the oxidation, beginning at the calculated time of rupture. Cladding thickness before oxidation means the radial distance from inside to outside the cladding, after any calculated rupture or swelling has occurred but before significant oxidation. Where the calculated conditions of transient pressure and temperature lead to a prediction of cladding swelling, with or without cladding rupture, the unoxidized cladding thickness must be defined as the cladding cross-sectional area, taken at a horizontal plane at the elevation of the rupture, if it occurs, or at the elevation of the highest cladding temperature if no rupture is calculated to occur, divided by the average circumference at that elevation. For ruptured cladding, the circumference does not include the rupture opening.

(3) *Maximum hydrogen generation.* The calculated total amount of hydrogen generated from the chemical reaction of the cladding with water or steam must not exceed 0.01 times the hypothetical amount that would be generated if all of the metal in the cladding cylinders surrounding the fuel, excluding the cladding surrounding the plenum volume, were to react.

(4) *Coolable geometry.* Calculated changes in core geometry must be such that the core remains amenable to cooling.

(5) *Long-term cooling.* After any calculated successful initial operation of the ECCS, the calculated core temperature must be maintained at an acceptably low value and decay heat must be removed for the extended period of time required by the long-lived radioactivity remaining in the core.

(c) As used in this section:

(1) LOCAs are hypothetical accidents that would result from the loss of reactor coolant, at a rate in excess of the capability of the reactor coolant makeup system, from breaks in pipes in the reactor coolant pressure boundary up to and including a break equivalent in size to the double-ended rupture of the largest pipe in the reactor coolant system.

(2) An evaluation model is the calculational framework for evaluating the behavior of the reactor system during a postulated LOCA. It includes one or more computer programs and all other information necessary for application of the calculational framework to a specific LOCA, such as mathematical models used, assumptions included in the programs, procedure for treating the program input and output information, specification of those portions of analysis not included in computer programs, values of parameters, and all other information necessary to specify the calculational procedure.

(d) The requirements of this section are in addition to any other requirements applicable to ECCS set forth in this part. The criteria set forth in paragraph (b) of this section, with cooling performance calculated in accordance with an acceptable evaluation model, are in implementation of the general requirements with respect to ECCS cooling performance design set forth in this part, including, in particular, criterion 35 of appendix A to this part.

■ 10. Revise § 50.46a to read as follows:

§ 50.46a Alternative acceptance criteria for emergency core cooling systems for light-water nuclear power reactors.

(a) *Definitions.* For the purposes of this section:

(1) *Changes enabled by this section* means changes to the facility, technical specifications, and procedures that satisfy the alternative ECCS analysis requirements under this section but do

not satisfy the ECCS requirements under § 50.46.

(2) *Cladding* means the material structure surrounding and containing the fissile material and providing a barrier to prevent fission product transport or release to the coolant.

(3) *Crud* means any foreign substance deposited on the surface of fuel cladding.

(4) *Entity* means an applicant for or a holder of a construction permit, operating license, combined license, standard design approval, or manufacturing license, or an applicant for a standard design certification (including such applicant after NRC issuance of a final standard design certification rule).

(5) *ECCS evaluation model* means the calculational framework for evaluating the behavior of the light-water reactor system (including fuel) during a postulated loss-of-coolant accident (LOCA). It includes one or more computer programs and all other information necessary for application of the calculational framework to a specific LOCA, such as mathematical models used, assumptions included in the programs, procedure for treating the program input and output information, specification of those portions of analysis not included in computer programs, values of parameters, and all other information necessary to specify the calculational procedure.

(6) *Loss-of-coolant accidents (LOCAs)* means the hypothetical accidents that would result from the loss of reactor coolant, at a rate in excess of the capability of the reactor coolant makeup system, from breaks in pipes in the reactor coolant pressure boundary up to and including a break equivalent in size to the double-ended rupture of the largest pipe in the reactor coolant system. LOCAs involving breaks at or below the transition break size are design basis accidents. LOCAs involving breaks larger than the transition break size are beyond-design-basis accidents.

(7) *Operating configuration* means those plant characteristics, such as power level, equipment unavailability (including unavailability caused by corrective and preventive maintenance), and equipment capability that affect plant response to a LOCA.

(8) *Quench* means the rapid cooling of the fuel cladding by liquid coolant water.

(9) *Transition break size (TBS)* for reactors authorized to operate under this part on December 31, 2015, is a break area equal to the largest cross-sectional flow area of the reactor coolant pressure boundary piping excluding the hot leg, cold leg, or crossover leg piping for a pressurized water reactor; the larger cross-sectional flow area of either the feedwater line or residual heat removal line inside containment for a boiling water reactor; or a plant-specific alternative break area. For reactors that are authorized to operate under this part after December 31, 2015, and for light-water reactors (LWRs) that are authorized to operate under part 52 of this chapter, the TBS will be determined on a plant-specific basis.

(b) *Applicability and scope.*

(1) Those entities listed in subparagraphs (i) through (vi) of this paragraph may apply under paragraph (c) of this section to use the requirements of this section. This section does not apply to a nuclear power reactor facility for which the certifications required under § 50.82(a)(1) or § 52.110(a) of this chapter have been submitted.

(i) Holders of an operating license under this part authorized to operate on December 31, 2015;

(ii) Holders of an operating license under this part authorized to operate after December 31, 2015, and whose reactor design is demonstrated under paragraph (c)(2) of this section to be similar to the designs of reactors authorized to operate under this part on December 31, 2015;

(iii) Holders of a construction permit issued under this part whose reactor design is demonstrated under paragraph (c)(2) of this section to be similar to the design of reactors authorized to operate under this part on December 31, 2015.

(iv) Holders of a combined license, standard design approval, or manufacturing license under part 52 of this chapter whose reactor design is demonstrated under paragraph (c)(2) of this section to be similar to the designs of reactors authorized to operate under this part on December 31, 2015.

(v) Applicants for a construction permit or operating license under this part whose reactor design is demonstrated under paragraph (c)(2) of this section to be similar to the designs of reactors authorized to operate under this part on December 31, 2015.

(vi) Applicants for a combined license, standard design approval, manufacturing license, or standard design certification (including such applicants after NRC issuance of a final standard design certification rule) under part 52 of this chapter whose reactor design is demonstrated under paragraph (c)(2) of this section to be similar to the designs of reactors authorized to operate under this part on December 31, 2015.

(2) The requirements of this section are in addition to any other requirements applicable to ECCS, with the exception of § 50.46. The criteria set forth in paragraph (e)(1) of this section, with cooling performance calculated in accordance with an acceptable evaluation model or analysis method under paragraphs (e)(2) and (3) of this section, are in implementation of the general requirements with respect to ECCS cooling performance design set forth in this part, including, in particular, criterion 35 of appendix A to this part.

(3) A licensee must inspect, under § 50.55a(g), for those reactor coolant pressure boundary piping whose inner diameter is greater than the TBS, an NRC-approved sampling of the similar metal piping circumferential welds in a PWR and the circumferential welds in a BWR that are classified as Category A welds before implementation of this section and in every subsequent in-service inspection interval (as defined in § 50.55a(y)). The sampling must include those circumferential welds with the highest failure potential. Credit may be taken for welds inspected as part of established inspection programs (*e.g.,* risk-informed inservice inspection programs). The effect on the TBS of any degradation identified during these inspections must be evaluated.

(c) *Application.*

(1) An entity seeking to implement this section must submit an application under § 50.34, 50.90, or part 52 of this chapter, as applicable, that contains the following information:

(i) A written evaluation demonstrating applicability of the TBS to the entity's facility or a proposed alternative TBS and a justification that the proposed TBS is consistent with the technical basis for this section. The effects of the initial plant changes proposed in the application must be considered as part of this evaluation.

(ii) As applicable, an inspection report that details the results of the inspection requirements in paragraph (b)(3) of this section and the evaluation of the impact of these results on the TBS.

(iii) Identification of the acceptable analysis method(s) for demonstrating compliance with the ECCS criteria in paragraph (e) of this section.

(iv) A description of the risk-informed evaluation used to demonstrate that the proposed changes to the facility meet the requirements in paragraph (h) of this section.

(v) For an entity other than a design certification applicant or a holder of a manufacturing license that wishes to make changes enabled by this section without prior NRC review and approval, a process to be used for evaluating the

acceptability of these changes, including:

(A) A description of the approach, methods, and decision-making process to be used for evaluating compliance with the acceptance criteria in paragraphs (h)(1), (2), and (3) of this section;

(B) A description of the probabilistic risk assessment (PRA) model and/or non-PRA risk assessment methods to be used for demonstrating compliance with paragraphs (h)(4) and (5) of this section; and

(C) A description of the approach, methods, and decision-making process to be used to evaluate the continued applicability of the TBS with the acceptance criteria used in the evaluation from paragraph (c)(1)(i) of this section for plants authorized to operate under this part on December 31, 2015, or from paragraph (c)(2) of this section for entities other than those authorized to operate under this part on December 31, 2015.

(vi) A description of non-safety equipment that is credited for demonstrating compliance with the ECCS acceptance criteria in paragraph (e) of this section.

(vii) A written evaluation demonstrating how the leak detection program in place at the facility satisfies the criteria in paragraph (d)(2) of this section.

(2) Each applicant, other than one authorized to operate under this part on December 31, 2015, seeking to implement the requirements of this section must submit, in addition to the information required by paragraphs (c)(1)(ii) through (vii) of this section, an analysis demonstrating why the proposed reactor design is similar to the designs of reactors authorized to operate under this part on December 31, 2015, such that the provisions of this section may properly apply. The analysis must also include a proposed TBS and a justification that the proposed TBS is consistent with the technical basis for this section. The effects of the initial plant changes proposed in the application must be considered as part of this evaluation.

(3) The NRC may approve an application to use this section if:

(i) The evaluation submitted under paragraph (c)(1)(i) of this section demonstrates the applicability of the TBS to the facility for reactors authorized to operate under this part on December 31, 2015;

(ii) The method(s) for demonstrating compliance with the ECCS acceptance criteria in paragraph (e)(1) of this section meet the requirements in paragraphs (e)(2) and (3) of this section;

(iii) The risk-informed evaluation used to make changes under this section is adequate for determining whether the acceptance criteria in paragraph (h) of this section have been met;

(iv) If applicable, the risk-informed evaluation process proposed for use to make changes under paragraph (h)(1) of this section is adequate for determining whether the acceptance criteria in paragraph (h) of this section have been met;

(v) For each reactor not authorized to operate on December 31, 2015, the evaluation submitted under paragraph (c)(2) of this section demonstrates that the reactor design is similar to the designs of reactors authorized to operate under this part on December 31, 2015, and the applicant demonstrates that its proposed TBS applies to its facility; and

(vi) The applicable standards and requirements of the Act and the Commission's regulations have been met.

(d) *Programmatic requirements.* An entity whose application under paragraph (c) of this section is approved by the NRC must comply with the following requirements as long as the entity is subject to the requirements in this section:

(1) The entity must maintain the ECCS evaluation models meeting the requirements in paragraphs (e)(1), (2), and (3) of this section after implementing any error corrections and changes;

(2) The entity must have leak detection systems available at the facility and must implement actions during operation as necessary to identify, monitor, and quantify leakage to ensure that adverse safety consequences do not result from leaking primary pressure boundary components that are larger than the TBS;

(3) Changes made under this section must, in addition to meeting other applicable NRC requirements, be evaluated by a risk-informed evaluation demonstrating that the acceptance criteria in paragraph (h) of this section are met;

(4) The entity must perform an evaluation to determine the effect of all planned facility changes and must not implement any facility change that would significantly increase LOCA frequencies or invalidate the evaluation demonstrating the applicability of the TBS performed pursuant to paragraph (c)(1)(i) of this section for an operating reactor licensee authorized to operate under this part on December 31, 2015, or the evaluation used to determine the plant-specific TBS performed pursuant to paragraph (c)(2) of this section for entities other than those authorized to operate under this part on December 31, 2015; and

(5) During operation, the licensees must perform the inspections prescribed in paragraph (b)(3) of this section during every subsequent inservice inspection interval (as defined in § 50.55a(y)) on the same samples inspected to satisfy paragraph (b)(3) of this section. The effect on the TBS of any additional degradation identified since the previous inspection must be evaluated.

(e) *ECCS Performance.*

(1) *Alternative ECCS acceptance criteria.* For each entity approved by the NRC to use this section, its reactor must be provided with an ECCS designed to satisfy the acceptance criteria in this paragraph in the event of, and following, a postulated LOCA. The demonstration of ECCS performance must comply with paragraph (e)(2) of this section for breaks at or below the TBS and paragraph (e)(3) of this section for breaks above the TBS.

(i) The ECCS provides sufficient coolant so that the fuel remains in a coolable geometry during and following the LOCA heatup and quench.

(ii) The ECCS provides sufficient coolant so that decay heat will be removed for the extended period of time required by the long-lived radioactivity remaining in the fuel.

(2) *ECCS evaluation performance demonstration for LOCAs involving breaks at or below the TBS.* ECCS cooling performance at or below the TBS must be calculated in accordance with an evaluation model that meets the requirements of either section I to appendix K to this part, or for realistic evaluation models, the following requirements.

(i) The evaluation model must be used for a number of postulated LOCAs of different sizes, locations (including LOCAs in piping systems with an inner diameter that is larger than the TBS), and other properties sufficient to provide assurance that the most severe postulated LOCAs involving breaks at or below the TBS are analyzed.

(ii) The evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a LOCA. Comparisons to applicable experimental data must be made and uncertainties in the analysis method and inputs must be identified and assessed so that the uncertainty in the calculated results can be estimated. This uncertainty must be accounted for, so that when the calculated ECCS cooling performance is compared to the ECCS performance criteria set forth in paragraph (e)(1) of this section and

addresses the fuel system acceptance criteria and modeling requirements in paragraph (f) of this section, there is a high level of probability that the criteria would be met.

(iii) The ECCS evaluation model must address changes in fuel geometry.

(3) *ECCS performance demonstration for LOCAs involving breaks larger than the TBS.* ECCS cooling performance for LOCAs involving breaks larger than the TBS must be calculated in accordance with an evaluation model that meets the requirements of either section I to appendix K to this part or, for realistic evaluation models, the following requirements. These calculations may take credit for the availability of offsite power and do not require the assumption of a single failure. Availability of safety-related or non-safety-related equipment may be assumed if supported by plant-specific data or analysis, and provided that onsite power can be readily provided through simple manual actions to equipment that is credited in the analysis.

(i) The evaluation model must be used for a number of postulated LOCAs of different sizes, locations, and other properties sufficient to provide assurance that the most severe postulated LOCAs larger than the TBS up to the double-ended rupture of the largest pipe in the reactor coolant system are analyzed.

(ii) The evaluation model must include sufficient supporting justification to show that the analytical technique realistically describes the behavior of the reactor system during a LOCA. Comparisons to applicable experimental data must be made so that there is assurance to at least a best-estimate level that the calculated ECCS cooling performance meets the ECCS performance criteria set forth in paragraph (e)(1) of this section and addresses the fuel system acceptance criteria and modeling requirements in paragraph (f) of this section.

(iii) The ECCS evaluation model must address changes in fuel geometry.

(4) *Required documentation.* The documentation requirements of this paragraph supersede the requirements in section II, ''Required Documentation,'' of appendix K to this part for those entities that are approved to use this section.

(i) (A) A description of the ECCS evaluation model must be submitted to the NRC. The description must be sufficiently complete to permit technical review of the analytical approach, including the equations used, their approximations in difference form, the assumptions made, and the values of all parameters or the procedure for their selection.

(B) A detailed source code of each computer program, in the same form as used in the ECCS evaluation model, must be provided to the NRC upon request.

(ii) For each computer program, solution convergence must be demonstrated by studies of system modeling, noding and calculational time steps, or both.

(iii) Appropriate sensitivity studies must be performed for each ECCS evaluation model to evaluate the effect on the calculated results of variations in noding, phenomena assumed in the calculation to predominate, including pump operation or locking, and values of parameters over their applicable ranges. For items to which results are shown to be sensitive, the choices made must be justified.

(iv) To the extent practicable, predictions of the ECCS evaluation model, or portions thereof, must be compared with applicable experimental information. The technical adequacy of the calculational methods used in the ECCS evaluation models must be documented. For realistic evaluation models, the documentation must demonstrate that the performance criteria of paragraphs (e)(1) and (f) of this section are met. For appendix K models, this documentation must demonstrate compliance with required features of section I of appendix K to this part and must demonstrate that the performance criteria of paragraphs (e)(1) and (f) of this section are met.

(v) The Director of the Office of Nuclear Reactor Regulation may impose restrictions on reactor operation if the NRC finds that the submitted evaluations of ECCS cooling performance are not consistent with paragraph (e) of this section.

(f) *Fuel performance criteria.* Fuel system designs must have NRC-approved limits that:

(1) Address cladding degradation phenomena;

(2) Maintain fuel coolability;

(3) Avoid explosive concentration of combustible gas; and

(4) Demonstrate that, after any calculated successful initial operation of the ECCS, the ECCS must provide sufficient coolant to remove decay heat and prevent further cladding failure for the extended period of time required by the long-lived radioactivity remaining in the fuel.

(g) *Use of NRC-approved fuel in reactor.*

(1) *Fuel load.* A licensee that is approved to use this section may not load fuel into a reactor unless the resulting core design satisfies the ECCS performance requirements of paragraph (e) of this section and the fuel system acceptance criteria and modeling requirements in paragraph (f) of this section, or otherwise complies with technical specifications governing lead test assemblies in its license.

(2) *Operation.* If a licensee that is approved to use this section determines that fuel in the reactor no longer complies with the ECCS performance requirements of paragraph (e) of this section and the fuel system acceptance criteria and modeling requirements in paragraph (f) of this section, then the licensee must take immediate action to come into compliance with paragraph (e) or (f) of this section, as applicable.

(h) *Changes to facility, technical specifications, or procedures.* An entity that wishes to make changes enabled by this section must perform a risk-informed evaluation.

(1) An entity other than a design certification applicant or holder of a manufacturing license may make changes enabled by this section, other than changes to the technical specifications, without prior NRC approval if:

(i) The change is permitted under § 50.59 for holders of operating licenses, combined licenses that do not reference a standard design certification or standard design approval, or manufacturing license (under § 52.98(b) of this chapter), or combined licenses that reference a standard design approval; or permitted under § 52.98(c) of this chapter for holders of combined licenses that reference a standard design certification; or permitted under § 52.98(d) of this chapter for holders of combined licenses that reference a manufacturing license;

(ii) The risk-informed evaluation process approved in accordance with paragraph (c)(1)(v) of this section demonstrates that any increases in the estimated risk are minimal and the criteria in paragraph (h)(3) of this section are met; and

(iii) The change does not significantly increase LOCA frequencies or invalidate the evaluation demonstrating the applicability of the TBS to the applicant's facility, performed pursuant to paragraph (c)(1)(i) of this section for an operating reactor licensee authorized to operate under this part on December 31, 2015, or the evaluation used to establish the plant-specific TBS, performed pursuant to paragraph (c)(2) of this section for entities other than those authorized to operate under this part on December 31, 2015.

(2) For implementing changes that are not permitted under paragraph (h)(1) of

this section, the entity must submit an application containing the following:

(i) For reactor licensees, the information required under § 50.90;

(ii) Information from the risk-informed evaluation demonstrating that the total increases in core damage frequency and large early release frequency are very small, the overall risk remains small, and the criteria in paragraph (h)(3) of this section are met;

(iii) If previous changes have been made under this section, information from the risk-informed evaluation on the cumulative effect on risk of the proposed change and all previous changes made under this section. If more than one plant change is combined, including plant changes not enabled by this section, into a group for the purposes of evaluating acceptable risk increases, then the evaluation of each individual change must be performed along with the evaluation of combined changes;

(iv) Information demonstrating that the criteria in paragraph (e) of this section are met; and

(v) Information demonstrating that the proposed change will not significantly increase the LOCA frequencies or invalidate the evaluation demonstrating the applicability of the TBS to the entity's facility, performed pursuant to paragraph (c)(1)(i) of this section for an operating reactor licensee authorized to operate under this part on December 31, 2015, or the evaluation used to establish the plant-specific TBS, performed pursuant to paragraph (c)(2) of this section for entities other than those authorized to operate under this part on December 31, 2015.

(3) All changes made under this section must meet the following criteria:

(i) Adequate defense-in-depth is maintained;

(ii) Adequate safety margins are retained to account for uncertainties; and

(iii) Adequate performance-measurement programs are implemented to ensure the risk-informed evaluation continues to reflect actual plant design and operation. These programs must be designed to detect degradation of the system, structure, or component before plant safety is compromised, provide feedback of information and timely corrective actions, and monitor systems, structures, or components at a level commensurate with their safety significance.

(4) Whenever a PRA is used in the risk-informed evaluation, the PRA must, with respect to the area of evaluation that is the subject of the PRA:

(i) Address initiating events from sources both internal and external to the plant and for all modes of operation, that would affect the regulatory decision in a substantial manner;

(ii) Reasonably represent the current configuration and operating practices at the plant;

(iii) Have sufficient technical acceptability (including consideration of uncertainty) and level of detail to provide confidence that the total risk estimates and the change in total risk estimates adequately reflect the plant and the effect of the proposed change on risk; and

(iv) Be determined, through peer review, to meet industry standards for PRA acceptability that have been endorsed or otherwise found acceptable by the NRC.

(5) Whenever risk assessment methods other than PRAs are used to develop quantitative or qualitative estimates of changes to risk in the risk-informed evaluation, an integrated and systematic process must be used. All aspects of the analyses must reasonably reflect the current plant configuration and operating practices and applicable plant and industry operating experience.

(i) *Authority to impose restrictions on operation.*

The Director of the Office of Nuclear Reactor Regulation may impose restrictions on reactor operation if the NRC finds that the submitted evaluations of ECCS cooling performance are not consistent with the requirements of this section.

(j) *Reporting.* Each entity subject to the requirements of this section must comply with the requirements of this paragraph.

(1) *ECCS evaluation model: reporting.*

(i) If the applicant for or holder of a construction permit, operating license, combined license, or manufacturing license identifies any change to, or error in, an ECCS evaluation model, or the application of such a model, that does not result in any predicted response that exceeds any of the acceptance criteria specified in this section and is itself not significant as defined in paragraph (k) of this section, then each of these entities must prepare a report describing each such change or error, its estimated effect on predicted response, and the basis for the entity's determination that the change or error is not significant. This entity must submit the report to the NRC, as specified in § 50.4 or § 52.3 of this chapter, at least annually.

(ii) If the applicant for or holder of a construction permit, operating license, combined license, or manufacturing license identifies any change to, or error in, an ECCS evaluation model, or the application of such a model, that does not result in any predicted response that exceeds any of the acceptance criteria specified in this section but is significant as defined in paragraph (k) of this section, then each of these entities must prepare a report describing each such change or error, its estimated effect on predicted response, proposed corrective actions, and a proposed scope and schedule for providing a reanalysis and for implementing the corrective actions. This entity must submit the report to the NRC, as specified in § 50.4 or § 52.3 of this chapter, within 60 days of the change or discovery of the error.

(iii) If an applicant for a standard design certification (including an applicant after the Commission has adopted a final design certification regulation) or an applicant for or holder of a standard design approval under part 52 of this chapter identifies any change to, or error in, an ECCS evaluation model, or the application of such a model, that does not result in any predicted response that exceeds any of the acceptance criteria specified in this section but is significant as defined in paragraph (k) of this section, then each of these entities must document the nature of the change or error and its estimated effect on the limiting ECCS analysis.

(iv) If a licensee identifies any change to, or error in, an ECCS evaluation model or the application of such a model, that results in any of the ECCS acceptance criteria specified in this section to be exceeded at the facility, then the licensee must submit a report describing each such change or error, its estimated effect on predicted response, proposed corrective actions, and a proposed scope and schedule for providing a reanalysis and for implementing the corrective actions. The licensee must submit the report to the NRC, as specified in § 50.4 or § 52.3 of this chapter, within 60 days of the change or discovery of the error. The report required by this paragraph is in addition to any reporting required by § 50.72.

(2) *ECCS evaluation model: corrective action.*

(i) If a licensee identifies any change to, or error in, an ECCS evaluation model or the application of such a model, that results in any of the acceptance criteria specified in this section to be exceeded at the facility, then the licensee (in the case of a combined license under part 52 of this chapter, after the Commission has made the finding under § 52.103(g) of this chapter) must take immediate action to bring the facility into compliance with

the acceptance criteria. In addition, the corrective action as described in the report required by paragraph (j)(1) of this section must be implemented.

(ii) If a standard design certification applicant (including an applicant after the Commission has adopted a final design certification regulation) is required by paragraph (j)(1)(iv) of this section to submit a reanalysis, or identifies a change to, or error in an ECCS evaluation model, or in the application of such a model, that results in any predicted response that exceeds any of the acceptance criteria specified in this section, then the standard design certification applicant (including an applicant after the Commission has adopted a final design certification regulation) must propose appropriate steps to the Commission, as specified in § 52.3 of this chapter, within 60 days to demonstrate compliance with § 50.46a requirements, along with a report of the nature of the changes or errors that resulted in an inability to assure compliance and an estimate of their effect on the limiting transient.

(iii) If an applicant for or holder of a standard design approval under part 52 of this chapter is required by paragraph (j)(1)(iv) of this section to submit a reanalysis, or identifies a change to, or error in an ECCS evaluation model, or in the application of such a model, that results in any predicted response that exceeds any of the acceptance criteria specified in this section, then the standard design approval applicant or holder must propose appropriate steps to the Commission, as specified in § 52.3 of this chapter, within 60 days to demonstrate compliance with § 50.46a requirements, along with a report of the nature of the changes or errors that resulted in an inability to assure compliance and an estimate of their effect on the limiting transient.

(3) *Minimal changes: reporting.* No later than 24 months after NRC approval of the entity's application and every 24 months thereafter, the entity must submit, as specified in § 50.4 or § 52.3 of this chapter, a short description of each change involving minimal changes in risk made under paragraph (h)(1) of this section in the preceding 24 months and a brief summary of the basis for the entity's determination pursuant to paragraph (h)(1)(iii) of this section that the change does not invalidate the applicability evaluation made under paragraph (c)(1)(i) of this section for an operating reactor licensee authorized to operate under this part on December 31, 2015, or the plant-specific TBS evaluation made under paragraph (c)(2) of this section for entities other than those authorized to operate under this part on December 31, 2015.

(4) *Inspection: reporting.* Within 120 days after completing the outage when the inspections specified in paragraph (d)(5) of this section were performed, the licensee must submit a summary report detailing the results of the inspections and the evaluation of the effect on the TBS of any additional degradation identified since the previous evaluation. This report can be combined with the summary report required by § 50.55a(b)(2)(xxxii).

(k) *Significant change or error in the ECCS evaluation model.*

(1) For LOCAs at or below the TBS, a significant change or error in the ECCS evaluation model for uranium oxide and mixed uranium-plutonium oxide pellets within cylindrical zirconium-alloy cladding is one that results in:

(i) A calculated peak fuel cladding temperature different by more than 50 °F from the temperature calculated for the limiting transient using the last acceptable evaluation model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective temperature changes is greater than 50 °F; or

(ii) A calculated integral time-at-temperature different by more than 1.0 percent equivalent cladding reacted from the oxidation calculated for the limiting transient using the last acceptable evaluation model, or is a cumulation of changes and errors such that the sum of the absolute magnitudes of the respective oxidation changes is greater than 1.0 percent equivalent cladding reacted.

(2) For LOCAs above the TBS, a significant change or error in the ECCS evaluation model for uranium oxide and mixed uranium-plutonium oxide pellets within cylindrical zirconium-alloy cladding is one that results in a significant reduction in the capability to meet the requirements of paragraphs (e)(1) and (f) of this section.

(3) For fuel that does not consist of uranium or mixed uranium-plutonium oxide pellets within cylindrical zirconium-alloy cladding, a significant change in the ECCS evaluation model is one that results in a significant reduction in the capability to meet the requirements of paragraphs (e)(1) and (f) of this section.

(l) *Documentation.* Following implementation of the requirements in this section, each entity subject to this section must maintain records sufficient to demonstrate compliance with the requirements in this section in accordance with § 50.71.

■ 11. Add § 50.46b under the undesignated center heading ''Standards for Licenses, Certifications, and Regulatory Approvals'' to read as follows:

§ 50.46b Acceptance criteria for reactor coolant system venting systems.

Each nuclear power reactor must be provided with high-point vents for the reactor coolant system, for the reactor vessel head, and for other systems required to maintain adequate core cooling if the accumulation of noncondensible gases would cause the loss of function of these systems. High-point vents are not required for the tubes in U-tube steam generators. Acceptable venting systems must meet the following criteria:

(a) The high-point vents must be remotely operated from the control room.

(b) The design of the vents and associated controls, instruments, and power sources must conform to appendix A and appendix B of this part.

(c) The vent system must be designed to ensure that:

(1) The vents will perform their safety functions; and

(2) There would not be inadvertent or irreversible actuation of a vent.

■ 12. In § 50.47,

■ a. In paragraph (b)(10), remove the word ''EPZ'' wherever it appears;

■ b. Revise paragraph (c)(2); and

■ c. Add paragraphs (g) and (h) to read as follows:

§ 50.47 Emergency plans.

* * * * *

(c) * * *

(2) Generally, the plume exposure pathway EPZ for nuclear power reactors shall consist of an area about 2 to 10 miles (3.2 to 16 km) in radius. For reactors with an authorized power level less than 300 MW thermal, the plume exposure pathway EPZ may be established at the site boundary. The need for and size of the EPZ may also be determined on a case-by-case basis as described in § 50.33(g)(2). The exact size and configuration of the EPZ surrounding a particular nuclear power reactor shall be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. Emergency plans must describe such actions as are appropriate to avoid or reduce dose within and beyond the EPZ or site boundary and to protect the ingestion pathway.

* * * * *

(g) A licensee desiring to change its plume exposure pathway EPZ must submit an application for a license

amendment under § 50.90 and receive NRC approval before implementing the change. Any such license amendment request must include documentation demonstrating that the applicable State, local, and Tribal governmental authorities have agreed to the EPZ change.

(h) A licensee desiring to comply with the requirements of § 50.160 in lieu of appendix E to this part, and for nuclear power reactor licensees, the planning standards of § 50.47(b), must submit an application for a license amendment under § 50.90 and receive NRC approval before implementing the change.

■ 13. In § 50.49, remove footnote 3, redesignate footnote 4 as footnote 1, and revise and republish paragraph (b) to read as follows:

§ 50.49 Environmental qualification of electric equipment important to safety for nuclear power plants.

* * * * *

(b) Electric equipment important to safety covered by this section is:

(1) Safety-related electric equipment.

(i) This equipment is that relied upon to remain functional during and following design basis events to ensure—

(A) The integrity of the reactor coolant pressure boundary;

(B) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(C) The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to the guidelines in § 50.34(a)(1), 50.67(b)(2), or 100.11 of this chapter, as applicable.

(ii) For applications submitted on or after [DATE 180 DAYS AFTER THE EFFECTIVE DATE OF FINAL RULE] for a license, permit, standard design certification, or standard design approval under this part or part 52 of this chapter, design basis events are defined in § 50.2. This definition also applies to other licenses, permits, standard design certifications, or standard design approvals for which the NRC has approved adopting the § 50.2 definition for design basis events. In all other cases, design basis events are defined as conditions of normal operation, including anticipated operational occurrences, design basis accidents, external events, and natural phenomena for which the plant must be designed to ensure functions (b)(1)(i)(A) through (C) of this section.

(2) Non-safety-related electric equipment whose failure under postulated environmental conditions could prevent satisfactory accomplishment of safety functions specified in subparagraphs (b)(1)(i)(A) through (C) of this section by the safety-related equipment.

(3) Certain post-accident monitoring equipment.[1]

* * * * *

[1] Specific guidance concerning the types of variables to be monitored is provided in Revision 2 of Regulatory Guide 1.97, ''Instrumentation for Light-Water-Cooled Nuclear Power Plants to Assess Plant and Environs Conditions During and Following an Accident.'' Copies of the Regulatory Guide may be purchased through the U.S. Government Publishing Office by calling 202–512–1800 or by writing to the U.S. Government Publishing Office, P.O. Box 37082, Washington, DC 20013–7082.

■ 14. In § 50.54, add paragraphs (a)(5) and (q)(1)(v) and revise paragraphs (a)(1), (q)(2), (q)(3), and (t) to read as follows:

§ 50.54 Conditions of licenses.

* * * * *

(a)(1) Each nuclear power plant or fuel reprocessing plant licensee subject to the quality assurance criteria in appendix B or T of this part shall implement, under § 50.34(b)(6)(ii) or § 52.79 of this chapter, the quality assurance program or quality management system, respectively, described or referenced in the safety analysis report, including changes to that report. However, a holder of a combined license under part 52 of this chapter shall implement the quality assurance program or quality management system described or referenced in the safety analysis report applicable to operation 30 days prior to the scheduled date for the initial loading of fuel.

* * * * *

(5) Changes to the quality management system must be submitted to the NRC and receive NRC approval prior to implementation, as follows:

(i) Changes made to the quality management system as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 50.4.

(ii) The submittal of a change to the Safety Analysis Report quality management system must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised quality management system incorporating the change continues to satisfy the criteria of appendix T of this part and the Safety Analysis Report quality management system commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(iv) Changes to the quality management system included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission.

* * * * *

(q) * * *

(1) * * *

(v) *Risk significant planning standard* means the most essential functions of emergency preparedness to ensure adequate protective measures are taken to protect the public in the event of a radiological emergency. For the purposes of this section, the risk significant planning standards are classification, notification, assessment, protective actions, staffing, and facilities.

(2) A holder of a license under this part, or a combined license under part 52 of this chapter after the Commission makes the finding under § 52.103(g) of this chapter, shall follow and maintain the effectiveness of an emergency plan that meets the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards of § 50.47(b), or an emergency plan that meets the requirements in § 50.160.

(3) A licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that:

(i) For planning standards that are risk significant, the changes do not reduce the effectiveness of the plan and the plan, as changed, continues to meet either the risk significant requirements of § 50.160 or the applicable requirements in appendix E to this part and, for nuclear power reactor licensees, the risk significant planning standards of § 50.47(b); and

(ii) For planning standards that are not risk-significant, the plan, as changed, continues to meet the applicable requirements.

* * * * *

(t) The licensee must provide for annual evaluation of the adequacy of the interfaces between the licensee and the applicable State, local, and Tribal governments, including licensee drills, exercises, capabilities, and procedures. The results of the evaluation, along with recommendations for improvements, must be documented, reported to the

licensee's corporate and plant management, retained for a period of 5 years, and must be made available to the appropriate State, local, and Tribal governments.

* * * * *

■ 15. In § 50.55, revise paragraph (f)(1) and add paragraph (f)(5) to read as follows:

§ 50.55 Conditions of construction permits, early site permits, combined licenses, and manufacturing licenses.

* * * * *

(f)(1) Each nuclear power plant or fuel reprocessing plant construction permit holder subject to the quality assurance criteria in appendix B or T of this part shall implement, pursuant to § 50.34(a)(7) of this part, the quality assurance program description or quality management system, respectively, described or referenced in the Safety Analysis Report, including changes to that report.

* * * * *

(5) Changes to the quality management system must be submitted to the NRC and receive NRC approval prior to implementation, as follows:

(i) Changes made to the quality management system as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 50.4.

(ii) The submittal of a change to the Safety Analysis Report quality management system must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised quality management system incorporating the change continues to satisfy the criteria of appendix T of this part and the Safety Analysis Report quality management system commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(iii) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(iv) Changes to the quality management system included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission.

* * * * *

§ 50.55a [Amended]

■ 16. In § 50.55a, in paragraph (z) introductory text, remove the phrase ''of paragraphs (b) through (h)''.

■ 17. In § 50.57, add paragraph (d) to read as follows:

§ 50.57 Issuance of operating license.[1]

* * * * *

(d) The Commission may afford generic finality to generic aspects of the design of a utilization facility, including postulated site parameters, and requirements submitted pursuant to § 50.34(b)(14), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design in accordance with applicable requirements and without undue risk to the health and safety of the public.

[1] The Commission may issue a provisional operating license pursuant to the regulations in this part in effect on March 30, 1970, for any facility for which a notice of hearing on an application for a provisional operating license or a notice of proposed issuance of a provisional operating license has been published on or before that date.

■ 18. In § 50.58, add paragraphs (b)(7) and (b)(8) to read as follows:

§ 50.58 Hearings and report of the Advisory Committee on Reactor Safeguards.

* * * * *

(b) * * *

(7) If an applicant requests generic finality under § 50.34(b)(14) for an operating license under this part, the Commission will include a request for generic finality as a proposed action in the notice of proposed action required by § 2.105 of this chapter.

(8) In a proceeding for issuance of a construction permit, operating license, or combined license, or in any enforcement hearing other than one initiated by the Commission under § 2.202(e)(1) of this chapter, in which an operating license issued under this subpart is referenced, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the referenced operating license, including, if applicable, the adequacy of a reactor design, if the referenced operating license was afforded finality pursuant to § 50.57(d).

■ 19. In § 50.59, revise paragraphs (c)(2)(viii) and (d)(1) and add paragraphs (e) and (f) to read as follows:

§ 50.59 Changes, tests, and experiments.

* * * * *

(c) * * *

(2) * * *

(viii) Result in a departure from a method of evaluation described in the FSAR (as updated) used in establishing the design bases or in the safety analyses, unless the licensee has demonstrated through a documented verification, validation, and uncertainty quantification (VVUQ) process, conducted under a VVUQ program that meets the requirements of § 50.221 and has been approved by the NRC for the intended application, that the departure from a method of evaluation described in the FSAR (as updated) meets the criteria established for credibility in the VVUQ program, including implementation of established VVUQ activities and assessments.

* * * * *

(d) (1) The licensee shall maintain records of changes in the facility, of changes in procedures, and of tests and experiments made pursuant to paragraph (c) or (f) of this section. These records must include a written evaluation which provides the bases for the determination that the change, test, or experiment does not require a license amendment pursuant to paragraph (c)(2) or (f) of this section.

* * * * *

(e) For the purposes of criteria § 50.59(c)(2)(i) and (ii), an increase may be demonstrated to not be a ''more than a minimal increase'' using quantitative risk results based on a probabilistic risk assessment of appropriate scope and quality that provides appropriate risk metrics. The change must also maintain defense-in-depth and safety margins.

(f) The holder of an operating license or a combined license that authorizes operation of a manufactured reactor may make changes in the facility as described in the final safety analysis report (as updated) and make changes in the procedures as described in the final safety analysis report (as updated) without obtaining a license amendment pursuant to § 50.90 if the changes are identical to changes approved by the Commission by amendment to the manufacturing license for the manufactured reactor and upon determining that implementation of the changes will be consistent with the basis for the Commission's approval of the amendment to the manufacturing license and not involve any additional changes that would require an amendment to its operating license or combined license.

■ 20. In § 50.67, revise and republish paragraph (b) to read as follows:

§ 50.67 Accident source term.

* * * * *

(b) *Requirements.*

(1) A licensee who seeks to revise its current accident source term in design basis radiological consequence analyses must apply for a license amendment

under § 50.90. The application must contain an evaluation of the consequences of applicable design basis accidents [1] previously analyzed in the safety analysis report.

(2) The NRC may issue the amendment only if the applicant's analysis demonstrates with reasonable assurance that:

(i) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE).

(ii) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage), would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE.

(iii) The necessary design, fabrication, construction, testing, and performance criteria for structures, systems, and components important to safety are provided to permit occupancy of the control room under accident conditions without calculated radiation exposures in excess of 10 rem (0.10 Sv) TEDE or a higher design criterion limit established in accordance with paragraph (b)(3) of this section for the duration of the accident.

(3) The licensee may establish a design criterion limit higher than 10 rem (0.10 Sv) TEDE but not greater than 25 rem [3] (0.25 Sv) TEDE for compliance with paragraph (b)(2)(iii) of this section provided the licensee demonstrates that the specified limit is consistent with the plant risk profile or commensurate with the risk of the plant.

[1] The fission product release assumed for these calculations should be based upon a major accident, hypothesized for purposes of design analyses or postulated from considerations of possible accidental events, that would result in potential hazards not exceeded by those from any accident considered credible. Such accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this value constitutes an acceptable limit for emergency doses to the public under accident conditions. Rather, this 25 rem (0.25 Sv) TEDE value has been stated in this section as a reference value, which can be used in the evaluation of proposed design basis changes with respect to potential reactor accidents of exceedingly low probability of occurrence and low risk of public exposure to radiation.

[3] The use of 25 rem (0.25 Sv) TEDE as the control room criterion is not intended to imply that this value constitutes an acceptable limit for emergency doses under accident conditions. Adequate radiological protection for occupationally exposed individuals is provided by the provisions of part 20 of this chapter and § 50.47(b)(11). This criterion is provided only to assess the acceptability of design provisions, in particular engineered safety features that mitigate fission product release, under postulated DBA conditions. The conditions assumed in these analyses, although credible, are of exceedingly low probability of occurrence and do not represent actual accident sequences but are specified as conservative surrogates to create bounding conditions for assessing the acceptability of engineered safety features.

■ 21. In § 50.68, revise paragraph (b)(7) to read as follows:

§ 50.68 Criticality accident requirements.

* * * * *

(b) * * *

(7) The maximum nominal U–235 enrichment of the fresh fuel assemblies is limited to five (5.0) percent by weight or to the value specified in the operating license which must be less than twenty (20.0) percent by weight.

* * * * *

§ 50.69 [Amended]

■ 22. In § 50.69, revise paragraph (b)(1)(ii) by removing the reference ''10 CFR 50.46a(b)'' and adding in its place ''§ 50.46b(b)''.

■ 23. In § 50.71, revise paragraph (f) to read as follows:

§ 50.71 Maintenance of records, making of reports.

* * * * *

(f) Each person licensed to manufacture a nuclear power reactor under subpart F of part 52 of this chapter shall update the FSAR originally submitted as part of the application to reflect the effects[2] of all changes made in the facility or procedures as described in the FSAR; all safety analyses and evaluations performed by the licensee either in support of approved amendments to the manufacturing license or in support of conclusions that changes did not require a license amendment in accordance with § 50.59(c)(2); and any new analyses of safety issues performed by or on behalf of the licensee at the NRC's request. This submittal shall contain all the changes necessary to reflect information and analyses submitted to the Commission by the licensee or prepared by the licensee with respect to the modification under § 52.171 of this chapter or the analyses requested by the Commission under § 52.171 of this chapter. The updated information shall be appropriately located within the update to the FSAR.

* * * * *

[2] See footnote 1.

■ 24. In § 50.75,

■ a. Revise paragraphs (b), (c), and (e)

■ b. In paragraph (g)(4)(iii), remove the phrase ''10 CFR Part 20, Subpart E'' and add in its place the phrase ''subpart E to part 20 of this chapter'';

■ c. In paragraph (h)(5), remove the reference ''(h)(3)'' and add in its place ''(3)''.

The revisions are to read as follows:

§ 50.75 Reporting and recordkeeping for decommissioning planning.

* * * * *

(b) Each power reactor applicant for or holder of an operating license, and each applicant for a combined license under subpart C of part 52 of this chapter for a production or utilization facility shall submit a decommissioning report, as required by § 50.33(k).

(1)(i) For an applicant for or holder of an operating license under this part of a type and power level specified in paragraph (c) of this section, the report must contain a certification that financial assurance for decommissioning will be (for a license applicant), or has been (for a license holder), provided in an amount which may be more, but not less, than the amount stated in the table in paragraph (c)(1) of this section adjusted using a rate at least equal to that stated in paragraph (c)(2) of this section. For an applicant for a combined license under subpart C of part 52 of this chapter of a type and power level specified in paragraph (c) of this section, the report must contain a certification that financial assurance for decommissioning will be provided no later than 30 days after the Commission publishes notice in the **Federal Register** under § 52.103(a) of this chapter in an amount which may be more, but not less, than the amount stated in the table in paragraph (c)(1) of this section, adjusted using a rate at least equal to that stated in paragraph (c)(2) of this section.

(ii) The amount to be provided must be adjusted annually using a rate at least equal to that stated in paragraph (c)(2) of this section.

(iii) The amount must be covered by one or more of the methods described in paragraph (e) of this section as acceptable to the NRC.

(iv) The amount stated in the applicant's or licensee's certification may be based on a site-specific cost estimate for decommissioning the facility. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section must be submitted to NRC; *provided, however,*

that an applicant for or holder of a combined license need not obtain such financial instrument or submit a copy to the Commission except as provided in paragraph (e)(3) of this section.

(2)(i) For an applicant for or holder of an operating license under this part or subpart C of part 52 of this chapter of a type and power level other than that specified in paragraph (c) of this section, the report must contain a certification that financial assurance for decommissioning will be (for a license applicant), or has been (for a license holder), provided in an amount that may be based on a design-specific decommissioning cost estimate or the amount stated in the table in paragraph (c)(1) of this section adjusted using a rate at least equal to that stated in paragraph (c)(2) of this section.

(ii) A certification relying on a design-specific decommissioning cost estimate must demonstrate that there is reasonable assurance that sufficient funds necessary for safely decommissioning the facility will be available, when needed, and provide the factors used to develop the design-specific decommissioning cost estimate, including reactor technology, power level (in MWt), and costs related to labor, energy, and waste burial. Additionally, design-specific decommissioning cost estimates must include plans for adjusting levels of funds assured for decommissioning to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the cost of decommissioning.

(iii) The amount to be provided must be adjusted annually using a rate at least equal to that stated in paragraph (c)(2) of this section.

(iv) The amount must be covered by one or more of the methods described in paragraph (e) of this section as acceptable to the NRC.

(v) The amount stated in the applicant's or licensee's certification may be based on a site-specific cost estimate for decommissioning the facility. As part of the certification, a copy of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section must be submitted to NRC; *provided, however,* that an applicant for or holder of a combined license need not obtain such financial instrument or submit a copy to the Commission except as provided in paragraph (e)(3) of this section.

(c) Table of minimum amounts (January 1986 dollars) required to demonstrate reasonable assurance of funds for decommissioning by reactor type and power level, P (in MWt); adjustment factor.[1]

		Millions
(1)(i) For a PWR:	greater than or equal to 3400 MWt	$105
	between 1200 MWt and 3400 MWt	$(75+0.0088P)
(ii) For a BWR:	greater than or equal to 3400 MWt	$135
	between 1200 MWt and 3400 MWt	$(104+0.009P)

(2) An adjustment factor at least equal to 0.65 L + 0.13 E + 0.22 B is to be used where L and E are escalation factors for labor and energy, respectively, and are to be taken from regional data of U.S. Department of Labor Bureau of Labor Statistics and B is an escalation factor for waste burial and is to be taken from NRC report NUREG–1307, ''Report on Waste Burial Charges.''

* * * * *

(e)(1) Financial assurance is to be provided by the following methods.

(i) *Prepayment.* Prepayment is the deposit made preceding the start of operation or the transfer of a license under § 50.80 into an account segregated from applicant or licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs at the time permanent termination of operations is expected. Prepayment may be in the form of a trust, escrow account, or Government fund with payment by, certificate of deposit, deposit of Government or other securities or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement shall be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal Government agency, or an entity whose operations in which the prepayment deposit is managed are regulated and examined by a Federal or State agency. An applicant or licensee that has prepaid funds based on a site-specific estimate under paragraph (b)(1) or (2) of this section may take credit for projected earnings on the prepaid decommissioning trust funds, using up to a 2-percent annual real rate of return from the time of future funds' collection through the projected decommissioning period, provided that the site-specific estimate is based on a period of safe storage that is specifically described in the estimate. This includes the periods of safe storage, final dismantlement, and license termination. An applicant or licensee that has prepaid funds based on a design-specific estimate under paragraph(b)(2) of this section or on the formulas in paragraph (c) of this section may take credit for projected earnings on the prepaid decommissioning funds using up to a 2-percent annual real rate of return up to the time of permanent termination of operations. An applicant or licensee may use a credit of greater than 2 percent if the applicant's or licensee's rate-setting authority has specifically authorized a higher rate. However, applicants or licensees certifying only to design-specific decommissioning cost estimates or formula amounts (*i.e.,* not a site-specific

estimate) can take a pro-rata credit during the immediate dismantlement period (*i.e.,* recognizing both cash expenditures and earnings the first 7 years after shutdown). Actual earnings on existing funds may be used to calculate future fund needs.

(ii) *External sinking fund.* An external sinking fund is a fund established and maintained by setting funds aside periodically in an account segregated from applicant or licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates in which the total amount of funds would be sufficient to pay decommissioning costs at the time permanent termination of operations is expected. An external sinking fund may be in the form of a trust, escrow account, or Government fund, with payment by certificate of deposit, deposit of Government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement shall be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal Government agency, or an entity whose operations in which the external sinking fund is managed are regulated and examined by a Federal or State agency. An applicant or licensee that has collected funds based on a site-specific estimate under paragraph (b)(1) or (2) of this section may take credit for projected earnings on the external sinking funds using up to a 2-percent annual real rate of return from the time of future funds' collection through the decommissioning period, provided that the site-specific estimate is based on a period of safe storage that is specifically described in the estimate. This includes the periods of safe storage, final dismantlement, and license termination. An applicant or licensee that has collected funds based on a design-specific estimate under paragraph (b)(2) of this section or on the formulas in paragraph (c) of this section may take credit for collected earnings on the decommissioning funds using up to a 2-percent annual real rate of return up to the time of permanent termination of operations. An applicant or licensee may use a credit of greater than 2 percent if the applicant's or licensee's rate-setting authority has specifically authorized a higher rate. However, applicants or licensees certifying only to design-specific decommissioning cost estimates or formula amounts (*i.e.,* not a site-specific estimate) can take a pro-rata credit during the dismantlement period (*i.e.,* recognizing both cash expenditures and earnings the first 7 years after shutdown). Actual earnings on existing funds may be used to calculate future fund needs. An applicant or licensee, whose rates for decommissioning costs cover only a portion of these costs, may make use of this method only for the portion of these costs that are collected in one of the manners described in this paragraph (e)(1)(ii). This method may be used as the exclusive mechanism relied upon for providing financial assurance for decommissioning in the following circumstances:

(A) By an applicant or licensee that recovers, either directly or indirectly, the estimated total cost of decommissioning through rates established by ''cost of service'' or similar ratemaking regulation. Public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, that establish their own rates and are able to recover their cost of service allocable to decommissioning, are assumed to meet this condition.

(B) By an applicant or licensee whose source of revenues for its external sinking fund is a ''non-bypassable charge,'' the total amount of which will provide funds estimated to be needed for decommissioning pursuant to paragraph (b), (c), or (f) of this section, or § 50.82.

(iii) *A surety method, insurance, or other guarantee method.*

(A) These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(*1*) The surety method or insurance must be open-ended, or, if written for a specified term, such as 5 years, must be renewed automatically, unless 90 days or more prior to the renewal day the issuer notifies the NRC, the beneficiary, and the applicant or licensee of its intention not to renew. The surety or insurance must also provide that the full-face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the applicant or licensee fails to provide a replacement acceptable to the NRC within 30 days after receipt of notification of cancellation.

(*2*) The surety or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the NRC. An acceptable trustee includes an appropriate State or Federal Government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(B) A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to part 30 of this chapter.

(C) For commercial companies that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to part 30 of this chapter. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to part 30 of this chapter. For non-profit entities, such as colleges, universities, and non-profit hospitals, a guarantee of funds by the applicant or licensee may be used if the guarantee and test are as contained in appendix E to part 30 of this chapter. A guarantee by the applicant or licensee may not be used in any situation in which the applicant or licensee has a parent company holding majority control of voting stock of the company.

(iv) *Statements of intent.* For a Federal applicant for or holder of a power reactor operating license, or for a Federal, State, or local government applicant or holder of an operating license for a non-power production or utilization facility, a statement of intent containing a cost estimate for decommissioning, and indicating that funds for decommissioning will be obtained when necessary.

(v) *Contractual obligations.* Contractual obligation(s) on the part of an applicant's or licensee's customer(s), the total amount of which over the duration of the contract(s) will provide the applicant's or licensee's total share of uncollected funds estimated to be needed for decommissioning pursuant to paragraph (b), (c), or (f) of this section, or § 50.82. To be acceptable to the NRC as a method of decommissioning funding assurance, the terms of the contract(s) shall include provisions that the electricity buyer(s) will pay for the decommissioning obligations specified in the contract(s), notwithstanding the operational status either of the licensed power reactor to which the contract(s) pertains or force majeure provisions. All proceeds from the contract(s) for decommissioning funding will be deposited to the external sinking fund. The NRC reserves the right to evaluate the terms of any contract(s) and the financial

qualifications of the contracting entity or entities offered as assurance for decommissioning funding.

(vi) *Other mechanisms.* Any other mechanism, or combination of mechanisms, that provides, as determined by the NRC upon its evaluation of the specific circumstances of each application or licensee submittal, assurance of decommissioning funding equivalent to that provided by the mechanisms specified in paragraphs (e)(1)(i) through (v) of this section. Applicants or licensees who do not have sources of funding described in paragraph (e)(1)(ii) of this section may use an external sinking fund in combination with a guarantee mechanism, as specified in paragraph (e)(1)(iii) of this section, provided that the total amount of funds estimated to be necessary for decommissioning is assured.

(2) The NRC reserves the right to take the following steps in order to ensure an applicant's or licensee's adequate accumulation of decommissioning funds: review, as needed, the rate of accumulation of decommissioning funds; and, either independently or in cooperation with the FERC and the applicant's or licensee's State PUC, take additional actions as appropriate on a case-by-case basis, including modification of an applicant's or licensee's schedule for the accumulation of decommissioning funds.

(3) Each holder of a combined license under subpart C of part 52 of this chapter shall, 2 years before and 1 year before the scheduled date for initial loading of fuel, consistent with the schedule required by § 52.99(a) of this chapter, submit a report to the NRC containing a certification updating the information described under paragraph (b) of this section, including a copy of the financial instrument to be used. No later than 30 days after the Commission publishes notice in the **Federal Register** under § 52.103(a) of this chapter, the licensee shall submit a report containing a certification that financial assurance for decommissioning is being provided in an amount specified in the licensee's most recent updated certification, including a copy of the financial instrument obtained to satisfy the requirements of paragraph (e) of this section.

* * * * *

[1] Amounts are based on activities related to the definition of ''Decommission'' in § 50.2 of this part and do not include the cost of removal and disposal of spent fuel or of nonradioactive structures and materials beyond that necessary to terminate the license.

■ 25. In § 50.160, revise the section heading and paragraphs (b)(1)(iv)(A)(2), (b)(3), and (c) to read as follows:

§ 50.160 Performance-based emergency preparedness standards.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(A) * * *

(*2*) Implement the emergency plan in response to a security event.

* * * * *

(3) *Emergency planning zone.* Determine and describe the boundary and physical characteristics of the EPZ in the emergency plan as required by § 50.33(g)(1) or 53.1109(g)(1) of this chapter.

* * * * *

(c) *Implementation.*

(1) An applicant for an operating license issued under this part after December 18, 2023, must establish, implement, and maintain an emergency preparedness program that meets the requirements of paragraph (b) of this section, as described in the emergency plan and license, and conduct an initial exercise to demonstrate this compliance before the issuance of an operating license for the facility described in the license application.

(2) A holder of a combined license issued under part 52 or 53 of this chapter before the Commission has made the finding under § 52.103(g) or 53.1452(g) of this chapter, must establish, implement, and maintain an emergency preparedness program that meets the requirements of paragraph (b) of this section, as described in the approved emergency plan and license, and conduct an initial exercise to demonstrate this compliance before the scheduled date for initial loading of fuel, or for a fueled manufactured reactor, before the scheduled date for initiating the removal of the features to prevent criticality required under § 53.620(d)(1) of this chapter.

(3) A licensee desiring to change its plume exposure pathway EPZ must submit an application for a license amendment under § 50.90 and receive NRC approval before implementing the change. Any such license amendment request must include documentation demonstrating that the applicable State and local governmental authorities have agreed to the EPZ change.

(4) A licensee desiring to comply with the requirements in appendix E to this part and, for nuclear power reactor licensees, the planning standards in § 50.47(b) in lieu of § 50.160 must submit an application for a license amendment under § 50.90 and receive NRC approval before implementing the change.

■ 26. Add § 50.220 under a new undesignated heading ''Risk-Informed and Performance-Based Alternatives'' consisting of § 50.220 and § 50.221 to read as follows:

Risk-Informed and Performance-Based Alternatives

§ 50.220 Use of risk-informed and performance-based alternatives to acceptance criteria.

(a) For each regulation in this part that provides specific acceptance criteria, licensees or applicants may propose, either through a license amendment request or as part of an application for an initial license, an alternative under paragraph (b) of this section. If a proposal under paragraph (b) of this section includes alternatives to acceptance criteria in more than one regulation in this part, it must analyze the cumulative effect of those changes to ensure that an appropriate level of safety is maintained.

(b) An applicant for or a holder of a construction permit or operating license under this part; or an applicant for or holder of a design approval, operating license, a combined license, or manufacturing license under this chapter; voluntarily choosing to implement this section must submit a license amendment application that contains the following information or include the following information in the initial application:

(1) The specific regulation and the acceptance criteria for which the alternative criteria are being proposed.

(2) The alternative criteria proposed in place of the acceptance criteria. If applicable, the alternative criteria must include either the selected performance targets or a description of the methodology that will be used to determine the performance targets.

(3) A description of the process followed to develop the alternative acceptance criteria. The process must:

(i) Consider results and insights from the plant- or design-specific probabilistic risk assessment (PRA) or systematic risk assessment or combination thereof to show that the alternate proposed criteria establish an equivalent level of safety to the existing acceptance criteria.

(ii) Reasonably reflect the current plant configuration and operating practices, and applicable plant, facility, and industry operational experience.

(iii) Achieve or maintain adequate defense-in-depth.

(iv) Achieve or maintain sufficient safety margins.

(v) Use an integrated panel of plant- or design-knowledgeable members whose collective expertise supports an integrated evaluation of the alternative criteria.

(vi) Include a performance monitoring program that will be used to periodically evaluate whether the alternative criteria remain valid and make timely adjustments to the design and/or operation of the plant or facility as necessary to maintain the validity.

(vii) Include an evaluation of the cumulative effect of the proposed alternative criteria with relevant NRC-approved alternative criteria.

■ 27. Add § 50.221 under the undesignated center heading ''Risk-Informed and Performance-Based Alternatives'' to read as follows:

§ 50.221 Credibility requirements for modeling and simulation.

(a) *Purpose and scope.*

(1) *Purpose.* This regulation establishes requirements for licensees or applicants to voluntarily adopt a verification, validation, and uncertainty quantification (VVUQ) program that will ensure the credibility of models and simulations (M&S), used to demonstrate compliance with NRC safety criteria for nuclear power plants.

(2) *Scope.* A VVUQ program may apply to any model or simulation whose results inform or directly support nuclear power plant safety assessments, performance criteria, regulatory decisions, or otherwise contribute to demonstrating compliance with regulatory requirements.

(b) *Definitions.* For the purpose of this section:

(1) *Credibility* means the degree to which a model's predictions for a specific purpose can be justifiably trusted such that it can be relied upon.

(2) *Verification, validation, and uncertainty quantification (VVUQ)* means activities related to verification, validation, and uncertainty quantification, as well as all other supporting tools and techniques used to establish and demonstrate the credibility of a model or simulation.

(3) *M&S risk* is defined as the combination of the likelihoods that the M&S is incorrect or misleading and the consequences of relying on the incorrect or misleading result for some decision making purpose. Because simulations inherently include multiple potential sources of error, assessing M&S risk is generally a cumulative process. M&S risk can serve as a basis for establishing a tiered review framework, organized into three levels: low, medium, and high.

(i) *Low risk.* Confirmation of the adequacy of VVUQ activities of M&S determined to have low risk may be accomplished using internal quality assurance procedures established by the licensee's or applicant's quality assurance program.

(ii) *Medium risk.* Confirmation of the adequacy of VVUQ activities of M&S determined to have medium risk may be provided by an external organization independent of the internal modeling group.

(iii) *High risk.* Confirmation of the adequacy of VVUQ activities of M&S determined to have high risk require review and approval by the NRC, generally through the submittal of license amendments or topical reports.

(c) *Credibility requirements.* The VVUQ program must establish credibility requirements. Credibility requirements address two complementary elements: the specific activities performed to establish model or simulation credibility (VVUQ Activities), and the evaluation demonstrating that the outcomes of these activities are sufficient and appropriate for the intended use of the model or simulation (VVUQ Assessments). Licensees and applicants may not adopt or rely on a model or simulation covered by the VVUQ program prior to successful completion of VVUQ activities and VVUQ assessments.

(1) *VVUQ activities.* The VVUQ program must specify the activities necessary to establish and ensure the credibility of M&S used in regulatory or safety applications for that specific VVUQ program. The specific activities required depend on the characteristics of the model or simulation, its intended application, and the associated M&S risk. When considering M&S risk, individual error sources and their associated likelihoods and consequences must be evaluated and then combined to quantify the overall risk. In addition to verification, validation, and uncertainty quantification, VVUQ programs may include a range of supporting activities. These include, but are not limited to, sensitivity analyses, scaling evaluations, comparisons against experimental or operational data, and any other relevant methods or techniques needed to adequately establish credibility.

(2) *VVUQ assessments.* The VVUQ program must require an evaluation of the outcomes of the VVUQ activities performed to determine whether they are sufficient to justify trust in the model or simulation for its specific application. This assessment must consider all relevant uncertainties and potential errors associated with the model or simulation, including but not limited to those stemming from computational methods, numerical approximations, input parameters, modeling assumptions, and comparisons to experimental or operational data. The VVUQ program must require identification of the applicability, limitations, and key assumptions inherent to the modeling or simulation approach, ensuring that the depth and rigor of the assessment appropriately reflect the intended use, scope, and associated risk of the specific model or simulation. Assessments must not only evaluate numerical or quantitative outcomes of the VVUQ activities, but also clearly interpret the significance of these outcomes within the context of their intended regulatory application.

■ 28. In appendix A to part 50,

■ a. Under the heading ''Introduction,'' in the last sentence of the last paragraph, remove the word ''must'' and add in its place the word ''may'' and remove the word ''justified.'' and add in its place the phrase ''justified within the licensing submittal without needing an exemption.''

■ b. Under the heading ''Criteria,'' criteria 17, 19, 28, 35, 38, 41, 44, and 50 are revised to read as follows:

Appendix A to Part 50—General Design Criteria for Nuclear Power Plants

* * * * *

Criterion 17—Electric power systems. An onsite electric power system and an offsite electric power system shall be provided to permit functioning of structures, systems, and components important to safety. The safety function for each system (assuming the other system is not functioning) shall be to provide sufficient capacity and capability to assure that:

(1) specified acceptable fuel design limits and design conditions of the reactor coolant pressure boundary are not exceeded as a result of anticipated operational occurrences and

(2) the core is cooled and containment integrity and other vital functions are maintained in the event of postulated accidents.

The onsite electric power supplies, including the batteries, and the onsite electric distribution system, shall have sufficient independence, redundancy, and testability to perform their safety functions assuming a single failure, except for loss-of-coolant accidents involving breaks in the reactor system coolant pressure boundary larger than the transition break size under § 50.46a, where a single failure of the onsite power supplies and electrical distribution system need not be assumed for plants under § 50.46a. For those breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

Electric power from the transmission network to the onsite electric distribution

system shall be supplied by two physically independent circuits (not necessarily on separate rights of way) designed and located so as to minimize, to the extent practical, the likelihood of their simultaneous failure under operating and postulated accident and environmental conditions. A switchyard common to both circuits is acceptable. Each of these circuits shall be designed to be available in sufficient time following a loss of all onsite alternating current power supplies and the other offsite electric power circuit, to assure that specified acceptable fuel design limits and design conditions of the reactor coolant pressure boundary are not exceeded. One of these circuits shall be designed to be available within a few seconds following a loss-of-coolant accident to assure that core cooling, containment integrity, and other vital safety functions are maintained.

Provisions shall be included to minimize the probability of losing electric power from any of the remaining supplies as a result of, or coincident with, the loss of power generated by the nuclear power unit, the loss of power from the transmission network, or the loss of power from the onsite electric power supplies.

* * * * *

Criterion 19—Control room. A control room shall be provided from which actions can be taken to operate the nuclear power unit safely under normal conditions and to maintain it in a safe condition under accident conditions, including loss-of-coolant accidents. The necessary design, fabrication, construction, testing, and performance criteria for structures, systems, and components important to safety are provided to permit occupancy of the control room under accident conditions without calculated radiation exposures in excess of 10 rem (0.10 Sv) whole body, or its equivalent to any part of the body, or a higher design criteria limit established in accordance with paragraph (2) of this section for the duration of the accident. Equipment at appropriate locations outside the control room shall be provided

(1) with a design capability for prompt hot shutdown of the reactor, including necessary instrumentation and controls to maintain the unit in a safe condition during hot shutdown;

(2) with a potential capability for subsequent cold shutdown of the reactor through the use of suitable procedures. Applicants for and holders of construction permits and operating licenses under this part who apply on or after January 10, 1997; applicants for standard design approvals or certifications under part 52 of this chapter who apply on or after January 10, 1997; applicants for and holders of combined licenses or manufacturing licenses under part 52 of this chapter who do not reference a standard design approval or certification; or holders of operating licenses using an alternative source term under § 50.67, shall meet the requirements of this criterion. The necessary design, fabrication, construction, testing, and performance criteria for structures, systems, and components important to safety are provided to permit occupancy of the control room under accident conditions without personnel receiving calculated radiation exposures in excess of 10 rem (0.10 Sv) total effective dose equivalent (TEDE) or a higher design criterion limit established in accordance with paragraph (3) of this section for the duration of the accident; and

(3) with a design criterion limit higher than 10 rem (0.10 Sv) TEDE but not greater than 25 rem [3] (0.25 Sv) TEDE for compliance with paragraph (2) of this section provided the licensee demonstrates that the specified limit is consistent with the plant risk profile or commensurate with the risk of the plant.

* * * * *

Criterion 28—Reactivity limits. The reactivity control systems shall be designed with appropriate limits on the potential amount and rate of reactivity increase to assure that the effects of postulated reactivity accidents can neither

(1) result in damage to the reactor coolant pressure boundary greater than limited local yielding nor

(2) sufficiently disturb the core, its support structures or other reactor pressure vessel internals to impair significantly the capability to cool the core. These postulated reactivity accidents shall include the maximum reactivity insertion and rate resulting from a failure or malfunction of the reactivity control systems, steam line rupture, changes in reactor coolant temperature and pressure, and cold-water addition.

* * * * *

Criterion 35—Emergency core cooling. A system to provide abundant emergency core cooling shall be provided. The system safety function shall be to transfer heat from the reactor core following any loss of reactor coolant at a rate such that

(1) fuel and clad damage that could interfere with continued effective core cooling is prevented and

(2) clad metal-water reaction is limited to negligible amounts.

Suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities shall be provided to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) the system safety function can be accomplished, assuming a single failure, except for loss-of-coolant accidents involving breaks in the reactor coolant system boundary larger than the transition break size under § 50.46a. For those breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

* * * * *

Criterion 38—Containment heat removal. A system to remove heat from the reactor containment shall be provided. The system safety function shall be to reduce rapidly, consistent with the functioning of other associated systems, the containment pressure and temperature following any loss-of-coolant accident and maintain them at acceptably low levels.

Suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities shall be provided to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) the system safety function can be accomplished, assuming a single failure, except for analysis of loss-of-coolant accidents involving breaks in the reactor coolant pressure boundary larger than the transition break size under § 50.46a. For those breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

* * * * *

Criterion 41—Containment atmosphere cleanup. Systems to control fission products, hydrogen, oxygen, and other substances which may be released into the reactor containment shall be provided as necessary to reduce, consistent with the functioning of other associated systems, the concentration and quality of fission products released to the environment following postulated accidents, and to control the concentration of hydrogen or oxygen and other substances in the containment atmosphere following postulated accidents to assure that containment integrity is maintained.

Each system shall have suitable redundancy in components and features, and suitable interconnections, leak detection, isolation, and containment capabilities to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) its safety function can be accomplished, assuming a single failure, except for analysis of loss-of-coolant accidents involving breaks in the reactor coolant pressure boundary larger than the transition break size under § 50.46a. For those breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

* * * * *

Criterion 44—Cooling water. A system to transfer heat from structures, systems, and components important to safety, to an ultimate heat sink shall be provided. The system safety function shall be to transfer the combined heat load of these structures, systems, and components under normal operating and accident conditions.

Suitable redundancy in components and features, and suitable interconnections, leak detection, and isolation capabilities shall be provided to assure that for onsite electric power system operation (assuming offsite power is not available) and for offsite electric power system operation (assuming onsite power is not available) the system safety function can be accomplished, assuming a single failure, except for analysis of loss-of-coolant accidents involving breaks in the reactor coolant pressure boundary larger than the transition break size under § 50.46a. For those breaks only, neither a single failure nor the unavailability of offsite power need be assumed.

* * * * *

Criterion 50—Containment design basis. The reactor containment structure, including access openings, penetrations, and the containment heat removal system shall be designed so that the containment structure and its internal compartments can

accommodate, without exceeding the design leakage rate and with sufficient margin, the calculated pressure and temperature conditions resulting from any loss-of-coolant accident. This margin shall reflect consideration of

(1) the effects of potential energy sources which have not been included in the determination of the peak conditions, such as energy in steam generators and as required by § 50.44 energy from metal-water and other chemical reactions that may result from degradation but not total failure of emergency core cooling functioning,

(2) the limited experience and experimental data available for defining accident phenomena and containment responses, and

(3) the conservatism of the calculational model and input parameters.

For reactors designed to comply with § 50.46a, the structural and leak tight integrity of the reactor containment structure, including access openings, penetrations, and its internal compartments, shall be maintained for realistically calculated pressure and temperature conditions resulting from any loss-of-coolant accident larger than the transition break size.

* * * * *

[3] The use of 25 rem (0.25 Sv) whole body, or its equivalent to any part of the body as the control room criterion is not intended to imply that this value constitutes an acceptable limit for emergency doses under accident conditions. This criterion is provided only to assess the acceptability of design provisions, in particular engineered safety features that mitigate fission product release under postulated DBA conditions. The conditions assumed in these analyses, although credible, are of exceedingly low probability of occurrence and do not represent actual accident sequences but are specified as conservative surrogates to create bounding conditions for assessing the acceptability of engineered safety features. Adequate radiological protection for occupationally exposed individuals is provided by the provisions of part 20 of this chapter and § 50.47(b)(11).

■ 29. In appendix E to part 50,

■ a. Revise section I;

■ b. Remove and reserve section II;

■ c. Revise paragraphs IV.3., IV.4., IV.D.2., IV.D.3., IV.E.8.b. introductory text, IV.E.9.d., IV.F.2. introductory text, IV.F.2.a., and IV.F.2.c. second sentence of the introductory text;

■ d. Remove and reserve paragraphs IV.5. through 7.;and

■ c. Revise footnote 1 to read as follows:

Appendix E to Part 50—Emergency Planning and Preparedness for Production and Utilization Facilities

* * * * *

I. Introduction

1. Each applicant for an operating license is required by § 50.34(b) or § 53.1369 of this chapter to include in the final safety analysis report plans for coping with emergencies. Each applicant for a combined license under subpart C of part 52 of this chapter or subpart H of part 53 of this chapter is required by § 52.79 or § 53.1416 of this chapter to include in the application plans for coping with emergencies. Each applicant for an early site permit under subpart A of part 52 or under subpart H of part 53 of this chapter may submit plans for coping with emergencies under § 52.17 or § 53.1146 of this chapter.

2. This appendix establishes minimum requirements for emergency plans for use in attaining an acceptable state of emergency preparedness. These plans shall be submitted as part of the final safety analysis report for an operating license. These plans, or major features thereof, may be submitted as part of the site safety analysis report for an early site permit.

3. The potential radiological hazards to the public associated with the operation of non-power production or utilization facilities licensed under this part and fuel facilities licensed under part 70 of this chapter involve considerations different than those associated with nuclear power reactors. Consequently, the size of Emergency Planning Zones [1] (EPZs) for facilities other than power reactors and the degree to which compliance with the requirements of this section and sections III, IV, and V of this appendix is necessary, will be determined on a case-by-case basis.[2]

4. Notwithstanding the above paragraphs, in the case of an operating license authorizing only fuel loading and/or low power operations up to 5 percent of rated power, no NRC or FEMA review, findings, or determinations concerning the state of offsite emergency preparedness or the adequacy of and the capability to implement State and local offsite emergency plans, as defined in this appendix, are required prior to the issuance of such a license.

5. For power reactors with site-boundary EPZs or no EPZ, the degree to which compliance with the requirements of this section and sections III, IV, and V of this appendix is necessary, will be determined on a case-by-case basis.

6. The Tennessee Valley Authority Watts Bar Nuclear Plant, Unit 2, holding a construction permit under the provisions of part 50 of this chapter, shall meet the requirements of the final rule issued November 23, 2011, as applicable to operating nuclear power reactor licensees.

7. For a fueled manufactured reactor licensed under part 53 of this chapter, the date for initiating the removal of the features to prevent criticality required under § 53.620(d)(1) is equivalent to the initial loading of fuel in this appendix.

II. [Reserved]

* * * * *

IV. * * *

3. Nuclear power reactor licensees shall use evacuation time estimates (ETEs) and updates to the ETEs in the formulation of predetermined, prompt protective action recommendations and shall provide the ETEs and ETE updates to State and local governmental authorities for use in developing offsite predetermined, prompt protective action strategies.

4. Within 365 days of the date of the availability of the most recent decennial census data from the U.S. Census Bureau, nuclear power reactor licensees shall develop an ETE analysis using this decennial data and submit it under § 50.4 or § 53.040 of this chapter to the NRC. These licensees shall submit this ETE analysis to the NRC at least 180 days before using it to form predetermined, prompt protective action recommendations and providing it to State and local governmental authorities for use in developing offsite predetermined, prompt protective action strategies.

5. [Reserved]

6. [Reserved]

7. [Reserved]

* * * * *

D. * * *

2. Provisions shall be described for yearly dissemination to the public within the plume exposure pathway EPZ of basic emergency planning information, such as the methods and times required for public notification and the protective actions planned if an accident occurs, general information as to the nature and effects of radiation, and a listing of media sources that will be used for dissemination of information during an emergency. Signs or other measures shall also be used to disseminate to any transient population within the plume exposure pathway EPZ appropriate information that would be helpful if an accident occurs.

3. A licensee shall have the capability to notify responsible State and local governmental agencies within 15 minutes after declaring an emergency. The licensee shall demonstrate that the appropriate governmental authorities have the capability to make a public alerting and notification decision promptly on being informed by the licensee of an emergency condition. Prior to initial operation greater than 5 percent of rated thermal power of the first reactor at a site, each nuclear power reactor licensee shall demonstrate that means have been established for alerting and providing prompt instructions to the public within the plume exposure pathway EPZ. The design objective of the alert and notification system (ANS) shall be to have the capability to essentially complete the initial alerting and initiate notification of the public within the plume exposure pathway EPZ within about 15 minutes. The use of this alerting and notification capability will range from immediate alerting and notification of the public (within 15 minutes of the time that State and local officials are notified that a situation exists requiring urgent action) to the more likely events where there is substantial time available for the appropriate governmental authorities to make a judgment whether or not to activate the ANS. The alerting and notification capability shall additionally include means for a backup method of ANS capable of being used in the event the primary method of alerting and notification is unavailable during an emergency to alert or notify all or portions of the plume exposure pathway EPZ population. Alternatively, if the ANS capability, as documented in the ANS Design Report, demonstrates that the primary method of alerting and notifying is robust and has multiple methods implemented in parallel, an independent backup method is

unnecessary. If a backup method is necessary, it shall have the capability to alert and notify the public within the plume exposure pathway EPZ, but does not need to meet the 15-minute design objective for the primary prompt public alert and notification system. When there is a decision to activate the alert and notification system, the appropriate governmental authorities will determine whether to activate the entire alert and notification system simultaneously or in a graduated or staged manner. The responsibility for activating such a public alert and notification system shall remain with the appropriate governmental authorities.

E. * * *

8. * * *

b. For a nuclear power reactor licensee's emergency operations facility required by paragraph 8.a of this section, either a facility located outside the EPZ or a backup facility outside the EPZ if the primary facility is within the EPZ or onsite. An emergency operations facility may serve more than one nuclear power reactor site. A licensee desiring to locate an emergency operations facility more than 25 miles from a nuclear power reactor site shall request prior Commission approval by submitting an application for an amendment to its license. For an emergency operations facility located more than 25 miles from a nuclear power reactor site, provisions must be made for locating NRC and offsite responders closer to the nuclear power reactor site so that NRC and offsite responders can interact face-to-face with emergency response personnel entering and leaving the nuclear power reactor site. Provisions for locating NRC and offsite responders closer to a nuclear power reactor site that is more than 25 miles from the emergency operations facility must include the following:

* * * * *

9. * * *

d. Provisions for communications by the licensee with the NRC Headquarters Operations Center from the nuclear power reactor control room, the onsite technical support center, and the emergency operations facility, as applicable. Such communications shall be tested monthly.

* * * * *

F. * * *

2. The plan shall describe provisions for the conduct of emergency preparedness drills and exercises.[3] Licensees must submit scenarios under § 50.4 or § 53.040 of this chapter no later than 60 days before use in a required drill or exercise. These scenarios must document the applicable regulation(s) the scenario is intended to meet.

a. A full participation [4] exercise which tests as much of the licensee, State, and local emergency plans as is reasonably achievable without mandatory public participation shall be conducted for each site at which a power reactor is located in order to validate the effectiveness of the onsite, and if necessary, the offsite emergency plans and offsite coordination.

(i) For an operating license issued under part 50 or part 53 of this chapter, and if there are no preexisting licensed power reactors at this site, this exercise must be conducted before the issuance of the first operating license for full power (one authorizing operation above 5 percent of rated thermal power) of the first reactor and must include participation by each State and local government within the plume exposure pathway EPZ, as applicable. If the applicant currently has an operating reactor at the site with similar onsite and offsite emergency plan elements, this exercise may be included within the operating reactor licensee's existing exercise schedules.

(ii) For a combined license issued under part 52 or part 53 of this chapter, this exercise must be conducted before the scheduled date for initial loading of fuel. If FEMA identifies one or more deficiencies in the state of offsite emergency preparedness as the result of the first full participation exercise, or if the Commission finds that the state of emergency preparedness does not provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency, the provisions of § 50.54(gg) apply.

(iii) For a combined license issued under part 52 or part 53 of this chapter, if the applicant currently has an operating reactor at the site with similar onsite and offsite emergency plan elements, this exercise may be included within the operating reactor licensee's existing exercise schedule. If the onsite emergency plan elements are not similar, then paragraph 2.a.(ii) of this section applies.

* * * * *

c. * * * Where the offsite authority has a role under a radiological response plan for more than one site, it shall fully participate in one exercise every two years and shall, at least, partially participate in other offsite plan exercises in this period.[5] * * *

* * * * *

[1] EPZs for power reactors are discussed in NUREG–0396; EPA 520/1–78–016, ''Planning Basis for the Development of State and Local Government Radiological Emergency Response Plans in Support of Light Water Nuclear Power Plants,'' December 1978.

[2] Regulatory Guide 2.6, ''Emergency Planning for Research and Test Reactors and Other Non-Power Production and Utilization Facilities,'' may be used as guidance for the acceptability of non-power production or utilization facility emergency response plans.

[3] Use of site-specific simulators or computers is acceptable for any exercise.

[4] Full participation when used in conjunction with emergency preparedness exercises for a particular site means appropriate offsite local and State authorities and licensee personnel physically and actively take part in testing their integrated capability to adequately assess and respond to an accident at a commercial nuclear power plant. Full participation includes testing major observable portions of the onsite and offsite emergency plans and mobilization of State, local and licensee personnel and other resources in sufficient numbers to verify the capability to respond to the accident scenario.

[5] Partial participation when used in conjunction with emergency preparedness exercises for a particular site means appropriate offsite authorities shall actively take part in the exercise sufficient to test direction and control functions; *i.e.,* (a) protective action decision making related to emergency action levels, and (b) communication capabilities among affected State and local authorities and the licensee.

* * * * *

■ 30. In appendix K to part 50,

■ a. Amend section I by revising paragraph C.6. by removing the text ''BWR's'' and adding, in its place, the text ''BWRs''.

■ b. Amend section II by adding paragraph 6 to read as follows:

Appendix K to Part 50—ECCS Evaluation Models

* * * * *

II. * * *

6. If an entity is approved to implement § 50.46a, then the documentation requirements in § 50.46a(e) apply and supersede the requirements of section II of this appendix for that entity and associated regulatory approval.

■ 31. Add appendix T to read as follows:

Appendix T to Part 50—Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

I. Introduction and Scope

Nuclear power plants and fuel reprocessing plants include structures, systems, and components (SSCs) that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those SSCs for applicants of these facilities that meet certain eligibility criteria. Those applicants may elect to use this appendix as an alternative to the quality assurance requirements in appendix B to this part, ''Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.'' To reference this appendix in an application for a construction permit, operating license, or combined license, an applicant must demonstrate it meets the following criteria:

A. The application is for an nth-of-a-kind construction permit, operating license, or combined license that identifies the first-of-a-kind reference plant in the application and any departures from the first-of-a-kind reference plant;

B. Departures from the first-of-a-kind reference plant do not change the classification, design, and method of manufacture, construction, operation, including the design and operational controls, of structures, systems, and components within the scope of this appendix; and

C. Procedures and work processes for implementing the requirements in this appendix, including a mechanism to identify and promptly correct adverse changes in performance reliability of SSCs within the scope of this appendix, have been established and included in the application.

II. Definitions

First-of-a-kind (FOAK) means those nuclear power plants and fuel reprocessing plants that are the initial implementation of a reactor design or technology or fuel reprocessing plant design that has not been previously constructed and operated at commercial scale.

Functional design criteria means metrics for the performance of SSCs. For SR SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in § 53.210. For NSRSS SSCs, these criteria define performance metrics necessary to demonstrate compliance with the safety criteria in § 53.220.

Non-safety-related but safety-significant (NSRSS) structures, systems, and components (SSCs) means those SSCs that are not safety-related but are relied on to achieve adequate defense in depth or perform risk-significant functions and warrant special treatment.

Nth-of-a-kind (NOAK) means those nuclear power plants and fuel reprocessing plants that are subsequent implementations of a reactor design or technology or fuel reprocessing plant design that reference the FOAK plant after the FOAK has been designed, constructed, and operated.

Quality assurance means all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those actions related to the physical characteristics of a material, structure, component, or system to ensure the material, structure, component, or system will meet predetermined requirements.

Quality assurance program means the overall program established to assign responsibilities and authorities, define policies and requirements, and provide for the performance and assessment of work.

Quality management system means a structured framework that documents an organization's processes, procedures, and responsibilities for ensuring quality.

III. General Requirements

A. *Integrated Quality Assurance Program.* The applicant must establish a quality assurance program, document the quality assurance program in the quality management system, and submit the quality management system to the NRC for review and approval. The quality management system must meet the requirements found in Section IV of this appendix. The applicant must implement the approved quality management system. A quality assurance program must be established that ensures that safety-related SSCs, as defined in § 50.2, and NSRSS SSCs, for applications under parts 50 and 52 of this chapter, and safety-related SSCs, as defined in § 53.020, and NSRSS SSCs, for applications under part 53 of this chapter, are designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions those structures, systems, and components perform. In describing the quality assurance program, the quality management system must identify, at the minimum, and explain in detail:

1. All relevant responsibilities and accountabilities of personnel performing functions related to implementation of the quality assurance program, including any delegation of such functions.

2. Measures for ensuring that—

i. the design bases requirements, for those applications under parts 50 and 52 of this chapter, and functional design criteria, for those applications under part 53, of the SSCs within the scope of the quality management system are adequately translated into technical specifications, drawings, procedures, and instructions;

ii. the design is verified to meet technical, quality, and regulatory requirements; and

iii. the as-built and as-operated SSCs are validated to meet the intended function and safety margin.

3. Bidirectional communication pathways for ensuring that all relevant requirements, expectations, concerns, and issues are transmitted through contractual obligations and other means between the applicant or licensee and vendors and third-party suppliers, as appropriate.

4. Measures to—

i. ensure that procured SSCs and related services meet technical and quality requirements; and

ii. to assess the capability of vendors or third-party suppliers that supply the SSCs and related services to meet expectations for product, service, or operational quality.

5. Measures established to—

i. verify and validate that products and services meet the technical and quality requirements of the procured products and services; and

ii. audit the vendors or third-party suppliers that are providing the products and services.

6. Processes implemented to identify, correct, and prevent reoccurrence of issues and failures that could adversely impact quality, safety, and regulatory compliance.

7. Recordkeeping and documentation protocols for the quality assurance program that support demonstrating that SSCs are properly designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety functions those components perform.

B. *Quality Assurance Program Development and Implementation.* The quality assurance program, as documented in the quality management system, must:

1. Contain a graded approach for all quality assurance activities based on the safety significance of the applicable covered SSCs. A graded approach must be used to implement the requirements of the quality assurance program.

i. The implementation of a graded approach must ensure quality assurance efforts are focused in proportion to the risks associated with a product, process, or project.

ii. A graded approach must provide a process for ensuring that the level of analysis, documentation, and actions used to comply with a requirement are commensurate with:

a. The relative importance to safety, safeguards, and security of each structure, system, and component that is governed by the quality assurance program.

b. The magnitude of any hazard involved.

c. The life-cycle stage of a facility.

d. The type of facility.

e. The particular characteristics of a facility.

f. The relative importance to radiological hazards.

g. Any other relevant factors.

iii. The basis of any graded approach must be documented for each applicable quality assurance requirement of this regulation and must be submitted as part of an application. The graded approach may not be used to negate any other applicable requirements.

2. The quality management system must describe how the requirements in Section IV of this appendix are met.

3. The applicable quality assurance requirements must be included in procurement documents from the applicant to all relevant contractors, vendors, suppliers, and third-parties.

4. Document the selection of American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)–1, ''Quality Assurance Requirements for Nuclear Facility Applications'' in accordance with § 50.55a(a)(1)(v)(B) or another appropriate industry standard.

i. The necessary level of detail from the standard(s) must be described to achieve quality consistent with regulatory requirements.

ii. Gaps between the selected industry standard(s) and Section IV of this appendix must be addressed within the quality management system.

IV. Quality Assurance Requirements

A. *Quality Assurance Criteria.* For all applications under this appendix, the quality assurance program must establish, identify, and implement processes for meeting the following criteria.

1. Criterion 1—Management: Program.

i. Establish an organizational structure, functional responsibilities, levels of authority, and interfaces for those managing, performing, and assessing quality assurance activities conducted pursuant to this appendix.

ii. Establish management processes, including planning, scheduling, and providing resources, for quality assurance activities conducted pursuant to this appendix.

2. Criterion 2—Management: Personnel Training and Qualification.

i. Ensure that personnel receive training and qualifications to be capable of performing their assigned work for activities covered by this appendix.

ii. Ensure continuing training to personnel to maintain their job proficiency for activities covered by this appendix.

3. Criterion 3—Management: Quality Improvement.

i. Ensure detection and prevention of quality problems for SSCs and activities covered by this appendix.

ii. Identify, control, and correct materials, parts, or components that do not meet established requirements.

iii. Identify the causes of problems and include prevention of recurrence as a part of corrective action planning.

iv. Identify and select opportunities for improvement for the quality assurance program.

4. Criterion 4—Management: Documents and the Associated Records.

i. Prepare, review, approve, issue, use, and revise documents to prescribe processes, specify requirements, or establish designs for SSCs and activities covered by this appendix.

ii. Specify, prepare, review, approve, and maintain these documents as records.

5. Criterion 5—Performance: Work Processes.

i. Perform work consistent with technical standards, administrative controls, and other hazard controls adopted to meet regulatory requirements using approved instructions, procedures, or other appropriate means.

ii. Identify and control materials, parts, and components, including partially fabricated assemblies, to ensure proper use.

iii. Maintain material and equipment to prevent damage, loss, or deterioration.

iv. Calibrate and maintain equipment used for activities affecting quality.

6. Criterion 6—Performance: Design.

i. Design of SSCs and design processes using sound engineering or scientific principles and appropriate standards.

ii. Incorporate applicable requirements, design bases, as defined in § 50.2, and functional design criteria in design work and design changes.

iii. Identify and control design interfaces.

iv. Verify and validate the adequacy of the design of structures, systems, and components using individuals or groups other than those who performed the work.

v. Verify the adequacy of the design of structures, systems, and components before approval and implementation of the design.

vi. Validate the design of the structure, system and components before relying on the structures, systems, and components to perform their intended safety function.

7. Criterion 7—Performance: Procurement.

i. Procure items and services that meet established requirements and verify items and services perform as specified.

ii. Evaluate and select prospective suppliers on the basis of specified criteria that will ensure the requirements of this appendix are met.

iii. Ensure that approved suppliers continue to provide acceptable items and services.

8. Criterion 8—Performance: Inspection and Acceptance Testing.

i. Inspect and test specified items, services, and processes using established acceptance and performance criteria.

ii. Calibrate and maintain equipment used for inspections and tests.

9. Criterion 9—Performance: Maintenance of structures, systems, and components. Control the storage of structures, systems, and components consistent with appropriate cleanliness and environmental standards.

10. Criterion 10—Assessment: Management Assessment. Ensure that managers assess their management processes and identify and correct problems that hinder the organization from achieving its objectives.

11. Criterion 11—Assessment: Independent Assessment.

i. Plan and conduct independent assessments to measure item and service quality, the adequacy of work performance, and to promote improvement.

ii. Establish sufficient authority and freedom from line management for independent assessment teams.

iii. Ensure personnel who perform independent assessments are technically qualified and knowledgeable in the areas to be assessed.

B. *Quality Assurance for Software Used in Design and Analysis, and Digital Items Important to Safety.* Processes for software quality assurance must be identified, established, and implemented within the quality assurance program and documented in the quality management system.

1. Software quality assurance processes must be applied to software used—

i. in digital items for SSCs within the scope of this appendix;

ii. for design verification for SSCs within the scope of this appendix; and

iii. for design analysis of SSCs within the scope of this appendix.

2. Software used for the applications identified in paragraph 1 of this section must be documented, managed, and controlled throughout its life cycle to ensure that the safety functions will be performed under design basis conditions.

3. Appropriate national or international software engineering standard(s) must be used (*e.g.,* ASME, Institute for Electrical and Electronics Engineers (IEEE), National Institutes of Standards and Technology (NIST), American Nuclear Society (ANS), etc.). These standards may include combinations of standards.

PART 51—ENVIRONMENTAL PROTECTION REGULATIONS FOR DOMESTIC LICENSING AND RELATED REGULATORY FUNCTIONS

■ 32. The authority citation for part 51 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 161, 193 (42 U.S.C. 2201, 2243); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); National Environmental Policy Act of 1969 (42 U.S.C. 4332, 4334, 4335); Nuclear Waste Policy Act of 1982, secs. 144(f), 121, 135, 141, 148 (42 U.S.C. 10134(f), 10141, 10155, 10161, 10168); 44 U.S.C. 3504 note.

Sections 51.20, 51.30, 51.60, 51.80, and 51.97 also issued under Nuclear Waste Policy Act secs. 135, 141, 148 (42 U.S.C. 10155, 10161, 10168).

Section 51.22 also issued under Atomic Energy Act sec. 274 (42 U.S.C. 2021) and under Nuclear Waste Policy Act sec. 121 (42 U.S.C. 10141).

Sections 51.43, 51.67, and 51.109 also issued under Nuclear Waste Policy Act sec. 114(f) (42 U.S.C. 10134(f)).

■ 33. In 51.4, revise the definition for ''*Construction*'' to read as follows:

§ 51.4 Definitions.

* * * * *

Construction means:

(1) For production and utilization facilities, the activities in paragraph (1)(i) of this definition.

(i) Activities constituting construction are the driving of piles, subsurface preparation, placement of backfill, concrete, or permanent retaining walls within an excavation, installation of foundations, or in-place assembly, erection, fabrication, or testing, which are for:

(A) Safety-related structures, systems, or components (SSCs) of a facility, as defined in § 50.2 of this chapter;

(B) SSCs that perform safety-significant functions; and

(C) SSCs necessary to comply with part 73 of this chapter.

(ii) With respect to production or utilization facilities, other than testing facilities and nuclear power plants, required to be licensed under section 104a. or section 104c. of the Act, construction does not include the erection of buildings which will be used for activities other than operation of a facility and which may also be used to house a facility (*e.g.,* the construction of a college laboratory building with space for installation of a training reactor).

(iii) Any activities that are determined to be outside the scope of those defined in the definition of construction in § 51.4 and that are undertaken by an applicant or on its behalf are entirely at the risk of the applicant and has no bearing on the issuance of an environmental assessment, environmental impact statement or finding of no significant impact with respect to NRC's regulated activities under the requirements of the Act, and rules, regulations issued under the Act.

(2) For materials licenses, taking any site-preparation activity at the site of a facility subject to the regulations in parts 30, 36, 40, and 70 of this chapter that has a reasonable nexus to radiological health and safety or the common defense and security; provided, however, that construction does not mean taking any other action that has no reasonable nexus to radiological health and safety or the common defense and security.

* * * * *

■ 34. In § 51.51, revise table note 1 of table S–3 to read as follows:

§ 51.51 Uranium fuel cycle environmental data—Table S–3.

* * * * *

(b) * * *

TABLE S–3—TABLE OF URANIUM FUEL CYCLE ENVIRONMENTAL DATA [1]

[Normalized to model LWR annual fuel requirement [WASH–1248] or reference reactor year [NUREG–0116]] [See footnotes at end of this table]

* * * * * * *

[1] In some cases where no entry appears it is clear from the background documents that the matter was addressed and that, in effect, the table should be read as if a specific zero entry had been made. However, there are other areas that are not addressed at all in the table. Table S–3 does not include health effects from the effluents described in the table or estimates of releases of Radon-222 from the uranium fuel cycle or estimates of Technetium-99 released from waste management or reprocessing activities. These issues may be the subject of litigation in the individual licensing proceedings.

Data supporting this table are given in the ''Environmental Survey of the Uranium Fuel Cycle,'' WASH–1248, April 1974; the ''Environmental Survey of the Reprocessing and Waste Management Portion of the LWR Fuel Cycle,'' NUREG–0116 (Supp.1 to WASH–1248); the ''Public Comments and Task Force Responses Regarding the Environmental Survey of the Reprocessing and Waste Management Portions of the LWR Fuel Cycle,'' NUREG–0216 (Supp. 2 to WASH–1248); and in the record of the final rulemaking pertaining to Uranium Fuel Cycle Impacts from Spent Fuel Reprocessing and Radioactive Waste Management, Docket RM–50–3. The contributions from reprocessing, waste management and transportation of wastes are maximized for either of the two fuel cycles (uranium only and no recycle). The contribution from transportation excludes transportation of cold fuel to a reactor and of irradiated fuel and radioactive wastes from a reactor which are considered in table S–4 of § 51.20(g). The contributions from the other steps of the fuel cycle are given in columns A–E of table S–3A of WASH–1248.

The analysis in NUREG–2249, ''Generic Environmental Impact Statement for Licensing of New Nuclear Reactors—Final Report,'' December 2025, extends this table up to an enrichment of 20.0 weight percent uranium-235 for environmental effects of uranium recovery (which replaced uranium mining and milling), the production of uranium hexafluoride, gaseous centrifuge isotopic enrichment (which replaced gaseous diffusion isotopic enrichment), and fuel fabrication. The analysis in NUREG–2266, ''Environmental Evaluation of Accident Tolerant Fuels with Increased Enrichment and Higher Burnup Levels,'' July 2024, extends the assembly averaged level of burnup of the irradiated fuel from the reactor of up to 80,000 megawatt-days per metric ton as related to uranium fuel cycle activities.

* * * * *

■ 35. Revise and republish § 51.52 to read as follows:

§ 51.52 Environmental effects of transportation of fuel and waste—Table S–4.

Under § 51.50, every environmental report prepared for the construction permit stage or early site permit stage or combined license stage of a light-water-cooled and other than light-water-cooled nuclear power reactor, and submitted after February 4, 1975, must contain a statement concerning transportation of fuel and radioactive wastes to and from the reactor. That statement must indicate that the reactor and this transportation meet either all of the conditions in paragraph (a) of this section or all of the conditions of paragraph (b) of this section.

(a)

(1) The reactor has a core thermal power level not exceeding 3,800 megawatts;

(2) The reactor fuel is in the form of sintered uranium dioxide pellets having a uranium-235 enrichment not exceeding 8% by weight, and the pellets are encapsulated in zircaloy rods;

(3) The average level of irradiation of the irradiated fuel from the reactor does not exceed 80,000 megawatt-days per metric ton, and no irradiated fuel assembly is shipped until at least 90 days after it is discharged from the reactor;

(4) With the exception of irradiated fuel, all radioactive waste shipped from the reactor is packaged and in a solid form;

(5) Unirradiated fuel is shipped to the reactor by truck; irradiated fuel is shipped from the reactor by truck, rail, or barge; and radioactive waste other than irradiated fuel is shipped from the reactor by truck or rail; and

(6) The environmental impacts of transportation of fuel and waste to and from the reactor, with respect to normal conditions of transport and possible accidents in transport, are as set forth in summary table S–4 in paragraph (c) of this section; and the values in the table represent the contribution of the transportation to the environmental costs of licensing the reactor.

(b) For light-water-cooled and other than light-water-cooled reactors not meeting the conditions of paragraph (a) of this section, the statement must contain a full description and detailed analysis of the environmental effects of transportation of fuel and wastes to and from the reactor, including values for the environmental impact under normal conditions of transport and for the environmental risk from accidents in transport. The statement must indicate that the values determined by the analysis represent the contribution of such effects to the environmental costs of licensing the reactor.

(c)

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Summary Table S–4—Environmental Impact of Transportation of Fuel and Waste To and From One Nuclear Power Reactor [1], [2] Normal Conditions of Transport

	Environmental impact
Heat (per irradiated fuel cask in transit)	250,000 Btu/hr
Weight (governed by Federal or State restrictions)	80,000 lb per truck; up to 210 tons per cask per rail car
Traffic density:	
Truck	Less than 1 per day
Rail	Less than 3 per month

Exposed population	Estimated number of persons exposed	Range of doses to exposed individuals[3] (per reactor year)
Transportation workers	200	0.01 to 300 millirem
General public:		
Onlookers	107,000	0.003 to 1.3 millirem
Along Route	1,362,000	0.0001 to 0.06 millirem

Accidents in Transport

	Environmental risk
Radiological effects	Small[4]
Common (nonradiological) causes	1 fatal injury in 100 reactor years; 1 nonfatal injury in 10 reactor years.

[1] Data supporting this table are given in the Commission's "Environmental Survey of Transportation of Radioactive Materials to and from Nuclear Power Plants," WASH–1238, December 1972; and Supp. 1 of NUREG–75/038, April 1975. Both documents are available for inspection and copying at the Commission's Public Document Room, One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland 20852 and may be obtained from National Technical Information Service, Springfield, VA 22161. The WASH–1238 is available from NTIS at a cost of $5.45 (microfiche, $2.25) and NUREG–75/038 is available at a cost of $3.25 (microfiche, $2.25).

[2] The analysis in NUREG-2266, "Environmental Evaluation of Accident Tolerant Fuels with Increased Enrichment and Higher Burnup Levels," July 2024, extends this table up to an enrichment of 8 weight percent uranium-235 and the assembly averaged level of irradiation of the irradiated fuel from the reactor of up to 80,000 megawatt-days per metric ton for UO_2 fuel and increases the estimated number of general public members exposed to radiation for the environmental impact of transportation of fuel and waste to and from one nuclear power reactor. The analysis in NUREG-2249, "Generic Environmental Impact Statement for Licensing of New Nuclear Reactors - Final Report," December 2025, extends this table to TRISO fuel with peak pellet burnup of up to133,000 MWd/MTU.

[3] The Federal Radiation Council has recommended that the radiation doses from all sources of radiation other than natural background and medical exposures should be limited to 5,000 millirem per year for individuals as a result of occupational exposure and should be limited to 500 millirem per year for individuals in the general population. The dose to individuals due to average natural background radiation is about 130 millirem per year.

[4] The environmental risk of radiological effects stemming from transportation accidents is small regardless of whether it is being applied to a single reactor or a multireactor site. Radioactive material would not be released in an accident if the fuel is contained in an inner welded canister inside the transport package. Only rail transport packages without inner welded canisters would release radioactive material and only then in exceptionally severe accidents.

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PART 52—LICENSES, CERTIFICATIONS, AND APPROVALS FOR NUCLEAR POWER PLANTS

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

Authority: Atomic Energy Act of 1954, secs. 103, 104, 147, 149, 161, 181, 182, 183, 185, 186, 189, 223, 234 (42 U.S.C. 2133, 2134, 2167, 2169, 2201, 2231, 2232, 2233, 2235, 2236, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); 44 U.S.C. 3504 note.

■ 37. In § 52.1, in paragraph (a), add in alphabetical order the definitions ''*Tier 1*'', ''*Tier 2*'', and ''*Tier 2**'' to read as follows:

§ 52.1 Definitions.

(a) * * *

Tier 1 means, for design certifications issued after [EFFECTIVE DATE OF FINAL RULE], the qualitative and functional-level portion of the design-related information contained in the generic design control document, including ITAAC, that is approved and certified by a standard design certification. The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. For design certifications issued prior to [EFFECTIVE DATE OF FINAL RULE], see the definition of this term in the applicable appendix to this part.

Tier 2 means, for design certifications issued after [EFFECTIVE DATE OF FINAL RULE], the portion of the design-related information contained in the generic design control document that is approved, but not certified, by a standard design certification. Compliance with Tier 2 is required, but generic changes to, and plant specific departures from, Tier 2 are governed by the process set out in the applicable appendix to this part. Compliance with Tier 2 provides a sufficient, but not the only acceptable, method for complying with Tier 1. Compliance methods differing from Tier 2 must satisfy the change process in the applicable appendix to this part. Regardless of these differences, an applicant or licensee must meet the requirement in the applicable appendix to this part to reference Tier 2 when referencing Tier 1. For design certifications issued prior to [EFFECTIVE DATE OF FINAL RULE], see the definition of this term in the applicable appendix to this part.

*Tier 2** means, for design certifications issued after [EFFECTIVE DATE OF FINAL RULE], the portion of the Tier 2 information containing the qualitative and functional-level portion of design-related information, designated as such in the generic design control document, that is subject to the change process for such information that is specified in a standard design certification rule. After a plant first achieves full power, Tier 2* information in the plant-specific design control document for that plant reverts to Tier 2 status and is thereafter subject to the change and departure provisions for Tier 2 information. For design certifications issued prior to [EFFECTIVE DATE OF FINAL RULE], see the definition of this term in the applicable appendix to this part.

* * * * *

§ 52.15 [Amended]

■ 38. In § 52.15, in paragraph (c), remove the word ''renewal'' and add in its place the word ''amendment''.

■ 39. In § 52.17, revise paragraph (a)(1)(ix) and footnotes 1 and 2 to read as follows:

§ 52.17 Contents of applications; technical information.

(a) * * *

(1) * * *

(ix) A description and safety assessment of the site on which a facility is to be located. The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(ix)(A) and (a)(1)(ix)(B) of this section. In performing this assessment, an applicant shall assume a fission product release [1] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE).

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE;

* * * * *

[1] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

■ 40. Revise § 52.18 to read as follows:

§ 52.18 Standards for review of applications.

Applications for the initial issuance of an early site permit filed under this subpart will be reviewed according to the applicable standards set out in part 50 of this chapter and its appendices and part 100 of this chapter. In addition, the Commission shall prepare an environmental impact statement during review of the application, in accordance with the provisions of part 51 of this chapter. The Commission shall determine, after consultation with Federal Emergency Management Agency, as applicable, whether the information required of the applicant by § 52.17(b)(1) shows that there is not a significant impediment to the development of emergency plans that cannot be mitigated or eliminated by measures proposed by the applicant, whether any major features of emergency plans submitted by the applicant under § 52.17(b)(2)(i) are acceptable in accordance with either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter, and whether any emergency plans submitted by the applicant under § 52.17(b)(2)(ii) provide reasonable assurance that adequate protective measures can and will be taken in the event of a radiological emergency.

§ 52.25 [Amended]

■ 41. In § 52.25, in the first sentence, remove the phrase ''performed and the site is not referenced in an application

for a construction permit or a combined license issued under subpart C of this part while the permit remains valid,'' and add in its place the phrase ''performed, and the early site permit holder has applied for termination,''.

■ 42. In § 52.26, revise paragraph (a) and remove and reserve paragraph (b) to read as follows:

§ 52.26 Duration of permit.

(a) An early site permit issued under this subpart will be issued with no fixed term.

(b) [Reserved]

* * * * *

■ 43. Revise § 52.29 to read as follows:

§ 52.29 Application for amendment to update an early site permit.

(a) An early site permit holder may choose to submit an application to amend an early site permit to update the data and information on which the permit is based at any time after issuance of the early site permit. The early site permit holder may provide updated information on as many issues as the early site permit holder chooses and may request to extend the period for which the agency will afford those issues finality up to 20 additional years from the date of the amendment's issuance. The early site permit holder may request such an extension for an already extended permit. The application must meet the requirements of §§ 50.90 and 50.92 of this chapter.

(b) An application submitted under paragraph (a) of this section must contain all information necessary to bring up to date the information and data contained in the previous application for those issues the early site permit holder has chosen to update.

(c) Each application must include an environmental report as required by part 51 of this chapter, or a request and justification for a categorical exclusion under part 51 of this chapter.

(d) Any person whose interest may be affected by the update of the permit may request a hearing on the application for the update. The request for a hearing must comply with § 2.309 of this chapter. If a hearing is granted, notice of the hearing will be published in accordance with § 2.309 of this chapter.

■ 44. Revise § 52.31 to read as follows:

§ 52.31 Issuance of amendment to update an early site permit.

The Commission shall grant amendment of an early site permit only if it determines that:

(a) The site complies with the Act, the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued, except early site permits issued before [EFFECTIVE DATE OF THE FINAL RULE] are no longer subject to § 52.26(a); and

(b) Any new requirements the Commission may wish to impose are necessary for adequate protection to public health and safety or common defense and security.

§ 52.33 [Removed and Reserved]

■ 45. Remove and reserve § 52.33.

■ 46. Revise § 52.35 to read as follows:

§ 52.35 Use of site for other purposes.

(a) A site for which an early site permit has been issued under this subpart may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder shall inform the Director, Office of Nuclear Reactor Regulation (Director), of any significant uses for the site which have not been approved in the early site permit. The information about the activities must be given to the Director at least 30 days in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, in accordance with the provisions of § 52.39.

(b) If the permit holder no longer intends to use the site for a nuclear power plant or for other reasons no longer wishes to hold the permit, as described in the request, the permit holder may at any time request the Director to terminate the early site permit. The request to terminate the permit must comply with the filing requirements of §§ 52.3 and 50.30 of this chapter, and identify the applicable requirements for site redress of § 52.25. Upon request, the Director may terminate the permit.

(c) Termination of the early site permit does not bar the permit holder or another applicant from filing a new application for the site.

■ 47. In § 52.39,

■ a. In paragraph (a)(1), remove the references ''§§ 52.26 or 52.33'' and add in its place the reference ''§ 52.26'';

■ b. In paragraph (a)(2) introductory text, remove the word ''renewal'' and add in its place the word ''amendment'';

■ c. Revise paragraphs (c)(1)(iv) and (v);

■ d. Add paragraph (c)(1)(vi);

■ e. In paragraph (d), remove the word ''renewed'' and add in its place the word ''amended''; and

■ f. In paragraph (e), remove the references ''10 CFR 50.90 and 50.92'' and add in its place the references ''§§ 50.90, 50.92, and 52.29 of this chapter''.

The revisions and additions are to read as follows:

§ 52.39 Finality of early site permit determinations.

* * * * *

(c) * * *

(1) * * *

(iv) New or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness;

(v) The information as required in the site safety analysis report in accordance with § 52.17(a)(1)(vi) through (ix) has not been updated after 20 years from the date of early site permit issuance or a previous update of the permit by amendment, whichever is later; and

(vi) (A) Any significant environmental issue that was not resolved in the early site permit proceeding;

(B) For an application that references an early site permit issued or updated by amendment, whichever is later, no more than 20 years before the submission of the application, any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified; or

(C) For an application that references an early site permit, issued or updated by amendment, whichever is later, more than 20 years before submission of the application, any issue involving the impacts of construction and operation of the facility regardless of whether the early site permit proceeding resolved the issue.

* * * * *

■ 48. In § 52.47,

■ a. Revise paragraph (a)(2)(iv);

■ b. In paragraph (a)(4), remove the last sentence; and

■ c. Redesignate footnotes 3 and 4 as footnotes 1 and 2 and revise footnotes 1 and 2 to read as follows:

§ 52.47 Contents of applications; technical information.

* * * * *

(a) * * *

(2) * * *

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an

applicant shall assume a fission product release [1] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE);

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE;

* * * * *

[1] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

■ 49. In § 52.54, revise paragraph (a) introductory text and paragraph (b) to read as follows:

§ 52.54 Issuance of standard design certification.

(a) After conducting a rulemaking proceeding under § 52.51 on an application for a standard design certification and receiving the report to be submitted by the Advisory Committee on Reactor Safeguards under § 52.53, the Commission may issue a standard design certification in the form of a rule for the design that is the subject of the application, if the Commission determines that:

* * * * *

(b) The standard design certification rule must specify the site parameters, design characteristics, and any additional requirements and restrictions of the standard design certification rule. A standard design certification rule that was reviewed and approved as meeting the requirements of § 50.46a of this chapter must specify the criteria governing departures that a referencing combined license must meet. The criteria must ensure that the safety bases for the NRC's approval of the certified design's compliance with § 50.46a of this chapter (including applicability of the transition break size) continue to apply despite the departure.

* * * * *

■ 50. In § 52.63,

■ a. In paragraph (a)(1)(v) at the end of the sentence, add the word ''or'' after ''information;'';

■ b. In paragraph (a)(1)(vi) at the end of the sentence, remove the phrase ''security; or'' and add in its place the word ''security.'';

■ c. Remove paragraph (a)(1)(vii); and

■ d. Revise paragraphs (a)(4)(ii) and (b)(1) to read as follows:

§ 52.63 Finality of standard design certifications.

(a) * * *

(4) * * *

(ii) Special circumstances as defined in § 52.7 are present.

* * * * *

(b)

(1) An applicant or licensee who references a design certification rule may request an exemption from one or more elements of the certification information if one is required by the applicable change process within the referenced design certification rule. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 52.7. The granting of an exemption on request of an applicant is subject to litigation in the same manner as other issues in the operating license or combined license hearing.

* * * * *

■ 51. In § 52.79,

■ a. Revise and republish paragraphs (a)(1)(vi), (a)(2)(iv), (a)(5), (a)(21), (a)(25), (a)(27), (a)(36)(i), and (b);

■ b. Add paragraph (a)(48); and

■ c. Redesignate footnotes 5 through 8 as footnotes 1 through 4 and revise footnotes 1 through 4 to read as follows:

§ 52.79 Contents of applications; technical information in final safety analysis report.

(a) * * *

(1) * * *

(vi) A description and safety assessment of the site on which the facility is to be located. The assessment must contain an analysis and evaluation of the major structures, systems, and components of the facility that bear significantly on the acceptability of the site under the radiological consequence evaluation factors identified in paragraphs (a)(1)(vi)(A) and (a)(1)(vi)(B) of this section. In performing this assessment, an applicant shall assume a fission product release [1] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable site characteristics, including site meteorology, to evaluate the offsite radiological consequences. Site characteristics must comply with part 100 of this chapter. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE).

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE; and

(2) * * *

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release [3] assuming that the facility is operated at the ultimate power level contemplated;

* * * * *

(5) An analysis and evaluation of the design and performance of structures, systems, and components with the objective of assessing the risk to public health and safety resulting from operation of the facility and including determination of the margins of safety

during normal operations and transient conditions anticipated during the life of the facility, and the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents.

* * * * *

(21) Emergency plans complying with either the requirements in § 50.160 of this chapter, or the requirements in appendix E to part 50 of this chapter and § 50.47(b) of this chapter;

* * * * *

(25) A description of the quality assurance program or a quality management system, applied to the design, and to be applied to the fabrication, construction, and testing, of the structures, systems, and components of the facility. Appendix B to part 50 of this chapter sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant must include a discussion of how the applicable requirements of appendix B to part 50 of this chapter have been and will be satisfied, including a discussion of how the quality assurance program will be implemented or for eligible combined license applications. Appendix T to part 50 of this chapter, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth streamlined requirements for quality assurance programs for nuclear power plants and fuel reprocessing plants that an eligible combined license applicant may voluntarily use as an alternative to appendix B to part 50 of this chapter. The quality management system, required by appendix T to part 50 of this chapter, for a nuclear power plant or fuel reprocessing plant shall include discussions of how the applicable requirements of appendix T to part 50 of this chapter will be satisfied;

* * * * *

(27) Managerial and administrative controls to be used to assure safe operation. Appendix B to part 50 of this chapter sets forth the requirements for these controls for nuclear power plants. The information on the controls to be used for a nuclear power plant shall include a discussion of how the applicable requirements of appendix B to part 50 of this chapter will be satisfied. Appendix T to part 50 of this chapter, ''Streamlined Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,'' sets forth streamlined requirements for such controls for nuclear power plants and fuel reprocessing plants that an eligible combined license applicant may voluntarily use as an alternative to appendix B to part 50 of this chapter. The quality management system, required by appendix T to part 50 of this chapter, for a nuclear power plant or fuel reprocessing plant shall include discussions of how the applicable requirements of appendix T to part 50 of this chapter will be satisfied;

* * * * *

(36) (i) A safeguards contingency plan in accordance with the criteria set forth in appendix C to part 73 of this chapter. The safeguards contingency plan shall include plans for dealing with threats, thefts, and radiological sabotage, as defined in part 73 of this chapter, relating to the special nuclear material and nuclear facilities licensed under this chapter and in the applicant's possession and control. Each application for this type of license shall include the information contained in the applicant's safeguards contingency plan.[4] (Implementing procedures required for this plan need not be submitted for approval.)

* * * * *

(48) An applicant may include in its application a request for generic finality, to generic aspects of the design under this part, such that information in the application, if approved by the NRC, is considered resolved in other proceedings where information approved for generic finality is referenced. An application for a combined license that requests generic finality must include applicable site parameters postulated for the design, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

(b) If the combined license application references an early site permit, then the following requirements apply:

(1) The final safety analysis report need not contain information or analyses submitted to the Commission in connection with the early site permit, provided, however, that the final safety analysis report must either include or incorporate by reference the early site permit site safety analysis report and must contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the final safety analysis report does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application shall include a request for a variance that complies with the requirements of §§ 52.39 and 52.93.

(3) If the early site permit site safety analysis report information required by § 52.17(a)(1)(vi) through (ix) has not been updated after 20 years from the date of early site permit issuance or a previous update of the permit by amendment, whichever is later, the combined license application shall include updated information and revised analyses, as necessary, in the final safety analysis report. The referencing application need not update the postulated source term stated in the early site permit if it falls within the source term derived from the design. If the postulated source term stated in the early site permit does not fall within the source term derived from the design, the referencing application must propose a variance from the early site permit that complies with the requirements of §§ 52.39 and 52.93.

(4) The final safety analysis report must demonstrate that all terms and conditions that have been included in the early site permit, other than those imposed under § 50.36b of this chapter, will be satisfied by the date of issuance of the combined license. Any terms or conditions of the early site permit that could not be met by the time of issuance of the combined license, must be set forth as terms or conditions of the combined license.

(5) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the final safety analysis report must include any new or additional information that updates and corrects the information that was provided under § 52.17(b), and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or would constitute a reduction in effectiveness under § 50.54(q) of this chapter.

(6) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(22) of this section are not required.

* * * * *

[1] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad

range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

[3] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[4] A physical security plan that contains all the information required in both § 73.55 of this chapter and appendix C to 10 CFR part 73 satisfies the requirement for a contingency.

■ 52. Revise § 52.85 to read as follows:

§ 52.85 Administrative review of applications; hearings.

(a) A proceeding on a combined license is subject to all applicable procedural requirements contained in part 2 of this chapter, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). If an applicant requests a Commission finding on certain ITAAC with the issuance of the combined license, then those ITAAC will be identified in the notice of hearing. All hearings on combined licenses are governed by the procedures contained in part 2 of this chapter.

(b) If an applicant requests generic finality under § 52.79(a)(48), the Commission will include a request for generic finality as a proposed action in the notice of hearing required by § 2.104 of this chapter.

§ 52.93 [Amended]

■ 53. In § 52.93, in paragraph (c) remove the last sentence.

■ 54. In § 52.97, add paragraph (d) to read as follows:

§ 52.97 Issuance of combined licenses.

* * * * *

(d) The Commission may afford generic finality to generic aspects of the design of a utilization facility, including postulated site parameters, and requirements submitted pursuant to § 52.79(a)(48), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design in accordance with applicable requirements and without undue risk to the health and safety of the public.

■ 55. In § 52.98, revise paragraph (b), remove and reserve paragraph (d), and add paragraph (h) to read as follows:

§ 52.98 Finality of combined licenses; information requests.

* * * * *

(b) If the combined license does not reference a design certification, then a licensee may make changes in the facility as described in the final safety analysis report (as updated), make changes in the procedures as described in the final safety analysis report (as updated), and conduct tests or experiments not described in the final safety analysis report (as updated) under the applicable change processes in part 50 of this chapter (*e.g.,* § 50.54, § 50.59, or § 50.90 of this chapter).

* * * * *

(d) [Reserved]

* * * * *

(h) In a proceeding for the issuance of a construction permit, operating license, or combined license, or in any enforcement hearing other than one initiated by the Commission under paragraph (a) of this section, in which a combined license issued under this subpart is referenced, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the referenced combined license, including, if applicable, the adequacy of a reactor design where the referenced combined license was afforded finality pursuant to § 52.97(d).

■ 56. In § 52.137,

■ a. Revise and republish paragraph (a)(2)(iv);

■ b. In paragraph (a)(4), remove the word ''SSC'' and add in its place the word ''SSCs'' and remove the last sentence; and

■ c. Redesignate footnotes 9 and 10 as footnotes 1 and 2 and revise footnotes 1 and 2 to read as follows:

§ 52.137 Contents of applications; technical information.

* * * * *

(a) * * *

(2) * * *

(iv) The safety features that are to be engineered into the facility and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to plant design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release [1] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(A) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE); and

(B) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE;

* * * * *

[1] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

■ 57. In § 52.157,

■ a. Revise and republish paragraph (d);

■ b. In paragraph (f)(1), remove the last sentence;

■ c. Redesignate footnotes 11 and 12 as footnotes 1 and 2 and revise footnotes 1 and 2.

The addition and revisions are to read as follows:

§ 52.157 Contents of applications; technical information in final safety analysis report.

* * * * *

(d) The safety features that are engineered into the reactor and those barriers that must be breached as a result of an accident before a release of radioactive material to the environment can occur. Special attention must be directed to reactor design features intended to mitigate the radiological consequences of accidents. In performing this assessment, an applicant shall assume a fission product release [1] assuming that the facility is operated at the ultimate power level contemplated. The applicant shall perform an evaluation and analysis of the postulated fission product release, using the expected demonstrable leakage rates from potential flow paths and any fission product cleanup systems intended to mitigate the consequences of the accidents, together with applicable postulated site parameters, including site meteorology, to evaluate the offsite radiological consequences. The evaluation must determine that:

(1) An individual located at any point on the boundary of the exclusion area for any 2-hour period following the onset of the postulated fission product release, would not receive a radiation dose in excess of 25 rem [2] (0.25 Sv) total effective dose equivalent (TEDE); and

(2) An individual located at any point on the outer boundary of the low population zone, who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a radiation dose in excess of 25 rem (0.25 Sv) TEDE;

* * * * *

[1] The fission product release assumed for this evaluation should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents. These accidents have generally been assumed to result in substantial meltdown of the core with subsequent release of appreciable quantities of fission products.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of plant design features with respect to postulated reactor accidents, to assure that these designs provide assurance of low risk of public exposure to radiation, in the event of an accident.

■ 58. Revise and republish § 52.158 to read as follows:

§ 52.158 Contents of application; additional technical information.

(a) *Inspections, tests, analyses, and acceptance criteria (ITAAC).* (1) The application must contain the proposed inspections, tests, and analyses that the licensee who will be operating the reactor shall perform, and the acceptance criteria that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria met:

(i) The reactor has been manufactured in conformity with the manufacturing license, the provisions of the Act, and the Commission's rules and regulations; and

(ii) The manufactured reactor will be operated in conformity with the approved design and any license authorizing operation of the manufactured reactor.

(2) If the application references a standard design certification, the ITAAC contained in the certified design must apply to those portions of the facility design which are covered by the design certification.

(3) If the application references a standard design certification, the application may include a notification that a required inspection, test, or analysis in the design certification ITAAC has been successfully completed and that the corresponding acceptance criterion has been met. The **Federal Register** notification required by § 52.163 must indicate that the application includes this notification.

(b) *Environmental report.* (1) The application must contain an environmental report as required by § 51.54 of this chapter.

(2) If the manufacturing license application references a standard design certification, the environmental report need not contain a discussion of severe accident mitigation design alternatives for the reactor.

(c) *Optional operational programs.* An applicant may include in its application descriptions of essentially complete programmatic controls, operational programs, or operational requirements beyond those required by § 52.157 in order to satisfy requirements for license applications that may reference a manufacturing license. If approved by the NRC as part of the manufacturing license, such programmatic controls, operational programs, and operational requirements would have finality under § 52.171.

■ 59. In § 52.171, revise paragraphs (a)(1) and (b) to read as follows:

§ 52.171 Finality of manufacturing licenses; information requests.

(a)(1) Notwithstanding any provision in § 50.109 of this chapter, during the term of a manufacturing license the Commission may not modify, rescind, or impose new requirements on the design of the nuclear power reactor being manufactured; the requirements for the manufacture of the nuclear power reactor; or the programmatic controls, operational programs, or operational requirements; unless the Commission determines that a modification is necessary to bring the design of the reactor or its manufacture into compliance with the Commission's requirements applicable and in effect at the time the manufacturing license was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

* * * * *

(b)(1) The holder of a manufacturing license may make a change to the facility or procedures as described in the final safety analysis report (as updated) associated with the manufacturing license without obtaining a license amendment pursuant to § 50.90 of this chapter if the change meets the criteria in § 50.59(c)(1) of this chapter. If needed, applications for amending an ML must be submitted and processed in accordance with §§ 50.90, 50.91, and 50.92 of this chapter.

(2) An applicant who references or uses a nuclear power reactor manufactured under a manufacturing license under this subpart may request a departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The granting of a departure on request of an applicant is subject to litigation in the same manner as other issues in the construction permit or combined license hearing.

* * * * *

§ 52.173 [Amended]

■ 60. In § 52.173, remove the phrase ''15 years'' and add in its place ''40 years''.

§ 52.181 [Amended]

■ 61. In § 52.181, remove the phrase ''15 years'' and add in its place ''40 years''.

■ 62. Revise subpart G consisting of § 52.220 and add § 52.220 to read as follows:

Subpart G—Risk-Informed and Performance-Based Alternatives

§ 52.220 Use of risk-informed and performance-based alternatives to acceptance criteria.

For each regulation in this part that provides specified acceptance criteria, applicants may propose an alternative following the requirements in § 50.220 of this chapter.

■ 63. In appendix A to part 52, revise paragraphs II.D., II.F., VI.B.4., VI.B.6., VIII.A., and VIII.B. to read as follows:

Appendix A to Part 52—Design Certification Rule for the U.S. Advanced Boiling Water Reactor

* * * * *

II. * * *

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions, which are located in the following sections of the ABWR Design Control Document, Revision 7: Section 1.0, ''Introduction''; Section 1.1, ''Definitions''; Section 1.2, ''General Provisions''; Appendix A, ''Legend for Figures''; Appendix B, ''Abbreviations and Acronyms Used in the ABWR Certified Design Material''; and Appendix C, ''Conversion to ASME Standard Units'';

2. Design descriptions, which are located in the following sections of the ABWR Design Control Document, Revision 7, and any figures and non-ITAAC tables referenced in these sections: Section 2.0, ''Certified Design for ABWR Systems,'' and Section 3.0, ''Additional Certified Design Material'';

3. Inspections, tests, analyses, and acceptance criteria (ITAAC), which are located in the inspections, tests, analyses column and the acceptance criteria column of the following tables of the ABWR Design Control Document, Revision 7: Tables 2.1.1d, 2.1.2, 2.1.3, 2.2.1, 2.2.2, 2.2.3, 2.2.4, 2.2.5, 2.2.6, 2.2.7, 2.2.8, 2.2.9, 2.2.10, 2.2.11, 2.3.1, 2.3.2, 2.3.3, 2.4.1, 2.4.2, 2.4.3, 2.4.4, 2.5.5, 2.5.6, 2.6.1, 2.6.2, 2.6.3, 2.7.1b, 2.7.3, 2.7.5, 2.8.4, 2.9.1, 2.10.1, 2.10.2a, 2.10.2b, 2.10.4, 2.10.7, 2.10.9, 2.10.13, 2.10.21, 2.10.22, 2.10.23, 2.11.1, 2.11.2, 2.11.3d, 2.11.4, 2.11.5, 2.11.6, 2.11.9, 2.11.10, 2.11.11, 2.11.12, 2.11.13, 2.11.20, 2.11.23, 2.12.1, 2.12.10, 2.12.11, 2.12.12, 2.12.13, 2.12.14, 2.12.15, 2.12.16, 2.12.17, 2.14.1, 2.14.4, 2.14.6, 2.14.7, 2.14.8, 2.14.9, 2.15.3, 2.15.5a, 2.15.5b, 2.15.5c, 2.15.5d, 2.15.5e, 2.15.5f, 2.15.5g, 2.15.5h, 2.15.5i, 2.15.5j, 2.15.5k, 2.15.5l, 2.15.5m, 2.15.6, 2.15.10, 2.15.11, 2.15.12, 2.15.13, 2.15.14, 2.15.15, 2.16.2, 2.17.1, 3.1, 3.2a, 3.2b, 3.3, 3.4, and 3.6.

4. Significant site parameters, which are located in the following section of the ABWR Design Control Document, Revision 7: Section 5.0, ''Site Parameters''; and

5. Significant interface requirements, which are located in the following section of the ABWR Design Control Document, Revision 7: Section 4.0, ''Interface Requirements.''

* * * * *

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in paragraph VIII.B.6 of this appendix. After a plant first achieves full power, Tier 2* information in the plant-specific design control document for that plant reverts to Tier 2 status and is thereafter subject to the departure provisions in paragraph VIII.B.5 of this appendix.

* * * * *

VI. * * *

B. * * *

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4, VIII.A.6, and VIII.B.4 of this appendix, but only for that plant;

* * * * *

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 1 and Tier 2 under and in compliance with the change processes in paragraphs VIII.A.5 and VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

* * * * *

VIII. * * *

A. Tier 1 Information

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraph A.3, A.4, A.5, A.6, or A.7 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).

4. Exemptions from Tier 1 information on definitions and general provisions, significant site parameters, and significant interface requirements are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

5. An applicant or licensee who references this appendix may depart from Tier 1 design description information, without NRC approval, unless the proposed departure requires an exemption under paragraph A.6 of this section.

6. A proposed departure from Tier 1 design descriptions would require an exemption if it would:

a. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

b. Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

c. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

d. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

e. Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

f. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

g. Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered;

h. Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses;

i. Result in a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

j. Result in a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

7. A licensee who references this appendix may not depart from Tier 1 ITAAC without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter and does not require an exemption from this appendix.

8. After the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information are subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information.

B. Tier 2 and Tier 2* Information

1. Generic changes to Tier 2 or Tier 2* information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 2 or Tier 2* information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraph B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 or Tier 2* information by plant-specific order, while this appendix is in effect under § 52.55 or § 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to ensure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in § 50.12(a) of this chapter are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 or Tier 2* information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 50.12(a) of this chapter. The Commission will deny a request for an exemption from Tier 2 or Tier 2*, if it finds that the design change will result in a significant decrease in the level of

safety otherwise provided by the design. The granting of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The granting of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5. a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information (if prior NRC approval is required by paragraph A of this section), Tier 2* information, or the TS, or requires a license amendment under paragraph B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD or one affecting information required by § 52.47(a)(28) to address aircraft impacts, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component important to safety and previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of a structure, system, or component important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of a structure, system, or component important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design-basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2, affecting resolution of a severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. A proposed departure from Tier 2 information required by § 52.47(a)(28) to address aircraft impacts shall consider the effect of the changed design feature or functional capability on the original aircraft impact assessment required by § 50.150(a) of this chapter. The applicant or licensee shall describe, in the plant-specific DCD, how the modified design features and functional capabilities continue to meet the aircraft impact assessment requirements in § 50.150(a)(1) of this chapter.

e. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by § 50.90 of this chapter.

f. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

g. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under § 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to complying with the general requirements of § 2.309 of this chapter, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a § 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6. a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with brackets, italicized text, and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and § 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter.

(1) Fuel burnup limit (4.2).

(2) Fuel design evaluation (4.2.3).

(3) Fuel licensing acceptance criteria (Appendix 4B).

(4) ASME Boiler & Pressure Vessel Code, Section III.

(5) ACI 349 and ANSI/AISC N–690.

(6) Motor-operated valves.

(7) Equipment seismic qualification methods.

(8) Piping design acceptance criteria.

(9) Fuel system and assembly design (4.2), except burnup limit.

(10) Nuclear design (4.3).

(11) Equilibrium cycle and control rod patterns (Appendix 4A).

(12) Control rod licensing acceptance criteria (Appendix 4C).

(13) Instrument setpoint methodology.

(14) EMS performance specifications and architecture.

(15) SSLC hardware and software qualification.

(16) Self-test system design testing features and commitments.

(17) Human factors engineering design and implementation process.

c. After the plant first achieves full power, all Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

* * * * *

■ 64. In appendix D to part 52, remove and reserve section IX, and revise paragraphs II.D., II.F., VI.B.4., VI.B.6, VIII.A., and VIII.B. to read as follows:

Appendix D to Part 52—Design Certification Rule for the AP1000 Design

* * * * *

II. * * *

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions, which are located in the following section of the AP1000 Design Control Document, Revision 19, and amendments thereto in Supplemental Information to Support the AP1000 Design Certification Extension, APP–GW–GL–705 Rev. 0: Section 1, ''Introduction'';

2. Design descriptions, which are located in the sections of the AP1000 Design Control Document, Revision 19, identified in Table 1 to Paragraph D of this appendix, and amendments thereto in Supplemental Information to Support the AP1000 Design Certification Extension, APP–GW–GL–705 Rev. 0 and any figures and non-ITAAC tables referenced in these sections:

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Table 1 to Paragraph D

Section	Title
2.1.1	Fuel Handling and Refueling System
2.1.2	Reactor Coolant System
2.1.3	Reactor System
2.2.1	Containment System
2.2.2	Passive Containment Cooling System
2.2.3	Passive Core Cooling System
2.2.4	Steam Generator System
2.2.5	Main Control Room Emergency Habitability System
2.3.1	Component Cooling Water System
2.3.2	Chemical and Volume Control System
2.3.3	Standby Diesel Fuel Oil System
2.3.4	Fire Protection System
2.3.5	Mechanical Handling System
2.3.6	Normal Residual Heat Removal System
2.3.7	Spent Fuel Pool Cooling System
2.3.8	Service Water System
2.3.9	Containment Hydrogen Control System
2.3.10	Liquid Radwaste System
2.3.11	Gaseous Radwaste System
2.3.12	Solid Radwaste System
2.3.13	Primary Sampling System
2.3.14	Demineralized Water Transfer and Storage System
2.3.15	Compressed and Instrument Air System
2.3.19	Communication System
2.3.29	Radioactive Waste Drain System
3.1	Emergency Response Facilities
3.2	Human Factors Engineering
3.3	Buildings
3.4	Initial Test Program
3.5	Radiation Monitoring
3.6	Reactor Coolant Pressure Boundary Leak Detection
3.7	Design Reliability Assurance Program

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3. Inspections, tests, analyses, and acceptance criteria (ITAAC), which are located in the inspections, tests, analyses column and the acceptance criteria column of the following tables of the AP1000 Design Control Document, Revision 19 and amendments thereto in Supplemental Information to Support the AP1000 Design Certification Extension, APP–GW–GL–705 Rev. 0: Tables 2.1.1–1, 2.1.2–4, 2.1.3–2, 2.2.1–3, 2.2.2–3, 2.2.3–4, 2.2.4–4, 2.2.5–5, 2.3.1–2, 2.3.2–4, 2.3.3–2, 2.3.4–2, 2.3.5–2, 2.3.6–4, 2.3.7–4, 2.3.8–2, 2.3.9–3, 2.3.10–4, 2.3.11–2, 2.3.12–1, 2.3.13–3, 2.3.14–2, 2.3.15–2, 2.3.19–2, 2.3.29–1, 3.1–1, 3.2–1, 3.3–6, 3.5–6, 3.6–1, and 3.7–3.

4. Significant site parameters, which are located in the following section of the AP1000 Design Control Document, Revision 19, and amendments thereto in Supplemental Information to Support the AP1000 Design Certification Extension, APP–GW–GL–705 Rev. 0: Section 5, ''Site Parameters''; and

5. Significant interface requirements, which are located in the following section of the AP1000 Design Control Document, Revision 19, and amendments thereto in Supplemental Information to Support the AP1000 Design Certification Extension, APP–GW–GL–705 Rev. 0: Section 4, ''Interface Requirements.''

* * * * *

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in Section VIII.B.5 of this appendix.

* * * * *

VI. * * *

B. * * *

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4, VIII.A.6, and VIII.B.4 of this appendix, but only for that plant;

* * * * *

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 1, Tier 2, and Tier 2* under and in compliance with the change processes in paragraphs VIII.A.5 and VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

* * * * *

VIII. * * *

A. Tier 1 information.

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under

paragraphs A.3, A.4, A.5, A.6, or A.7 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).

4. Exemptions from Tier 1 information on definitions and general provisions, significant site parameters, and significant interface requirements are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

5. An applicant or licensee who references this appendix may depart from Tier 1 design description information, without NRC approval, unless the proposed departure requires an exemption under paragraph A.6 of this section.

6. A proposed departure from Tier 1 design descriptions would require an exemption if it would:

a. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

b. Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

c. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

d. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

e. Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

f. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

g. Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered;

h. Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses;

i. Result in a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

j. Result in a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

7. A licensee who references this appendix may not depart from Tier 1 ITAAC without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter and does not require an exemption from this appendix.

8. After the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information are subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information.

B. Tier 2 and Tier 2* information.

1. Generic changes to Tier 2 or Tier 2* information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 2 or Tier 2* information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, or B.5 of this section.

3. The Commission may not require new requirements on Tier 2 or Tier 2* information by plant-specific order while this appendix is in effect under § 52.55 or § 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to ensure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in § 50.12(a) of this chapter are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 or Tier 2* information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 50.12(a) of this chapter. The Commission will deny a request for an exemption from Tier 2 or Tier 2*, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5. a. An applicant or licensee who references this appendix may depart from Tier 2 or Tier 2* information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information (if prior NRC approval is required by paragraph A of this section) or the TS, or requires a license amendment under paragraphs B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2 or Tier 2*, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD or one affecting information required by § 52.47(a)(28) to address § 50.150 of this chapter, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 or Tier 2* affecting resolution of a severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. If an applicant or licensee proposes to depart from the information required by § 52.47(a)(28) to be included in the FSAR for the standard design certification, then the applicant or licensee shall consider the effect of the changed feature or capability on the original assessment required by § 50.150(a) of this chapter. The applicant or licensee must also document how the modified design features and functional capabilities continue to meet the assessment requirements in § 50.150(a)(1) of this chapter in accordance with Section X of this appendix.

e. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by § 50.90 of this chapter.

f. A departure from Tier 2 or Tier 2* information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

g. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under § 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to compliance with the general requirements of § 2.309 of this chapter, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a § 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and

any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

* * * * *

■ 65. In appendix E to part 52, revise paragraphs II.D., II.F, VI.B.4., VI.B.6., VIII.A., and VIII.B. to read as follows:

Appendix E to Part 52—Design Certification Rule for the ESBWR Design

* * * * *

II. * * *

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions, which are located in the following sections of the ESBWR Design Control Document, Revision 10: Section 1, ''Introduction,'' Section 1.1, ''Definitions and General Provisions,'' Section 1.2, ''Figure Legend,'' Section 1.3, ''Table Legend,'' and Section 1.4, ''Design Acceptance Criteria'';

2. Design descriptions, which are located in the following sections of the ESBWR Design Control Document, Revision 10, and any figures and non-ITAAC tables referenced in these sections: Section 2, ''Design Descriptions and ITAAC,'' and Section 3, ''Non-System Based Material'';

3. Inspections, tests, analyses, and acceptance criteria (ITAAC), which are located in the inspections, tests, analyses column and the acceptance criteria column of the following tables of the ESBWR Design Control Document, Revision 10: Tables 2.1.1–3, 2.1.2–3, 2.2.1–6, 2.2.2–7, 2.2.3–4, 2.2.4–6, 2.2.5–4, 2.2.6–3, 2.2.7–4, 2.2.9–3, 2.2.12–5, 2.2.13–4, 2.2.14–4, 2.2.15–2, 2.2.16–4, 2.3.1–2, 2.3.2–2, 2.4.1–3, 2.4.2–3, 2.5.5–1, 2.5.6–1, 2.5.10–1, 2.6.1–2, 2.6.2–2, 2.10.1–2, 2.10.2–2, 2.10.3–1, 2.11.1–1, 2.11.2–1, 2.11.4–2, 2.11.5–1, 2.11.6–1, 2.11.7–1, 2.12.3–1, 2.12.5–1, 2.12.7–1, 2.13.1–2, 2.13.3–2, 2.13.4–2, 2.13.5–2, 2.13.8–1, 2.13.9–1, 2.15.1–2, 2.15.3–2, 2.15.4–2, 2.15.5–2, 2.15.7–2, 2.15.8–1, 2.16.1–1, 2.16.2–2, 2.16.2–4, 2.16.2–6, 2.16.2–7, 2.16.2–9, 2.16.2–10, 2.16.3–2, 2.16.3.1–1, 2.16.4–1, 2.16.5–2, 2.16.6–2, 2.16.7–2, 2.16.8–1, 2.16.9–1, 2.16.10–1, 2.16.11–1, 2.16.12–1, 2.16.13–1, 2.16.14–1, 2.19–1, 3.1–1, 3.3–2, 3.4–1, 3.6–1, 3.7–1, and 3.8–2.

4. Significant site parameters, which are located in the following section of the ESBWR Design Control Document, Revision 10: Section 5, ''Site Parameters''; and

5. Significant interface requirements, which are located in the following section of the ESBWR Design Control Document, Revision 10: Section 4, ''Interface Material.''

* * * * *

F. *Tier 2** means the portion of the Tier 2 information, designated as such in the generic DCD, which is subject to the change process in paragraph VIII.B.6 of this appendix. After a plant first achieves full power, Tier 2* information in the plant-specific design control document for that plant reverts to Tier 2 status and is thereafter subject to the departure provisions in paragraph VIII.B.5 of this appendix.

* * * * *

VI. * * *

B. * * *

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4, VIII.A.6, and VIII.B.4 of this appendix, but only for that plant;

* * * * *

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 1 and Tier 2 under and in compliance with the change processes in paragraphs VIII.A.5 and VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

* * * * *

VIII. * * *

A. Tier 1 information

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3, A.4, A.5, A.6, or A.7 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).

4. Exemptions from Tier 1 information on definitions and general provisions, significant site parameters, and significant interface requirements are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

5. An applicant or licensee who references this appendix may depart from Tier 1 design description information, without NRC approval, unless the proposed departure requires an exemption under paragraph A.6 of this section.

6. A proposed departure from Tier 1 design descriptions would require an exemption if it would:

a. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

b. Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

c. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

d. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

e. Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

f. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

g. Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered;

h. Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses;

i. Result in a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

j. Result in a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

7. A licensee who references this appendix may not depart from Tier 1 ITAAC without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter and does not require an exemption from this appendix.

8. After the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information are subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information.

B. Tier 2 and Tier 2* information

1. Generic changes to Tier 2 or Tier 2* information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 2 or Tier 2* information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs B.3, B.4, B.5, or B.6 of this section.

3. The Commission may not require new requirements on Tier 2 or Tier 2* information by plant-specific order while this appendix is in effect under § 52.55 or § 52.61, unless:

a. A modification is necessary to secure compliance with the Commission's regulations applicable and in effect at the time this appendix was approved, as set forth in Section V of this appendix, or to ensure adequate protection of the public health and safety or the common defense and security; and

b. Special circumstances as defined in § 50.12(a) of this chapter are present.

4. An applicant or licensee who references this appendix may request an exemption from Tier 2 or Tier 2* information. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 50.12(a) of this chapter. The Commission will deny a request for an exemption from Tier 2 or Tier 2*, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design. The grant of an exemption to an applicant must be subject to litigation in the same manner as other issues material to the license

hearing. The grant of an exemption to a licensee must be subject to an opportunity for a hearing in the same manner as license amendments.

5. a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information (if prior NRC approval is required by paragraph A of this section), Tier 2* information, or the TS, or requires a license amendment under paragraph B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

b. A proposed departure from Tier 2, other than one affecting resolution of a severe accident issue identified in the plant-specific DCD or one affecting information required by § 52.47(a)(28) to address aircraft impacts, requires a license amendment if it would:

(1) Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

(2) Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

(3) Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

(4) Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

(5) Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

(6) Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

(7) Result in a design-basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered; or

(8) Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

c. A proposed departure from Tier 2 affecting resolution of a severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

d. A proposed departure from Tier 2 information required by § 52.47(a)(28) to address aircraft impacts shall consider the effect of the changed design feature or functional capability on the original aircraft impact assessment required by § 50.150(a) of this chapter. The applicant or licensee shall describe in the plant-specific DCD how the modified design features and functional capabilities continue to meet the aircraft impact assessment requirements in § 50.150(a)(1) of this chapter.

e. If a departure requires a license amendment under paragraph B.5.b or B.5.c of this section, it is governed by § 50.90 of this chapter.

f. A departure from Tier 2 information that is made under paragraph B.5 of this section does not require an exemption from this appendix.

g. A party to an adjudicatory proceeding for either the issuance, amendment, or renewal of a license or for operation under § 52.103(a), who believes that an applicant or licensee who references this appendix has not complied with paragraph VIII.B.5 of this appendix when departing from Tier 2 information, may petition to admit into the proceeding such a contention. In addition to compliance with the general requirements of § 2.309 of this chapter, the petition must demonstrate that the departure does not comply with paragraph VIII.B.5 of this appendix. Further, the petition must demonstrate that the change bears on an asserted noncompliance with an ITAAC acceptance criterion in the case of a § 52.103 preoperational hearing, or that the change bears directly on the amendment request in the case of a hearing on a license amendment. Any other party may file a response. If, on the basis of the petition and any response, the presiding officer determines that a sufficient showing has been made, the presiding officer shall certify the matter directly to the Commission for determination of the admissibility of the contention. The Commission may admit such a contention if it determines the petition raises a genuine issue of material fact regarding compliance with paragraph VIII.B.5 of this appendix.

6. a. An applicant who references this appendix may not depart from Tier 2* information, which is designated with italicized text or brackets and an asterisk in the generic DCD, without NRC approval. The departure will not be considered a resolved issue, within the meaning of Section VI of this appendix and § 52.63(a)(5).

b. A licensee who references this appendix may not depart from the following Tier 2* matters without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter.

(1) Fuel mechanical and thermal-mechanical design evaluation reports, including fuel burnup limits.

(2) Control rod mechanical and nuclear design reports.

(3) Fuel nuclear design report.

(4) Critical power correlation.

(5) Fuel licensing acceptance criteria.

(6) Control rod licensing acceptance criteria.

(7) Mechanical and structural design of spent fuel storage racks.

(8) Steam dryer pressure load analysis methodology.

(9) ASME Boiler and Pressure Vessel Code, Section III, Subsections NE (Division 1) and CC (Division 2) for containment vessel design.

(10) American Concrete Institute 349 and American National Standards Institute/American Institute of Steel Construction—N690.

(11) Power-operated valves.

(12) Equipment seismic qualification methods.

(13) Piping design acceptance criteria.

(14) Instrument setpoint methodology.

(15) Safety-Related Distribution Control and Information System performance specification and architecture.

(16) Safety System Logic and Control hardware and software.

(17) Human factors engineering design and implementation.

(18) First of a kind testing for reactor stability (first plant only).

(19) Reactor precritical heatup with reactor water cleanup/shutdown cooling (first plant only).

(20) Isolation condenser system heatup and steady state operation (first plant only).

(21) Power maneuvering in the feedwater temperature operating domain (first plant only).

(22) Load maneuvering capability (first plant only).

(23) Defense-in-depth stability solution evaluation test (first plant only).

c. After the plant first achieves full power, all Tier 2* matters revert to Tier 2 status and are thereafter subject to the departure provisions in paragraph B.5 of this section.

d. Departures from Tier 2* information that are made under paragraph B.6 of this section do not require an exemption from this appendix.

* * * * *

■ 66. In appendix F to part 52, revise paragraphs II.D., VI.B.4., VI.B.6., VIII.A., VIII.B.5.a., and VIII.B.5.c.

Appendix F to Part 52—Design Certification Rule for the APR1400 Design

* * * * *

II. * * *

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions, which are located in the following section of the APR1400 Design Control Document Tier 1, Revision 3: Section 1.0, ''Introduction'';

2. Design descriptions, which are located in the sections of the APR1400 Design Control Document Tier 1, Revision 3, identified in Table 1 to Paragraph D of this appendix, and any figures and non-ITAAC tables referenced in these sections:

Table 1 to Paragraph D

Section	Title
2.2	Structural and System Engineering
2.3	Piping Systems and Components
2.4	Reactor Systems
2.5	Instrumentation and Control
2.6	Electric Power
2.7	Plant Systems
2.8	Radiation Protection
2.9	Human Factors Engineering
2.10	Emergency Planning
2.11	Containment System
2.12	Physical Security Hardware
2.13	Design Reliability Assurance Program

3. Inspections, tests, analyses, and acceptance criteria (ITAAC), which are located in the inspections, tests, analyses column, and the acceptance criteria column of the following tables of the APR1400 Design Control Document Tier 1, Revision 3: Tables 2.2.1–3, 2.2.2–2, 2.2.3–1, 2.2.4–1, 2.2.5–1, 2.2.6–2, 2.2.7–2, 2.2.8–1, 2.2.9–1, 2.3–3, 2.4.1–4, 2.4.2–4, 2.4.3.4, 2.4.4–4, 2.4.5–4, 2.4.6–4, 2.4.7–1, 2.5.1–5, 2.5.2–5, 2.5.3–3, 2.5.4–5, 2.5.5–2, 2.6.1–3, 2.6.2–3, 2.6.3–3, 2.6.4–3, 2.6.5–1, 2.6.6–1, 2.6.7–1, 2.6.8–1, 2.6.9–1, 2.7.1.1–1, 2.7.1.2–4, 2.7.1.4–4, 2.7.1.5–4, 2.7.1.8–3, 2.7.2.1–4, 2.7.2.2–4, 2.7.2.3–4, 2.7.2.4–1, 2.7.2.5–4, 2.7.2.6–4, 2.7.3.1–3, 2.7.3.2–3, 2.7.3.3–3, 2.7.3.5–3, 2.7.3.6–1, 2.7.4.1–1, 2.7.4.2–1, 2.7.4.3–4, 2.7.4.4–2, 2.7.4.5–1, 2.7.5.2–3, 2.7.6.1–2, 2.7.6.2–4, 2.7.6.3–2, 2.7.6.4–3, 2.7.6.5–3, 2.8–2, 2.9–1, 2.10–1, 2.11.1–2, 2.11.2–4, 2.11.3–2, 2.11.4–3, 2.12–1, and 2.13–1.

4. Significant site parameters, which are located in the following section of the APR1400 Design Control Document Tier 1, Revision 3: Section 2.1, ''Site Parameters''; and

5. Significant interface requirements, which are located in the following section of the APR1400 Design Control Document Tier 1, Revision 3: Section 3.0, ''Interface Requirement.''

* * * * *

VI. * * *

B. * * *

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4, VIII.A.6, and VIII.B.4 of this appendix, but only for that plant;

* * * * *

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 1 and Tier 2 under and in compliance with the change processes in paragraphs VIII.A.5 and VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

* * * * *

VIII. * * *

A. Tier 1 Information

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3, A.4, A.5, A.6, or A.7 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).

4. Exemptions from Tier 1 information on definitions and general provisions, significant site parameters, and significant interface requirements are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

5. An applicant or licensee who references this appendix may depart from Tier 1 design description information, without NRC approval, unless the proposed departure requires an exemption under paragraph A.6 of this section.

6. A proposed departure from Tier 1 design descriptions would require an exemption if it would:

a. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

b. Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

c. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

d. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

e. Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

f. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

g. Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered;

h. Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

i. Result in a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

j. Result in a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

7. A licensee who references this appendix may not depart from Tier 1 ITAAC without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter and does not require an exemption from this appendix.

8. After the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information are subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information.

B. * * *

5. a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information (if prior NRC approval is required by paragraph A of this section) or the TS, or requires a license amendment under paragraph B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

* * * * *

c. A proposed departure from Tier 2, affecting resolution of a severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously

reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

* * * * *

■ 67. In appendix G to part 52, revise paragraphs II.D., V.B.1., V.B.9., VI.B.4, V.B.6., VIII.A., VIII.B.5.a., and VIII.B.5.c. to read as follows:

Appendix G to Part 52—Design Certification Rule for NuScale

* * * * *

II. * * *

D. *Tier 1* means the portion of the design-related information contained in the generic DCD that is approved and certified by this appendix (Tier 1 information). The design descriptions, interface requirements, and site parameters are derived from Tier 2 information. Tier 1 information includes:

1. Definitions and general provisions, which are located in the following sections of the NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5: Section 1.0, ''Introduction,'' Section 1.1, ''Definitions,'' and Section 1.2, ''General Provisions'';

2. Design descriptions, which are located in the following chapters of the NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5 and any figures and non-ITAAC tables referenced in these sections: Chapter 2, ''Unit Specific Structures, Systems, and Components Design Descriptions and Inspections, Tests, Analyses, and Acceptance Criteria,'' and Chapter 3, ''Shared Structures, Systems, and Components and Non-Structures, Systems, and Components Design Descriptions and Inspections, Tests, Analyses, and Acceptance Criteria'';

3. Inspections, tests, analyses, and acceptance criteria (ITAAC), which are located in the inspections, tests, analyses column and the acceptance criteria column of the following tables of the NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5: Tables 2.1–4, 2.2–3, 2.3–1, 2.5–7, 2.6–1, 2.7–2, 2.8–2, 3.0–1, 3.1–2, 3.2–2, 3.3–1, 3.4–1, 3.5–1, 3.6–2, 3.7–1, 3.8–1, 3.9–2, 3.10–2, 3.11–2, 3.12–2, 3.13–1, 3.14–2, 3.15–1, 3.16–1, 3.17–2, and 3.18–2.

4. Significant site parameters, which are located in the following chapter of the NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5: Chapter 5, ''Site Parameters''; and

5. Significant interface requirements which are located in the following chapter of the NuScale Standard Plant Design Certification Application, Certified Design Descriptions and Inspections, Tests, Analyses, & Acceptance Criteria (ITAAC), Part 2—Tier 1, Revision 5: Chapter 4, ''Interface Requirements.''

* * * * *

V. * * *

B. * * *

1. Paragraph (f)(2)(vi) of 10 CFR 50.34 and 10 CFR 50.46b—High point venting for the reactor coolant system and reactor pressure vessel head.

* * * * *

9. Appendix A of 10 CFR part 50—Electric Power Systems GDCs: * * *

* * * * *

VI. * * *

B. * * *

4. All exemptions from the DCD under and in compliance with the change processes in paragraphs VIII.A.4, VIII.A.6, and VIII.B.4 of this appendix, but only for that plant;

* * * * *

6. Except as provided in paragraph VIII.B.5.g of this appendix, all departures from Tier 1 and Tier 2 under and in compliance with the change processes in paragraphs VIII.A.5 and VIII.B.5 of this appendix that do not require prior NRC approval, but only for that plant; and

* * * * *

VIII. * * *

A. Tier 1 Information

1. Generic changes to Tier 1 information are governed by the requirements in § 52.63(a)(1).

2. Generic changes to Tier 1 information are applicable to all applicants or licensees who reference this appendix, except those for which the change has been rendered technically irrelevant by action taken under paragraphs A.3, A.4, A.5, A.6, or A.7 of this section.

3. Departures from Tier 1 information that are required by the Commission through plant-specific orders are governed by the requirements in § 52.63(a)(4).

4. Exemptions from Tier 1 information on definitions and general provisions, significant site parameters, and significant interface requirements are governed by the requirements in §§ 52.63(b)(1) and 52.98(f). The Commission will deny a request for an exemption from Tier 1, if it finds that the design change will result in a significant decrease in the level of safety otherwise provided by the design.

5. An applicant or licensee who references this appendix may depart from Tier 1 design description information, without NRC approval, unless the proposed departure requires an exemption under paragraph A.6 of this section.

6. A proposed departure from Tier 1 design descriptions would require an exemption if it would:

a. Result in more than a minimal increase in the frequency of occurrence of an accident previously evaluated in the plant-specific DCD;

b. Result in more than a minimal increase in the likelihood of occurrence of a malfunction of a structure, system, or component (SSC) important to safety and previously evaluated in the plant-specific DCD;

c. Result in more than a minimal increase in the consequences of an accident previously evaluated in the plant-specific DCD;

d. Result in more than a minimal increase in the consequences of a malfunction of an SSC important to safety previously evaluated in the plant-specific DCD;

e. Create a possibility for an accident of a different type than any evaluated previously in the plant-specific DCD;

f. Create a possibility for a malfunction of an SSC important to safety with a different result than any evaluated previously in the plant-specific DCD;

g. Result in a design basis limit for a fission product barrier as described in the plant-specific DCD being exceeded or altered;

h. Result in a departure from a method of evaluation described in the plant-specific DCD used in establishing the design bases or in the safety analyses.

i. Result in a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

j. Result in a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

7. A licensee who references this appendix may not depart from Tier 1 ITAAC without prior NRC approval. A request for a departure will be treated as a request for a license amendment under § 50.90 of this chapter and does not require an exemption from this appendix.

8. After the plant first achieves full power, licensee-initiated plant-specific departures from Tier 1 information are subject to the same requirements as licensee-initiated plant-specific departures from Tier 2 information.

* * * * *

B. * * *

5.

a. An applicant or licensee who references this appendix may depart from Tier 2 information, without prior NRC approval, unless the proposed departure involves a change to or departure from Tier 1 information (if prior NRC approval is required by paragraph A of this section) or the TS, or requires a license amendment under paragraph B.5.b or B.5.c of this section. When evaluating the proposed departure, an applicant or licensee shall consider all matters described in the plant-specific DCD.

* * * * *

c. A proposed departure from Tier 2, affecting resolution of a severe accident design feature identified in the plant-specific DCD, requires a license amendment if:

(1) There is a substantial increase in the probability of a severe accident such that a particular severe accident previously reviewed and determined to be not credible could become credible; or

(2) There is a substantial increase in the consequences to the public of a particular severe accident previously reviewed.

* * * * *

PART 53—RISK-INFORMED, TECHNOLOGY-INCLUSIVE REGULATORY FRAMEWORK FOR COMMERCIAL NUCLEAR PLANTS

■ 68. The authority citation for part 53 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 11, 101, 103, 108, 122, 147, 161, 181, 182, 183, 184, 185, 186, 187, 189, 223, 234 (42 U.S.C. 2014, 2131, 2132, 2133, 2134, 2135, 2138, 2152, 2167, 2169, 2201, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 306 (42 U.S.C. 10226); National Environmental Policy Act of 1969 (42 U.S.C. 4332); 44 U.S.C. 3504 note; Pub. L. 115–439, 132 Stat. 5571.

■ 69. In § 53.020, revise the definitions for ''*Construction*'' and ''*Quality Assurance (QA)*'' to read as follows:

§ 53.020 Definitions.

* * * * *

Construction means those activities which are conducted on-site to build the commercial nuclear plant, including the driving of piles; subsurface preparation; placement of backfill, concrete, or permanent retaining walls within an excavation; installation of foundations; or in-place assembly, erection, fabrication, or testing, which are for:

(1) Safety-related (SR) SSCs and those non-safety-related but safety-significant (NSRSS) SSCs of a facility for which special treatment includes requirements on design or installation, including associated quality assurance measures;

(2) SSCs necessary to comply with 10 CFR part 73.

* * * * *

Quality assurance (QA) means all those planned and systematic actions necessary to ensure that a structure, system, or component will perform satisfactorily in service. Quality assurance includes quality control, which comprises those QA actions related to the physical characteristics of a material, structure, component, or system which provide a means to ensure the material, structure, component, or system meets predetermined requirements.

* * * * *

■ 70. In § 53.040, revise paragraph (b)(7)(ii) and add (b)(7)(iii) to read as follows:

§ 53.040 Written communications.

* * * * *

(b) * * *

(7) * * *

(ii) A change to an NRC-accepted QA topical report or quality management system topical report from non-licensees (*i.e.,* architect/engineers, nuclear steam supply system suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC's Document Control Desk. If the communication is on paper, the signed original must be sent.

(iii) A change to the Safety Analysis report quality management system under § 53.1565, or a change to a licensee's NRC-accepted quality management system topical report under § 53.1565, must be submitted to the NRC's Document Control Desk, with a copy to the appropriate Regional Office, and a copy to the appropriate NRC Resident Inspector if one has been assigned to the site of the facility or the place of manufacture of a reactor licensed under this part. If the communication is on paper, the submission to the Document Control Desk must be the signed original.

* * * * *

■ 71. In § 53.460, revise paragraphs (b)(1) and (b)(2) to read as follows:

§ 53.460 Safety categorization and special treatments.

* * * * *

(b) * * *

(1) The special treatments for SR SSCs must include meeting the applicable quality assurance requirements from appendix B of part 50 of this chapter or, for eligible applicants, applicable quality assurance requirements from appendix T of part 50 of this chapter.

(2) The special treatments for NSRSS SSCs and special treatments for SR SSCs beyond those required under paragraph (b)(1) of this section may include meeting selected quality assurance requirements from appendix B of part 50 of this chapter or, for eligible applicants, meeting selected quality assurance requirements from appendix T of part 50 of this chapter when such treatment is needed to address performance requirements, equipment reliability, or uncertainties.

* * * * *

■ 72. In § 53.500, revise paragraph (b) to read as follows:

§ 53.500 General siting and siting assessment.

* * * * *

(b) Activities performed to identify site characteristics or otherwise needed to determine site-specific contributors to functional design criteria or analysis assumptions under subpart C of this part satisfy the applicable special treatment requirements of § 53.460, including, where applicable, the quality assurance requirements from appendix B of part 50 of this chapter or, for eligible applicants, meeting applicable quality assurance requirements from appendix T of part 50 of this chapter.

■ 73. In § 53.610, revise paragraph (b) introductory text to read as follows:

§ 53.610 Construction.

* * * * *

(b) *Construction activities.* No person may begin the construction of a commercial nuclear plant on a site on which the facility is to be operated under this part until that person has been issued either a CP or COL, an early site permit authorizing activities under § 53.1130, or a general license or LWA authorizing activities under § 53.1130.

* * * * *

■ 74. In § 53.855, add paragraphs (c) and (d) to read as follows:

§ 53.855 Emergency preparedness.

* * * * *

(c) A licensee desiring to change its plume exposure pathway EPZ must submit an application for a license amendment under § 53.1510 and receive NRC approval before implementing the change. Any such license amendment request must include documentation demonstrating that the applicable State, local, and Tribal governmental authorities have agreed to the EPZ change.

(d) A licensee desiring to change its emergency plan to comply with either the requirements of § 50.160 of this chapter or appendix E to part 50 of this chapter and the planning standards of § 50.47(b) of this chapter, must submit an application for a license amendment under § 53.1510 and receive NRC approval before implementing the change.

■ 75. Revise § 53.865 to read as follows:

§ 53.865 Quality assurance.

Each holder of an OL or COL under this part must develop, implement, and maintain a quality assurance program in accordance with appendix B of part 50 of this chapter or, for eligible OL or COL holders, a quality management system in accordance with appendix T of part 50 of this chapter. A written quality assurance program manual must be developed and used to guide the conduct of the program.

■ 76. In § 53.1010, revise paragraph (b)(2) to read as follows:

§ 53.1010 Financial assurance for decommissioning.

* * * * *

(b) * * *

(2) The amount of financial assurance for decommissioning to be provided may be based on a design-specific or site-specific cost estimate for

decommissioning the facility under § 53.1020.

* * * * *

■ 77. Revise § 53.1020 to read as follows:

§ 53.1020 Cost estimates for decommissioning.

(a) A certification relying on a design-specific decommissioning cost estimate must demonstrate that there is reasonable assurance that sufficient funds necessary for safely decommissioning the facility will be available, when needed, and provide the factors used to develop the design-specific decommissioning cost estimate, including reactor technology, power level (in MWt), and costs related to labor, energy, and waste burial. The amount to be provided must also address the approach to annual adjustments required by § 53.1030. Finally, design-specific decommissioning cost estimates must include plans for adjusting levels of funds assured for decommissioning to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the cost of decommissioning.

(b) Site-specific decommissioning cost estimates (DCEs) must be in an amount that may be more, but not less, than the amount stated in paragraph (a) of this section. Site-specific DCEs must account for the engineering, labor, equipment, transportation, disposal, and related charges needed to support termination of the license. They must include the costs for decontaminating structures, systems, and components and the site environs; removal of contaminated components and materials from the plant and the site environs; disposal of removed components and materials in appropriate facilities; and any other activities supporting the release of the property and termination of the license. They must also address the approach to annual adjustments required by § 53.1030. Finally, site-specific DCEs must include plans for adjusting levels of funds assured for decommissioning to demonstrate that a reasonable level of assurance will be provided that funds will be available when needed to cover the cost of decommissioning.

■ 78. Revise § 53.1040 to read as follows:

§ 53.1040 Methods for providing financial assurance for decommissioning.

Financial assurance for decommissioning is to be provided by the following methods.

(a) *Prepayment.* Prepayment is the deposit made preceding the start of operation or the transfer of a license under § 53.1570 into an account segregated from applicant or licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates of cash or liquid assets such that the amount of funds would be sufficient to pay decommissioning costs. Prepayment may be in the form of a trust, escrow account, or Government fund with payment by certificate of deposit, deposit of government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement must be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the prepayment deposit is managed are regulated and examined by a Federal or State agency. An applicant or licensee that has prepaid funds based on a design-specific or site-specific decommissioning cost estimate under § 53.1020 may take credit for projected earnings on the prepaid decommissioning trust funds, using up to a 2 percent annual real rate of return through the time of termination of the license. An applicant or licensee may use a credit of greater than 2 percent if the applicant's or licensee's rate-setting authority has specifically authorized a higher rate. However, applicants or licensees certifying only to design-specific decommissioning cost estimates can take a pro-rata credit during the dismantlement period (*i.e.,* recognizing both cash expenditures and earnings the first 7 years after shutdown). Actual earnings on existing funds may be used to calculate future fund needs.

(b) *External sinking fund.* An external sinking fund is a fund established and maintained by setting funds aside periodically in an account segregated from applicant or licensee assets and outside the administrative control of the applicant or licensee and its subsidiaries or affiliates in which the total amount of funds would be sufficient to pay decommissioning costs. An external sinking fund may be in the form of a trust, escrow account, or Government fund, with payment by certificate of deposit, deposit of government or other securities, or other method acceptable to the NRC. This trust, escrow account, Government fund, or other type of agreement must be established in writing and maintained at all times in the United States with an entity that is an appropriate State or Federal government agency, or an entity whose operations in which the external sinking fund is managed are regulated and examined by a Federal or State agency. An applicant or licensee that has collected funds based on a design-specific or site-specific decommissioning cost estimate under § 53.1020 may take credit for projected earnings on the external sinking funds using up to a 2 percent annual real rate of return from the time of future funds' collection through the time of termination of the license. An applicant or licensee may use a credit of greater than 2 percent if the applicant's or licensee's rate-setting authority has specifically authorized a higher rate. However, applicants or licensees certifying only to design-specific decommissioning cost estimates can take a pro-rata credit during the dismantlement period (*i.e.,* recognizing both cash expenditures and earnings the first 7 years after shutdown). Actual earnings on existing funds may be used to calculate future fund needs. An applicant or licensee whose rates for decommissioning costs cover only a portion of these costs may make use of this method only for the portion of these costs that are collected in one of the manners described in this paragraph (b). This method may be used as the exclusive mechanism relied upon for providing financial assurance for decommissioning in the following circumstances:

(1) By an applicant or licensee that recovers, either directly or indirectly, the estimated total cost of decommissioning through rates established by ''cost of service'' or similar ratemaking regulation. Public utility districts, municipalities, rural electric cooperatives, and State and Federal agencies, including associations of any of the foregoing, that establish their own rates and are able to recover their cost of service allocable to decommissioning, are deemed to satisfy this condition.

(2) By an applicant or licensee whose source of revenues for its external sinking fund is a ''non-bypassable charge,'' the total amount of which will provide funds estimated to be needed for decommissioning pursuant to § 53.1020, § 53.1060, or § 53.1575.

(c) *A surety method, insurance, or other guarantee method.*

(1) These methods guarantee that decommissioning costs will be paid. A surety method may be in the form of a surety bond, or letter of credit. Any surety method or insurance used to provide financial assurance for decommissioning must contain the following conditions:

(i) The surety method or insurance must be open-ended, or, if written for a

specified term, such as 5 years, must be renewed automatically, unless 90 days or more prior to the renewal day the issuer notifies the NRC, the beneficiary, and the applicant or licensee of its intention not to renew. The surety or insurance must also provide that the full-face amount be paid to the beneficiary automatically prior to the expiration without proof of forfeiture if the applicant or licensee fails to provide a replacement acceptable to the NRC within 30 days after receipt of notification of cancellation.

(ii) The surety or insurance must be payable to a trust established for decommissioning costs. The trustee and trust must be acceptable to the NRC. An acceptable trustee includes an appropriate State or Federal government agency or an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal or State agency.

(2) A parent company guarantee of funds for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix A to 10 CFR part 30.

(3) For commercial companies that issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs based on a financial test may be used if the guarantee and test are as contained in appendix C to 10 CFR part 30. For commercial companies that do not issue bonds, a guarantee of funds by the applicant or licensee for decommissioning costs may be used if the guarantee and test are as contained in appendix D to 10 CFR part 30. A guarantee by the applicant or licensee may not be used in any situation in which the applicant or licensee has a parent company holding majority control of voting stock of the company.

(d) *Funding method for Federal licensees.* For a Federal licensee, a statement of intent containing a cost estimate for decommissioning and indicating that funds for decommissioning will be obtained when necessary.

(e) *Contractual funding method.* Contractual obligation(s) on the part of an applicant's or licensee's customer(s), the total amount of which over the duration of the contract(s) will provide the applicant's or licensee's total share of uncollected funds estimated to be needed for decommissioning pursuant to § 53.1020, § 53.1060, or § 53.1575. To be acceptable to the NRC as a method of decommissioning funding assurance, the terms of the contract(s) must include provisions that the buyer(s) of electricity or other products will pay for the decommissioning obligations specified in the contract(s), notwithstanding the operational status either of the licensed plant to which the contract(s) pertains or force majeure provisions. All proceeds from the contract(s) for decommissioning funding will be deposited to the external sinking fund. The NRC reserves the right to evaluate the terms of any contract(s) and the financial qualifications of the contracting entity or entities offered as assurance for decommissioning funding.

(f) *Other funding mechanisms.* Any other mechanism, or combination of mechanisms, that provides, as determined by the NRC upon its evaluation of the specific circumstances of each application or licensee submittal, assurance of decommissioning funding equivalent to that provided by the mechanisms specified in paragraphs (a) through (e) of this section. Applicants or licensees who do not have sources of funding described in paragraph (b) of this section may use an external sinking fund in combination with a guarantee mechanism, as specified in paragraph (c) of this section, provided that the total amount of funds estimated to be necessary for decommissioning is assured.

■ 79. Revise § 53.1050 to read as follows:

§ 53.1050 NRC oversight.

The NRC reserves the right to take the following steps in order to ensure an applicant's or licensee's adequate accumulation of decommissioning funds: review, as needed, the rate of accumulation of decommissioning funds and, either independently or in cooperation with FERC and the applicant's or licensee's State Public Utility Commission, take additional actions as appropriate on a case-by-case basis, including modification of an applicant's or licensee's schedule for the accumulation of decommissioning funds.

■ 80. In § 53.1109, revise paragraph (g) to read as follows:

§ 53.1109 Contents of applications; general information.

* * * * *

(g)(1) If the application is for an OL or COL for a commercial nuclear plant, or if the application is for an early site permit for a commercial nuclear plant and contains plans for coping with emergencies under § 53.1146(b)(2)(ii), the applicant must coordinate radiological emergency preparedness activities with offsite organizations with responsibilities for coping with emergencies including State, local, and Tribal governmental agencies, as applicable. Specifically, the applicant must ensure that these response organizations are aware of the potential radiological consequences of the facility and have been consulted on appropriate protective measures including the extent of any emergency planning zone (EPZ) for implementing predetermined, prompt protective measures. The application must include information that describes the extent of the applicant's interaction with these response organizations. If the application is for an early site permit that, under § 53.1146(b)(2)(i), proposes major features of the emergency plans describing the EPZs, then the descriptions of the EPZs must meet the requirements of this paragraph (g)(1). Generally, the plume exposure pathway EPZ for a commercial nuclear plant must consist of an area about 2 to 10 miles (3.2 to 16 km) in radius. For reactors with an authorized power level less than 300 MW thermal, the plume exposure pathway EPZ may be established at the site boundary. The need for and size of the EPZ may also be determined on a case-by-case basis as described in § 53.1109(g)(2). The exact size and configuration of the EPZs surrounding a particular commercial nuclear plant must be determined in relation to the local emergency response needs and capabilities as they are affected by such conditions as demography, topography, land characteristics, access routes, and jurisdictional boundaries. Emergency plans must describe such actions as are appropriate to avoid or reduce dose within and beyond the EPZ or site boundary and to protect the ingestion pathway.

(2) For a case-by-case EPZ determination, the applicant or licensee must submit an analysis used to determine whether the criteria in § 53.1109(g)(2)(i)(A) and (B) are met and, if they are met, the size of the plume exposure pathway EPZ.

(i) The plume exposure pathway EPZ is the area within which:

(A) Dose to an individual is projected to exceed 1 rem (10 millisieverts) total effective dose equivalent over 96 hours from the release of radioactive materials from the facility considering accident likelihood and source term, timing of the accident sequence, and meteorology; and

(B) Pre-determined, prompt protective measures are necessary.

(ii) [Reserved]

* * * * *

■ 81. In 53.1130, revise the section heading and paragraphs (a)(3)(ii), (b)(1)(i), and (c) and add paragraph (e) to read as follows:

§ 53.1130 Limited work authorizations, general licenses.

(a) * * *

(3) * * *

(ii) Information to demonstrate the applicability of a categorical exclusion, or if a categorical exclusion is not applicable, an environmental report in accordance with part 51 of this chapter; and

* * * * *

(b) * * *

(1) * * *

(i) The NRC staff issues the final documentation required under NEPA and all applicable Federal environmental consultations have been complete, in accordance with part 51 of this chapter;

* * * * *

(c) *Effect of limited work authorization.*

(1) Any activities undertaken under an LWA are entirely at the risk of the applicant and, except as to the matters determined under paragraph (b)(1) of this section, the issuance of the LWA has no bearing on the issuance of a CP or COL with respect to the requirements of the Act and rules, regulations, or orders issued under the Act. The environmental impact statement for a CP or COL application for which an LWA was previously issued will not address, and the presiding officer in a contested hearing will not consider, the sunk costs of the holder of the LWA in determining the proposed action (*i.e.,* issuance of the CP or COL).

(2) Any activities that are determined to be outside the scope of those defined in the definition of construction in § 53.020 and that are undertaken by an applicant or on its behalf are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act.

* * * * *

(e) *Issuance of general license.* A general license is hereby issued to an applicant for a construction permit or combined license for a utilization facility under this part for construction activities on a site that is specified in the application, subject to the following conditions:

(1) The applicant has submitted and the Commission has docketed a CP or COL application for a commercial nuclear plant under this part that meets the following criteria;

(i) The application references a reactor design for which the Commission issued an operating license under this part or issued a combined license under this part and made the finding under § 53.1452(g) and for which the Commission afforded generic finality under § 53.1387(e) or § 53.1440(d); and

(ii) The operating license or combined license described in paragraph (e)(1)(i) of this section met the criteria for a categorical exclusion or resulted in a finding of no significant impact from an environmental assessment in accordance with part 51 of this chapter;

(iii) The application utilizing the general license includes a plan for redress of any adverse environmental impact from conduct of activities under the general license should such redress be necessary; and

(iv) The application must contain information demonstrating that the site characteristics are bounded by the site parameters postulated for the approval of generic finality.

(2) The applicant may perform construction only upon notification to the NRC Director of NRR using instructions in § 53.040 before the start of construction. The notice must state that all applicable permits, licenses, approvals, and other entitlements in connection with the proposed action have been obtained. The notice may be in the form of a letter, but must contain the applicant's name, address, and the name and means of contacting a person responsible for providing additional information concerning construction under this general license;

(3) All applicable Federal environmental consultations have been completed;

(4) The general license only authorizes construction of those generic aspects of the design of the commercial nuclear plant for which the Commission afforded generic finality and does not authorize installation of the reactor vessel, the reactor coolant system, or associated reactivity control and heat removal systems;

(5) The applicant must allow for NRC inspections that the Commission deems necessary related to activities performed under the general license; and

(6) Any activities undertaken by the applicant or on its behalf under the general license are entirely at the risk of the applicant and have no bearing on the issuance of a license with respect to the requirements of the Act, and rules, regulations, or orders issued under the Act.

■ 82. Revise § 53.1161 to read as follows:

§ 53.1161 Extent of activities permitted.

If the activities authorized by § 53.1158(c) are performed and the early site permit holder has applied for termination, then the early site permit remains in effect solely for the purpose of site redress, and the holder of the permit must redress the site under the terms of the site redress plan required by § 53.1146(c). If, before redress is complete, a use not envisaged in the redress plan is found for the site or parts thereof, the holder of the permit must carry out the redress plan to the greatest extent possible consistent with the alternate use.

■ 83. In § 53.1164, revise paragraph (a) and remove and reserve paragraph (b) to read as follows:

§ 53.1164 Duration of permit.

(a) An early site permit issued under this subpart will be issued with no fixed term.

(b) [Reserved]

* * * * *

■ 84. Revise § 53.1173 to read as follows:

§ 53.1173 Application for amendment to update an early site permit.

(a) An early site permit holder may choose to submit an application to amend an early site permit to update the data and information on which the permit is based at any time after issuance of the early site permit. The early site permit holder may provide updated information on as many issues as the early site permit holder chooses and may request to extend the period for which the agency will afford those issues finality up to 20 additional years from the date of the amendment's issuance. The early site permit holder may request such an extension for an already extended permit. The application must meet the requirements of §§ 53.1510 and 53.1520.

(b) An application submitted under paragraph (a) of this section must contain all information necessary to bring up to date the information and data contained in the previous application for those issues the early site permit holder has chosen to update.

(c) Each application must include a complete environmental report as required by part 51 of this chapter, or a request and justification for a categorical exclusion under part 51 of this chapter.

(d) Any person whose interest may be affected by the update of the permit may request a hearing on the application for the update. The request for a hearing must comply with § 2.309 of this chapter. If a hearing is granted, notice of the hearing will be published in accordance with § 2.309 of this chapter.

■ 85. Revise § 53.1176 to read as follows:

§ 53.1176 Issuance of amendment to update an early site permit.

The Commission shall grant amendment of an early site permit only if it determines that:

(a) The site complies with the Act, the Commission's regulations, and orders applicable and in effect at the time the site permit was originally issued; and

(b) Any new requirements the Commission may wish to impose are necessary for adequate protection to public health and safety or common defense and security.

§ 53.1179 [Removed and Reserved]

■ 86. Remove and reserve § 53.1179.

■ 87. Revise § 53.1182 to read as follows:

§ 53.1182 Use of site for other purposes.

(a) A site for which an early site permit has been issued under this part may be used for purposes other than those described in the permit, including the location of other types of energy facilities. The permit holder must inform the Director, Office of Nuclear Reactor Regulation (Director), of any significant uses for the site which have not been approved in the early site permit. The information about the activities must be given to the Director at least 30 days in advance of any actual construction or site modification for the activities. The information provided could be the basis for imposing new requirements on the permit, under the provisions of § 53.1188.

(b) If the permit holder no longer intends to use the site for a nuclear power plant or for other reasons no longer wishes to hold the permit, as described in the request, the permit holder may at any time request the Director to terminate the early site permit. The request to terminate the permit must comply with the filing requirements of §§ 53.040 and 53.1100 and identify the applicable requirements for site redress of § 53.1161. Upon request, the Director may terminate the permit.

(c) Termination of the early site permit does not bar the permit holder or another applicant from filing a new application for the site.

■ 88. In § 53.1188,

■ a. In paragraph (a)(1), remove the phrase ''or § 53.1179'';

■ b. In paragraph (a)(2), wherever it appears remove the word ''renewal'' and add in its place the word ''amendment'';

■ c. Revise and republish paragraph (c)(1);

■ d. In paragraph (d), remove the word ''renewed'' and in its place the word ''amended'';

■ e. In paragraph (e), in the last sentence add in sequential order the reference ''53.1173''.

The revision is to read as follows:

§ 53.1188 Finality of early site permit determinations.

* * * * *

(c) * * *

(1) In any proceeding for the issuance of a CP, OL, or COL referencing an early site permit, contentions on the following matters may be litigated in the same manner as other issues material to the proceeding:

(i) The nuclear reactor proposed to be built does not fit within one or more of the site characteristics or design parameters included in the early site permit;

(ii) One or more of the terms and conditions of the early site permit have not been met;

(iii) A variance requested under paragraph (d) of this section is unwarranted or should be modified;

(iv) New or additional information is provided in the application that substantially alters the bases for a previous NRC conclusion or constitutes a sufficient basis for the Commission to modify or impose new terms and conditions related to emergency preparedness;

(v) The information as required in the site safety analysis report in accordance with § 53.1146(a)(1)(vi) through (ix) has not been updated after 20 years from the date of early site permit issuance or a previous update of the permit by amendment, whichever is later, or

(vi)(A) Any significant environmental issue that was not resolved in the early site permit proceeding;

(B) For an application that references an early site permit issued or updated by amendment, whichever is later, no more than 20 years before the submission of the application, any issue involving the impacts of construction and operation of the facility that was resolved in the early site permit proceeding for which significant new information has been identified; and

(C) For an application that references an early site permit, issued or updated by amendment, whichever is later, more than 20 years before submission of the application, any issue involving the impacts of construction and operation of the facility regardless of whether the early site permit proceeding resolved the issue.

* * * * *

■ 89. In § 53.1263,

■ a. Revise paragraphs (a)(1)(v) and (vi), and remove paragraph (a)(1)(vii);

■ b. In paragraph (a)(4)(ii), remove the last sentence; and

■ c. Revise paragraph (b).

The revisions are to read as follows:

§ 53.1263 Finality of standard design certifications.

(a)(1) * * *

(v) Is necessary to correct material errors in the certification information; or

(vi) Substantially increases overall safety, reliability, or security of facility design, construction, or operation, and the direct and indirect costs of implementation of the rule change are justified in view of this increased safety, reliability, or security.

* * * * *

(b) An applicant who references a design certification rule may request an exemption from one or more elements of the certification information, if one is required per § 53.1525. The Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080. The granting of an exemption on request of an applicant is subject to litigation in the same manner as other issues in the OL or COL hearing.

* * * * *

■ 90. In § 53.1282, add paragraph (e) to read as follows:

§ 53.1282 Contents of applications for manufacturing licenses; other application content.

* * * * *

(e) *Optional operational programs.* An applicant may include in its application descriptions of essentially complete programmatic controls, operational programs, or operational requirements beyond those required by § 53.1279 in order to satisfy requirements for license applications that may reference a manufacturing license. If approved by the NRC as part of the manufacturing license, such programmatic controls, operational programs, and operational requirements would have finality under § 53.1288.

■ 91. In § 53.1288, revise paragraphs (a)(1) and (b) to read as follows:

§ 53.1288 Finality of manufacturing licenses.

(a)(1) During the term of an ML issued under this part, the Commission may not modify, rescind, or impose new requirements on the design of the manufactured reactor; the requirements for the manufacture of the manufactured reactor; or the programmatic controls, operational programs, or operational requirements, unless the Commission determines that a modification is necessary to bring the design of the reactor or its manufacture into compliance with the Commission's requirements applicable and in effect at

the time the ML was issued, or to provide reasonable assurance of adequate protection to public health and safety or common defense and security.

* * * * *

(b) An applicant who references or uses a manufactured reactor manufactured under an ML under this part may include in the application a request for a departure from the design characteristics, site parameters, terms and conditions, or approved design of the manufactured reactor. The granting of a departure on request of an applicant is subject to litigation in the same manner as other issues in the COL or CP hearing.

■ 92. In § 53.1309, revise paragraph (a)(2)(i) and remove and reserve paragraph (a)(4) to read as follows:

§ 53.1309 Contents of applications for construction permits; technical information.

* * * * *

(a) * * *

(2) * * *

(i) *Quality assurance program.* A description of the QAP or, for eligible applicants, the quality management system to be applied to the design, fabrication, construction, and testing of the SSCs of the facility under § 53.610(a)(6), including a discussion of how the requirements of appendix B of part 50 of this chapter or, for eligible applicants, how the requirements of appendix T of part 50 of this chapter will be satisfied.

* * * * *

(4) [Reserved]

* * * * *

■ 93. In § 53.1369, revise paragraph (l) and add paragraph (bb) to read as follows:

§ 53.1369 Contents of applications for operating licenses; technical information.

* * * * *

(l) *Quality assurance.* A description of the QAP or, for eligible applicants, the quality management system that demonstrates compliance with the requirements under § 53.865.

* * * * *

(bb) *Requests for generic finality.* An applicant may include in its application a request for generic finality, to generic aspects of the design under this part, such that information in the application, if approved by the NRC, is considered resolved in other proceedings where information approved for generic finality is referenced. An application for an operating license that requests generic finality must include applicable site parameters postulated for the design, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

■ 94. In § 53.1375, revise paragraph (b) to read as follows:

§ 53.1375 Review of applications.

* * * * *

(b) *Administrative review of applications; hearings.*

(1) A proceeding on an OL is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). All hearings on OLs are governed by the procedures contained in 10 CFR part 2.

(2) If an applicant requests generic finality under § 53.1369(bb) for an OL under this part, the Commission will include a request for generic finality as a proposed action in the notice of proposed action required by § 2.105 of this chapter.

■ 95. In § 53.1387, add paragraph (e) to read as follows:

§ 53.1387 Issuance of operating licenses.

* * * * *

(e) The Commission may afford generic finality to generic aspects of the design of a commercial nuclear plant under this part, including postulated site parameters, and requirements submitted pursuant to § 53.1369(bb), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design in accordance with applicable requirements and without undue risk to the health and safety of the public.

■ 96. Revise § 53.1390 to read as follows:

§ 53.1390 Finality of operating licenses.

(a) After issuance of an OL, the Commission may not modify, add, or delete any term or condition of the OL, except in accordance with the provisions of § 53.1590.

(b) In a proceeding for the issuance of a CP, OL, or COL, or in any enforcement hearing other than one initiated by the Commission under paragraph (a) of this section, in which an OL issued under § 53.1387 is referenced, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the referenced OL including, if applicable, the adequacy of a reactor design, where the referenced OL was afforded finality pursuant to § 53.1387(e).

■ 97. In § 53.1416, revise paragraphs (a)(12) and (d) and add paragraph (i) to read as follows:

§ 53.1416 Contents of applications for combined licenses; technical information.

* * * * *

(a) * * *

(12) *Quality assurance.* A description of the QAP or, for eligible applicants, the quality management system under § 53.865.

* * * * *

(d) If the COL application references an early site permit, then the following requirements apply:

(1) The FSAR need not contain information or analyses submitted to the Commission in connection with the early site permit provided that the FSAR must either include or incorporate by reference the early site permit Site Safety Analysis Report and contain, in addition to the information and analyses otherwise required, information sufficient to demonstrate that the design of the facility falls within the site characteristics and design parameters specified in the early site permit.

(2) If the FSAR does not demonstrate that design of the facility falls within the site characteristics and design parameters, the application must include a request for a variance that complies with the requirements of §§ 53.1188(d) and 53.1437.

(3) If the early site permit site safety analysis report information required by § 53.1146(a)(1)(vi) through (ix) has not been updated after 20 years from the date of early site permit issuance or a previous update of the permit by amendment, whichever is later; the combined license application shall include updated information and revised analyses, as necessary, in the final safety analysis report.

(4) The FSAR must demonstrate that all terms and conditions that have been included in the early site permit will be satisfied by the date of issuance of the COL. Any terms or conditions of the early site permit that could not be met by the time of issuance of the COL must be set forth as terms or conditions of the COL.

(5) If the early site permit approves complete and integrated emergency plans, or major features of emergency plans, then the FSAR must include any new or additional information that updates and corrects the information that was provided under § 53.1146(b)(2) and discuss whether the new or additional information materially changes the bases for compliance with the applicable requirements. The application must identify changes to the emergency plans or major features of emergency plans that have been incorporated into the proposed facility emergency plans and that constitute or

would constitute a change in an emergency plan that results in reducing the licensee's capability to perform an emergency planning function in the event of a radiological emergency.

(6) If complete and integrated emergency plans are approved as part of the early site permit, new certifications meeting the requirements of paragraph (a)(9)(i) of this section are not required.

* * * * *

(i) An applicant may include in its application a request for generic finality, to generic aspects of the design under this part, such that information in the application, if approved by the NRC, is considered resolved in other proceedings where information approved for generic finality is referenced. An application for a combined license that requests generic finality must include applicable site parameters postulated for the design under this part, including the design-basis external hazard levels for the relevant external hazards, and an analysis and evaluation of the design in terms of those site parameters.

■ 98. In § 53.1422, revise paragraph (b) to read as follows:

§ 53.1422 Review of applications.

* * * * *

(b) *Administrative review of applications; hearings.*

(1) A proceeding on a COL is subject to all applicable procedural requirements contained in 10 CFR part 2, including the requirements for docketing (§ 2.101 of this chapter) and issuance of a notice of hearing (§ 2.104 of this chapter). If an applicant requests a Commission finding on certain ITAAC with the issuance of the COL, then those ITAAC will be identified in the notice of hearing. All contested hearings on COLs are governed by the procedures contained in 10 CFR part 2.

(2) If an applicant requests generic finality under § 53.1416(i) for a COL under this part, the Commission will include a request for generic finality as a proposed action in the notice of hearing required by § 2.104 of this chapter.

§ 53.1437 [Amended]

■ 99. In § 53.1437, in paragraph (c), remove the last sentence.

■ 100. In § 53.1440, add paragraph (d) to read as follows:

§ 53.1440 Issuance of combined licenses.

* * * * *

(d) The Commission may afford generic finality to generic aspects of the design of a commercial nuclear plant under this part, including postulated site parameters, and requirements submitted pursuant to § 53.1416(i), if it finds that the proposed generic design can be constructed and operated at sites having characteristics that fall within the site parameters postulated for the design in accordance with applicable requirements and without undue risk to the health and safety of the public.

■ 101. In § 53.1443, add paragraph (g) to read as follows:

§ 53.1443 Finality of combined licenses.

* * * * *

(g) In a proceeding for the issuance of a CP, OL, or COL, or in any enforcement hearing other than one initiated by the Commission under paragraph (a) of this section, in which a COL issued under § 53.1440 is referenced, the Commission must treat as resolved those matters resolved in the proceeding on the application for issuance or renewal of the referenced COL including, if applicable, the adequacy of a reactor design, where the referenced COL was afforded finality pursuant to § 53.1440(d).

■ 102. In § 53.1525, revise paragraphs (a) and (b) to read as follows:

§ 53.1525 Revising certification information within a design certification rule.

(a) A holder of a license who references a design certification rule issued under this part must request a license amendment in accordance with §§ 53.1510, 53.1515, and 53.1520 if proposing to change certification information that has been incorporated into the license.

(b) For certification information that has not been incorporated into the license, a holder of a license who references a design certification rule issued under this part may make changes to the certification information without requesting an exemption, if the changes meet the criteria in § 53.1550(a)(1) and (2) using the specifications in § 53.1550(b)(2) and (3). If an exemption is requested, the Commission may grant such a request only if it determines that the exemption will comply with the requirements of § 53.080.

* * * * *

■ 103. In § 53.1530, in paragraph (a) revise the last sentence to read as follows:

§ 53.1530 Revising information within a Final Safety Analysis Report associated with a manufacturing license.

* * * In those cases where an ML references a design certification rule, the provisions of § 53.1525 apply.

* * * * *

■ 104. Revise § 53.1535 to read as follows:

§ 53.1535 Amendments and exemptions during construction.

(a) The holder of a CP or limited work authorization (LWA) under this part may request an amendment to the CP or LWA in order to gain Commission approval of the safety of selected design features or specifications, including proposed departures from a design certification rule or ML. Amendments to CPs or LWAs under this part must be requested and processed under §§ 53.1510 and 53.1520. The holder of a CP or LWA under this part may also request an exemption, if required by § 53.1525, to depart from a design certification rule.

(b) The holder of a COL under this part for which the NRC has not yet made a finding in accordance with § 53.1452(g) must request exemptions required by § 53.1525 and amendments required by § 53.1525 or 53.1550 no later than 45 days from the date the licensee begins the construction of the SSCs to implement the change or departure requiring NRC approval. The licensee proceeds with such changes at its own risk recognizing that there is a possibility that the exemption or amendment will not be granted.

■ 105. Revise § 53.1550 to read as follows:

§ 53.1550 Evaluating changes to facility as described in Final Safety Analysis Reports.

(a) The holder of an OL or COL may make changes in the facility as described in the FSAR (as updated) and make changes in the procedures as described in the FSAR (as updated) without obtaining an exemption pursuant to § 53.1525 or license amendment pursuant to § 53.1510 only if—

(1) A change to the technical specifications or other certification information incorporated in the license is not required; and

(2) The change meets all of the following criteria:

(i) Does not result in an increase to the frequency or consequences of an event sequence such that an event sequence not previously identified as risk significant becomes risk significant by the analyses performed in accordance with § 53.450(e).

(ii) Does not result in an increase to the frequency or consequences of an event sequence such that an event sequence exceeds the licensing-basis event evaluation criteria required to be established in accordance with § 53.450(e).

(iii) Does not involve either of the following:

(A) A change to the NRC-approved comprehensive risk metric(s) or

associated risk performance objective under § 53.220(b), or

(B) An increase to the frequency or consequences of one or more event sequences such that any calculated comprehensive risk metric exceeds the associated risk performance objective established in accordance with § 53.220.

(iv) Does not involve a departure from a method of evaluation described in the FSAR (as updated) used in assessing design basis accidents in accordance with § 53.450(f) unless the results of the analysis under § 53.450(f) are conservative or essentially the same; the revised method of evaluation has been previously approved by the NRC for the intended application; the revised method of evaluation can be used under an NRC-endorsed consensus code or standard; or the licensee has demonstrated through a documented verification, validation, and uncertainty quantification (VVUQ) process, conducted under a VVUQ program that meets the requirements of § 50.221 of this chapter and has been approved by the NRC for the intended application, that the departure from a method of evaluation described in the FSAR (as updated) meets the criteria established for credibility in the VVUQ program.

(v) Does not result in a change to the safety classification of an SSC from non-safety-related to safety-related, from non-safety-related but safety-significant to safety-related, or from safety-related to either non-safety-related but safety-significant or non-safety-related.

(vi) Does not result in more than a minimal decrease in defense in depth.

(vii) For commercial nuclear plants licensed under this part for which alternative evaluation criteria are adopted in accordance with § 53.470, does not result in a change to the frequency or consequences of event sequences such that the alternate evaluation criteria are exceeded.

(viii) Does not result in the identification of a new design-basis accident in accordance with § 53.450(f).

(ix) Does not result in more than a minimal increase in the consequences of any design-basis accident.

(3) In implementing this paragraph (a), the FSAR (as updated) is considered to include FSAR changes since submittal of the last update of the FSAR under § 53.1545.

(4) The provisions in this section do not apply to changes to the facility or procedures when the applicable regulations establish more specific criteria for accomplishing such changes.

(b)(1) A licensee who references a design certification rule may make departures from the standard design, without prior Commission approval, unless the proposed departure involves a change to the design as described in the rule certifying the design, in which case the requirements of § 53.1525 are applicable.

(2) The licensee must maintain records of all departures from the certified design of the facility and these records must be maintained and available for audit until the termination of the license. The licensee must identify the location and nature of departures from licensing-basis information within supporting documents for a certified design within the updates to the Safety Analysis Report required by § 53.1545.

(3) Licensees for which the NRC has docketed the certifications required under § 53.1070 need not retain records of departures from the design of the facility associated with SSCs that have been permanently removed from service using an NRC-approved change process.

(c) The holder of an OL or COL that authorizes operation of a manufactured reactor may make changes in the facility as described in the FSAR (as updated) and make changes in the procedures as described in the FSAR (as updated) without obtaining a license amendment pursuant to § 53.1510 if the changes are identical to changes approved by the Commission by amendment to the manufacturing license for the manufactured reactor and upon determining that implementation of the changes will be consistent with the basis for the Commission's approval of the amendment to the manufacturing license and not involve any additional changes that would require an amendment to the OL or COL.

(d)(1) The licensee must maintain records of changes in the facility and procedures made under paragraphs (a) and (c) of this section. These records must include a written evaluation which provides the bases for the determination that the change does not require a license amendment under paragraph (a)(2) or (c) of this section.

(2) The licensee must submit, as specified in § 53.040, a report containing a brief description of any departures and changes, including a summary of the evaluation of each. A report must be submitted at intervals not to exceed 24 months. For COLs, the report must be submitted at intervals not to exceed 6 months during the period from the date of application for a COL to the date the Commission makes its findings under § 53.1452(g).

(3) The records of changes in the facility must be maintained until the termination of an OL or COL issued under this part, or the termination of a renewed license issued under § 53.1595—whichever is later. Records of changes in procedures must be maintained for a period of 5 years.

■ 106. In § 53.1565, in paragraph (d), revise (1)(i) introductory text, add (1)(iii), revise (2), add (3)(i)(E), and revise (3)(ii), (iii), and (vii) to read as follows:

§ 53.1565 Evaluating changes to programs included in licensing-basis information.

* * * * *

(d) * * *

(1) * * *

(i) Each holder under this part of an OL or COL, after the Commission makes the finding under § 53.1452(g), subject to the quality assurance criteria in appendix B of part 50 of this chapter, may make a change to a previously accepted quality assurance program (QAP) description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description as accepted by the NRC. Changes to the QAP description that do not reduce the commitments must be submitted to the NRC in accordance with the requirements of § 53.1545. In addition to QAP changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items, the following changes are not considered to be reductions in commitment:

* * * * *

(iii) Each holder of an OL or COL after the Commission makes the finding under § 53.1452(g), subject to the quality assurance criteria in appendix T of part 50 of this chapter, must submit changes to the quality management system to the NRC and receive NRC approval prior to implementation as follows:

(A) Changes made to the quality management system as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 53.040.

(B) The submittal of a change to the Safety Analysis Report quality management system must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised quality management system incorporating the change continues to satisfy the criteria of appendix T of part 50 of this chapter and the Safety Analysis Report quality management system commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(D) Changes to the quality management system included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission.

(2) *Quality assurance program—siting, construction, and manufacturing.*

(i) Each holder of an LWA, early site permit, CP, ML, or COL, before the Commission makes the finding under § 53.1452(g), subject to the quality assurance criteria in appendix B to part 50 of this chapter, may make a change to a previously accepted QAP description included or referenced in the Safety Analysis Report without prior NRC approval, provided the change does not reduce the commitments in the program description previously accepted by the NRC. Changes to the QAP description that do not reduce the commitments must be submitted to NRC within 90 days. Changes to the QAP description that reduce the commitments must be submitted to NRC and receive NRC approval before implementation, as follows:

(A) Changes to the Safety Analysis Report must be submitted for review as specified in § 53.040. Changes made to NRC-accepted QA topical report descriptions must be submitted as specified in § 53.040.

(B) The submittal of a change to the Safety Analysis Report QAP description must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised program incorporating the change continues to satisfy the criteria of appendix B of part 50 of this chapter and the Safety Analysis Report QAP description commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the changes must be maintained as a facility record for 3 years.

(D) Changes to the QAP description included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission or 60 days after submittal to the Commission, whichever occurs first.

(ii) Each holder of a CP or COL, before the Commission makes the finding under § 53.1452(g), subject to the quality assurance criteria in appendix T of part 50 of this chapter, must submit changes to the quality management system to the NRC and receive NRC approval prior to implementation as follows:

(A) Changes made to the quality management system as presented in the Safety Analysis Report or in a topical report must be submitted as specified in § 53.040.

(B) The submittal of a change to the Safety Analysis Report quality management system must include all pages affected by that change and must be accompanied by a forwarding letter identifying the change, the reason for the change, and the basis for concluding that the revised quality management system incorporating the change continues to satisfy the criteria of appendix T of part 50 of this chapter and the Safety Analysis Report quality management system commitments previously accepted by the NRC (the letter need not provide the basis for changes that correct spelling, punctuation, or editorial items).

(C) A copy of the forwarding letter identifying the change must be maintained as a facility record for three years.

(D) Changes to the quality management system included or referenced in the Safety Analysis Report shall be regarded as accepted by the Commission upon receipt of a letter to this effect from the appropriate reviewing office of the Commission.

(3) * * *

(i) * * *

(E) *Risk significant planning standard* means the most essential functions of emergency preparedness to ensure adequate protective measures are taken to protect the public in the event of a radiological emergency. For the purposes of this section, the risk significant planning standards are classification, notification, assessment, protective actions, staffing, and facilities.

(ii) A holder of an OL under this part, or a COL under this part after the Commission makes the finding under § 53.1452(g), must follow and maintain the effectiveness of an emergency plan that meets the requirements in appendix E to part 50 of this chapter and the planning standards of § 50.47(b) of this chapter, or an emergency plan that meets the requirements in § 50.160 of this chapter.

(iii) A licensee may make changes to its emergency plan without NRC approval only if the licensee performs and retains an analysis demonstrating that:

(A) For planning standards that are risk significant, the changes do not reduce the effectiveness of the plan and the plan, as changed, continues to meet either the risk-significant requirements of § 50.160 of this chapter or the applicable requirements in appendix E to part 50 of this chapter and the risk significant planning standards of § 50.47(b) of this chapter; and

(B) For planning standards that are not risk-significant, the plan, as changed, continues to meet the applicable requirements.

* * * * *

(vii) The licensee must provide for annual evaluation of the adequacy of the interfaces between the licensee and the applicable State, local, and Tribal governments, including licensee drills, exercises, capabilities, and procedures. The results of the evaluation, along with recommendations for improvements, must be documented, reported to the licensee's corporate and plant management, retained for a period of 5 years, and must be made available to the appropriate State, local, and Tribal governments.

* * * * *

PART 54—REQUIREMENTS FOR RENEWAL OF OPERATING LICENSES FOR NUCLEAR POWER PLANTS

■ 107. The authority citation for part 54 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 102, 103, 104, 161, 181, 182, 183, 186, 189, 223, 234 (42 U.S.C. 2132, 2133, 2134, 2136, 2137, 2201, 2231, 2232, 2233, 2236, 2239, 2273, 2282); Energy Reorganization Act of 1974, secs. 201, 202, 206 (42 U.S.C. 5841, 5842, 5846); 44 U.S.C. 3504 note.

Section 54.17 also issued under E.O. 12829, 58 FR 3479, 3 CFR, 1993 Comp., p. 570; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp., p. 298; E.O. 12968, 60 FR 40245, 3 CFR, 1995 Comp., p. 391; ADVANCE Act of 2024, sec. 301 (42 U.S.C. 2133 note).

§ 54.9 [Amended]

■ 108. In § 54.9, in paragraph (b), remove the reference ''54.22''.

■ 109. In § 54.17, revise paragraph (c) to read as follows:

§ 54.17 Filing of application.

* * * * *

(c) An application for a renewed license may not be submitted to the Commission earlier than the start of the period of operation that directly precedes the requested renewal period.

* * * * *

■ 110. In § 54.21, add paragraph (a)(4) and remove and reserve paragraph (c)(2) to read as follows:

§ 54.21 Contents of application—technical information.

* * * * *

(a) * * *

(4) An applicant may voluntarily use risk-informed and performance-based alternatives to the requirements in paragraphs (a)(1), (a)(2), and (a)(3) of this section. The application must describe the alternatives, justify their basis, and include a description of the underlying systematic analysis.

* * * * *

(c) * * *

(2) [Reserved]

* * * * *

§ 54.22 [Removed and Reserved]

■ 111. Remove and reserve § 54.22.

■ 112. In § 54.29, revise paragraphs (a) introductory text and (a)(1) to read as follows:

§ 54.29 Standards for issuance of a renewed license.

(a) Appropriate actions have been identified and have been or will be taken with respect to the matters identified in paragraphs (a)(1) and (a)(2) of this section, such that there is reasonable assurance that the activities authorized by the renewed license will continue to be conducted in accordance with the CLB, and that any changes made to the plant's CLB in order to comply with this paragraph are in accord with the Act and the Commission's regulations. These matters are:

(1) managing the effects of aging during the period of extended operation on the functionality of structures and components that have been identified to require review under § 54.21(a)(1) and alternatives authorized by § 54.21(a)(4); and

* * * * *

■ 113. In § 54.31, revise paragraphs (b) and (c) to read as follows:

§ 54.31 Issuance of renewed license.

* * * * *

(b) A renewed license will be issued for a fixed period of time, not to exceed 40 years.

(c) A renewed license will become effective upon expiration of the operating license or combined license previously in effect. Prior to the renewed license becoming effective, the licensee shall take all necessary steps to ensure the renewed license remains up to date, consistent with the CLB.

* * * * *

■ 114. In § 54.37, revise paragraph (b) to read as follows:

§ 54.37 Additional records and recordkeeping requirements.

* * * * *

(b) After the renewed license is in effect, FSAR updates required by 10 CFR 50.71(e) must contain any changes to summary descriptions of how the effects of aging will be managed for any newly identified systems, structures, and components that require aging management or an evaluation of time-limited aging analyses in accordance with § 54.21. Documentation of the related aging management review or evaluation of time-limited aging analyses shall be retained in accordance with § 54.37(a).

§ 54.43 [Amended]

■ 115. In § 54.43, in paragraph (b), remove the reference ''54.22''.

PART 71—PACKAGING AND TRANSPORTATION OF RADIOACTIVE MATERIAL

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

Authority: Atomic Energy Act of 1954, secs. 53, 57, 62, 63, 81, 161, 182, 183, 223, 234, 1701 (42 U.S.C. 2073, 2077, 2092, 2093, 2111, 2201, 2232, 2233, 2273, 2282, 2297f); Energy Reorganization Act of 1974, secs. 201, 202, 206, 211 (42 U.S.C. 5841, 5842, 5846, 5851); Nuclear Waste Policy Act of 1982, sec. 180 (42 U.S.C. 10175); 44 U.S.C. 3504 note.

Section 71.97 also issued under Sec. 301, Pub. L. 96–295, 94 Stat. 789 (42 U.S.C. 5841 note).

■ 117. In § 71.55, revise and republish paragraph (g) to read as follows:

§ 71.55 General requirements for fissile material packages.

* * * * *

(g) Packages containing uranium hexafluoride only are excepted from the requirements of paragraph (b) of this section provided that:

(1) Following the tests specified in § 71.73, there is no physical contact between the valve body and any other component of the packaging, other than at its original point of attachment, and the valve remains leak tight;

(2) There is an adequate quality control in the manufacture, maintenance, and repair of packagings;

(3) Each package is tested to demonstrate closure before each shipment;

(4) The uranium is enriched to not more than 10 weight percent uranium-235; and

(5) A design feature is incorporated to protect the valve or other fill device from impact for contents with uranium-235 enriched above 5 weight percent and up to 10 weight percent.

PART 100—REACTOR SITE CRITERIA

■ 118. The authority citation for part 100 continues to read as follows:

Authority: Atomic Energy Act of 1954, secs. 103, 104, 161, 182 (42 U.S.C. 2133, 2134, 2201, 2232); Energy Reorganization Act of 1974, secs. 201, 202 (42 U.S.C. 5841, 5842); 44 U.S.C. 3504 note.

§ 100.1 [Amended]

■ 119. In § 100.1, in paragraphs (a) and (d), remove the word ''stationary''.

§ 100.2 [Amended]

■ 120. In § 100.2, remove the word ''stationary''.

■ 121. In § 100.3, add in alphabetical order the definitions ''*Tier 1 reactor*'' and ''*Tier 2 reactor*'' to read as follows:

§ 100.3 Definitions.

* * * * *

Tier 1 reactor means a *power reactor* having an unmitigated consequence of less than 25 rem (0.25 Sv) TEDE at the site EAB.

Tier 2 reactor means a *power reactor* having an unmitigated consequence of greater than 25 rem (0.25 Sv) TEDE at the site EAB or where the unmitigated consequence is undetermined.

* * * * *

■ 122. In § 100.8, revise paragraph (b) to read as follows:

§ 100.8 Information collection requirements: OMB approval.

* * * * *

(b) The approved information collection requirements contained in this part appear in §§ 100.10, 100.11, 100.20, 100.21, and 100.23.

■ 123. Revise subpart A section heading consisting of § 100.10 through § 100.11 to read as follows:

Subpart A—Evaluation Factors for Tier 1 Power and Testing Reactors

* * * * *

■ 124. Revise § 100.10 to read as follows:

§ 100.10 Factors to be considered when evaluating sites.

This approach to evaluating sites applies to Tier 1 power reactors and testing reactors. The Commission will take the following factors into consideration in determining the acceptability of a site for a Tier 1 power or testing reactor:

(a) Characteristics of reactor design and proposed operation.

(b) Population density and use characteristics of the site environs, including the exclusion area, low population zone, and population center distance (or alternate area assessed by consideration of societal risks and benefits).

(c) Physical characteristics of the site, including seismology, meteorology, geology, and hydrology. Applications to

earthquake engineering criteria are contained in appendix S to part 50 of this chapter.

(d) Where unfavorable physical characteristics of the site exist, the proposed site may nevertheless be found to be acceptable if the design of the facility includes appropriate and adequate compensating engineering safeguards.

(e) For siting criteria described in § 100.11(a)(3)(i)(B), a comparison of societal risks and societal benefits.

■ 125. Revise § 100.11 to read as follows:

§ 100.11 Determination of exclusion area, low population zone, and population considerations.

(a) As an aid in evaluating a proposed site, an applicant should assume a fission product release,[1] the expected demonstrable leak rates from potential flow paths, and the meteorological conditions pertinent to the site to derive an exclusion area, a low population zone, and population center distance. For the purpose of this analysis the applicant should determine the following:

(1) An exclusion area of such size that an individual located at any point on its boundary for any 2-hour period following the onset of the postulated fission product release would not receive a radiation dose in excess of 25 rem [2] TEDE.

(2) A low population zone of such size that an individual located at any point on its outer boundary who is exposed to the radioactive cloud resulting from the postulated fission product release (during the entire period of its passage) would not receive a total radiation dose in excess of 25 rem (0.25 Sv) TEDE.

(3)(i) The reactor site must either:

(A) Provide a population center distance of at least one and one-third times the distance from the reactor to the outer boundary of the low population zone; or

(B) Be found acceptable to the NRC based on assessments of societal risks in comparison to societal benefits for the specific site.

(ii) The boundary of the population center or the alternate area assessed considering societal risks and benefits must be determined upon consideration of population distribution. Political boundaries are not controlling in the calculation of population center distance or the alternate area assessed considering societal risks and benefits.

(b) [Reserved]

[1] The fission product release assumed for these calculations should be based upon a major accident, hypothesized for purposes of site analysis or postulated from considerations of possible accidental events to bound a broad range of design basis accidents.

[2] The use of 25 rem (0.25 Sv) TEDE is not intended to imply that this number constitutes an acceptable limit for an emergency dose to the public under accident conditions. Rather, this dose value has been set forth in this section as a reference value, which can be used in the evaluation of reactor sites with respect to potential reactor accidents of exceedingly low probability of occurrence, and low risk of public exposure to radiation in the event of an accident.

■ 126. Revise subpart B section heading to read as follows:

Subpart B—Evaluation Factors for Tier 2 Power Reactor Site Applications

* * * * *

■ 127. In § 100.20, revise the introductory paragraph to read as follows:

§ 100.20 Factors to be considered when evaluating sites.

This approach to evaluating sites applies to Tier 2 power reactors. The Commission will take the following factors into consideration in determining the acceptability of a site for a Tier 2 power reactor:

* * * * *

■ 128. In § 100.21, redesignate footnote 3 as footnote 1 and revise footnote 1 and paragraphs (b), (g), and (h) to read as follows:

§ 100.21 Non-seismic siting criteria.

* * * * *

(b) (1) The reactor site must either:

(i) Provide a population center distance, as defined in § 100.3, of at least one and one-third times the distance from the reactor to the outer boundary of the low population zone; or

(ii) Be found acceptable to the NRC based on assessments of societal risks in comparison to societal benefits for the specific site;

(2) The boundary of the population center or the alternate area assessed considering societal risks and benefits must be determined upon consideration of population distribution. Political boundaries are not controlling in the calculation of population center distance or the alternate area assessed considering societal risks and benefits;

* * * * *

(g) Physical characteristics unique to the proposed site that could pose a significant impediment to the development of emergency plans must be identified; and

(h) Reactor sites should be located away from very densely populated centers or otherwise be shown to be acceptable by assessments of societal risks in comparison to societal benefits for the specific site. Areas of low population density are, generally, preferred. However, in determining the acceptability of a particular site located away from a very densely populated center but not in an area of low density or when assessing a site considering societal risks and benefits, consideration will be given to safety, environmental, economic, or other factors, which may result in the site being found acceptable [1].

[1] Examples of these factors include, but are not limited to, such factors as the higher population density site having superior seismic characteristics, better access to skilled labor for construction, better rail and highway access, shorter transmission line requirements, the ability to use existing infrastructure for a retired fossil fuel power plant, or less environmental impact on undeveloped areas, wetlands or endangered species, etc. Some of these factors are included in, or impact, the other criteria included in this section.

■ 129. In § 100.23, revise paragraph (a) to read as follows:

§ 100.23 Geologic and seismic siting criteria.

* * * * *

(a) *Applicability.* The requirements in paragraphs (c) and (d) of this section apply to applicants for an early site permit or combined license pursuant to part 52 of this chapter, or a construction permit or operating license for a nuclear power plant pursuant to part 50 of this chapter that do not meet the entry criteria for subpart A of this part.

* * * * *

Appendix A to Part 100 [Removed]

■ 130. Remove appendix A to part 100.

Dated: July 14, 2026.

For the Nuclear Regulatory Commission.

Jody Martin,

Secretary of the Commission.

[FR Doc. 2026–14341 Filed 7–15–26; 8:45 am]

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FEDERAL REGISTER

Vol. 91 Thursday,
No. 135 July 16, 2026

Part VI

The President

Proclamation 11041—Regulatory Relief for Certain Stationary Sources To Promote American Chemical Manufacturing Security
Notice of July 13, 2026—Continuation of the National Emergency With Respect to Hostage-Taking and the Wrongful Detention of United States Nationals Abroad
Notice of July 13, 2026—Continuation of the National Emergency With Respect to Significant Transnational Criminal Organizations

Federal Register
Vol. 91, No. 135
Thursday, July 16, 2026

Presidential Documents

Title 3—

The President

Proclamation 11041 of July 9, 2026

Regulatory Relief for Certain Stationary Sources To Promote American Chemical Manufacturing Security

By the President of the United States of America

A Proclamation

1. The United States relies on a strong chemical manufacturing sector to support industries like energy, national defense, agriculture, and health care. These facilities produce essential inputs for critical infrastructure, advanced manufacturing, medical sterilization, semiconductors, and national defense systems. Maintaining a robust domestic chemical industry is vital to safeguarding the supply chains that underpin our economy and to reducing the Nation's dependence on foreign control over materials critical to national resilience. As adversaries expand influence over key inputs, continued domestic production is essential not only to economic resilience but also to military readiness, public health, and national preparedness.

2. On May 16, 2024, the Environmental Protection Agency published a final rule titled *New Source Performance Standards for the Synthetic Organic Chemical Manufacturing Industry and National Emission Standards for Hazardous Air Pollutants for the Synthetic Organic Chemical Manufacturing Industry and Group I & II Polymers and Resins Industry,* 89 FR 42932 (HON Rule). The HON Rule imposes new emissions-control requirements on certain chemical manufacturing facilities, some of which were promulgated pursuant to section 112 of the Clean Air Act, 42 U.S.C. 7412.

3. The HON Rule imposes substantial burdens on chemical manufacturers already operating under stringent regulations. Many of the testing and monitoring requirements outlined in the HON Rule rely on technologies that are not practically available, not demonstrated at the necessary scale, or cannot be implemented safely or consistently under real-world conditions. For many facilities, the timeline for compliance as set forth in the HON Rule at 89 FR 42953–42955 would require shutdowns or massive capital investments before any proven pathway to compliance exists. The HON Rule imposes requirements that assume uniform technological availability across facilities, despite significant variation in site conditions, permitting realities, and equipment configurations. A disruption of this capacity would weaken key supply chains, increase dependence on foreign producers, and impair our ability to respond effectively in a time of crisis. These consequences would ripple across sectors vital to America's growing industrial strength and emergency readiness.

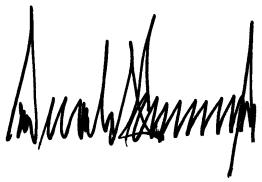
NOW, THEREFORE, I, DONALD J. TRUMP, President of the United States of America, by the authority vested in me by the Constitution and the laws of the United States, including section 112(i)(4) of the Clean Air Act, 42 U.S.C. 7412(i)(4), do hereby proclaim that certain stationary sources subject to the HON Rule, as identified in Annex I of this proclamation, are exempt from compliance with those aspects of the HON Rule that were promulgated under section 112 of the Clean Air Act, 42 U.S.C. 7412, for a period of 2 years beyond the HON Rule's relevant compliance dates (Exemption). This Exemption applies to all compliance deadlines established under the HON Rule applicable to the stationary sources listed in Annex I, with each such deadline extended by 2 years from the date originally required for such deadline. The effect of this Exemption is that, during

each such 2-year period, these stationary sources will be subject to the emissions and compliance obligations that they are currently subject to under the applicable standard as that standard existed prior to the HON Rule. In support of this Exemption, I hereby make the following determinations:

a. The technology to implement the HON Rule is not available. Such technology does not exist in a commercially viable form sufficient to allow implementation of and compliance with the HON Rule by the compliance dates in the HON Rule.

b. It is in the national security interests of the United States to issue this Exemption for the reasons stated in paragraphs 1 and 3 of this proclamation.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of July, in the year of our Lord two thousand twenty-six, and of the Independence of the United States of America the two hundred and fifty-first.



Billing code 3395–F4–P

ANNEX I

1. INEOS US Chemicals Company
   i. Affected Facility/Source: Cooper River Facility, South Carolina
2. INEOS Nitriles USA LLC
   i. Affected Facility/Source:
      a. Green Lake Facility, Texas
      b. Lima Facility, Ohio
3. Occidental Chemical Corporation
   i. Affected Facility/Source:
      a. Geismar Plant, Louisiana
      b. Wichita Plant, Kansas
4. Zeon Chemicals LP
   i. Affected Facility/Source:
      a. Louisville Facility, Kentucky
      b. Zeon Chemicals LP Mississippi Plant, Mississippi
5. Westlake Vinyls Inc.
   i. Affected Facility/Source: Calvert City Facility, Kentucky
6. Westlake Epoxy Inc.
   i. Affected Facility/Source: Deer Park Facility, Texas
7. Westlake Chemicals and Vinyls LLC
   i. Affected Facility/Source: Plaquemine Facility, Louisiana

8. Westlake Vinyls Company, LP

   i. Affected Facility/Source: Geismar Facility, Louisiana

9. Eastman Chemical Company

   i. Affected Facility/Source: Kingsport Facility, Tennessee

10. Hexion Inc.

   i. Affected Facility/Source: Hexion Fayetteville Facility, North Carolina

11. Indorama Ventures Oxides, LLC

   i. Affected Facility/Source: LAB Chocolate Bayou Facility, Texas

12. Methanex USA LLC

   i. Affected Facility/Source: Geismar Facility, Louisiana

13. Methanex Beaumont, LLC

   i. Affected Facility/Source: Beaumont Facility, Texas

14. Alpek Polyester USA, LLC

   i. Affected Facility/Source: Columbia Site, South Carolina

15. Shintech Louisiana LLC

   i. Affected Facility/Source: Plaquemine Complex, Louisiana

16. Nouryon Functional Chemicals LLC

   i. Affected Facility/Source: Axis Facility, Alabama

17. AdvanSix Resins & Chemicals LLC

i. Affected Facility/Source: Frankford Plant, Pennsylvania

[FR Doc. 2026–14452
Filed 7–15–26; 11:15 am]
Billing code 3395–F4–C

Presidential Documents

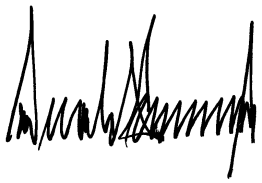
Notice of July 13, 2026

Continuation of the National Emergency With Respect to Hostage-Taking and the Wrongful Detention of United States Nationals Abroad

On July 19, 2022, by Executive Order 14078, the President declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by hostage-taking and the wrongful detention of United States nationals abroad.

Hostage-taking and the wrongful detention of United States nationals are heinous acts that undermine the rule of law. Terrorist organizations, criminal groups, and other malicious actors who take hostages for financial, political, or other gain—as well as foreign states that engage in the practice of wrongful detention, including for political leverage or to seek concessions from the United States—threaten the integrity of the international political system and the safety of United States nationals and other persons abroad. Hostage-taking and the wrongful detention of United States nationals abroad continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For this reason, the national emergency declared in Executive Order 14078 of July 19, 2022, must continue in effect beyond July 19, 2026. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency declared in Executive Order 14078 with respect to hostage-taking and the wrongful detention of United States nationals abroad.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
July 13, 2026.

[FR Doc. 2026–14453
Filed 7–15–26; 11:15 am]
Billing code 3395–F4–P

Presidential Documents

Notice of July 13, 2026

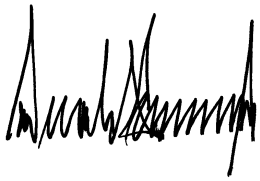
Continuation of the National Emergency With Respect to Significant Transnational Criminal Organizations

On July 24, 2011, by Executive Order 13581, the President declared a national emergency pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by significant transnational criminal organizations.

On March 15, 2019, by Executive Order 13863, the President took additional steps to deal with the national emergency with respect to significant transnational criminal organizations in view of the evolution of these organizations as well as the increasing sophistication of their activities, which threaten international political and economic systems and pose a direct threat to the safety and welfare of the United States and its citizens, and given the ability of these organizations to derive revenue through widespread illegal conduct, including acts of violence and abuse that exhibit a wanton disregard for human life as well as many other crimes enriching and empowering these organizations.

Significant transnational criminal organizations continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States. For these reasons, the national emergency declared in Executive Order 13581 of July 24, 2011, under which additional steps were taken in Executive Order 13863 of March 15, 2019, must continue in effect beyond July 24, 2026. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to significant transnational criminal organizations declared in Executive Order 13581.

This notice shall be published in the *Federal Register* and transmitted to the Congress.



THE WHITE HOUSE,
July 13, 2026.

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S. 629/P.L. 119–102

Emergency Conservation Program Improvement Act of 2025 (July 12, 2026; 140 Stat. 985)

Note: Upon expiration of the 10-day period prescribed by the Constitution of the United States, S. 629 became law on July 12, 2026, without the President's signature.

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